2013

ACHIEVING BALANCE
in Federal and State Pain Policy

A Guide to Evaluation (CY 2013)

Pain & Policy Studies Group

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There are important ongoing efforts in the U.S. to address simultaneously two major public health crises — (1) the medical under-treatment of pain and (2) the non-medical use of controlled substances — both of which involve the opioid analgesic class of medications. Patients with pain may receive many pharmaceutical and non-pharmaceutical treatments, depending on the diagnosis, but opioid analgesics are not always needed. However, opioid analgesics remain a very important treatment option, yet are sometimes difficult to obtain when clinically warranted. On the other hand, people who use controlled substances non-medically typically ingest multiple substances, including prescription medications or illicit opioids such as heroin. Policy efforts to address pain relief and non-medical use share the common aim of protecting public health and improving quality of life, either by alleviating pain and its debilitating effects or by addressing substance use disorders and their tragic consequences. If done in a *balanced* manner, both efforts should have measurably effective outcomes and neither should interfere with the other.

As will be seen in this report, achieving balance in the control of medications that are used for pain relief, but which also can be abused, is an undisputed public good that has been well-established in international treaties and U.S. federal drug control policy, and in state professional practice policies. These policies establish the drug approval and drug control systems, creating the parameters in which these systems should function to ensure adequate medication availability for healthcare purposes and to control diversion (i.e., movement of medications from licit to illicit distribution or use). Understanding this policy context is necessary when considering ways to achieve effective and balanced responses both to the problems of unrelieved pain and to diversion and abuse of prescription medications.

Understanding the drug approval and control system

When thinking about drugs for medical use, it is important to distinguish between the federal policies governing drug approval and drug control. Both are established under authority of the U.S. Congress and federal administrative agencies. The Federal Food, Drug, and Cosmetics Act (FFDCA) (21 USC §301 et seq) provides the underlying drug approval framework for non-prescription and prescription medications. The Food and Drug Administration (FDA) administers the FFDCA and approves medications for human use when they are determined to be safe and effective for *their intended medical uses.* Prescription medications, including opioid analgesics, are deemed unsafe for any over-the-counter self-administration; they are lawfully available to legitimate patients only on the prescription of practitioners licensed under state law.

By law, the official labeling for each medication is approved by the FDA and contains the information needed for safe and effective use, including warnings and consequences, contraindications, and adverse reactions. The FDA-approved label provides several examples of non-medical uses of opioid analgesics, such as unauthorized increases in dose, use with alcohol or illicit substances, compromising the integrity of the product (e.g., crushing and using unapproved routes of administration). These uses are common in cases of opioid analgesic-involved overdose and death.

Recently, the Congress authorized the FDA to require pharmaceutical manufacturers to develop Risk Evaluation and Mitigation Strategies (REMS), when warranted, as a means to ensure that the treatment benefits of certain products outweigh their risks. Messages conveyed through Package Inserts,

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Medication Guides, and REMS specify that use of prescription medications without a valid prescription issued by a properly licensed practitioner for a legitimate medical purpose, or in ways that are contraindicated, is likely to compound the risk of adverse consequences.

If an approved prescription medication does have an abuse liability, such as with opioid analgesics, it comes under the additional control of the federal Controlled Substances Act (CSA) (21 USC §801 et seq), which is implemented by the Drug Enforcement Administration (DEA). Federal controlled substances laws do not supersede the FDA-approved uses of medications, and the state has the jurisdiction to regulate healthcare professionals and their practice. States have adopted laws, regulations, and guidelines relevant to prescribing medications, including controlled substances, and professional practice.

The CSA establishes a national *drug control system* to distribute approved medications to patients; it is analogous to a pipeline for moving valuable material that should not leak. The drug control system is a "closed" system — that is, all enterprises and individuals involved in production, distribution, prescribing, dispensing, possession, research, and disposal of prescription-only controlled substances must be registered with the DEA and also the state if required. Conditions of registration include:

- adhering to laws and regulations that limit medication availability to legitimate medical uses and patients,
- implementing safeguards against diversion, and
- reporting to the DEA of amounts distributed to all registrants at the retail level, as well as amounts that are lost or stolen.

Physicians can lose their DEA registration and be subject to criminal or civil penalties if they issue prescriptions for non-medical purposes or outside the usual course of medical practice (i.e., to individuals who are not legitimate patients). Many states have policies that acknowledge a practitioner's need to understand and comply with relevant federal and state laws when prescribing controlled substances.

Patients, by virtue of their being recipients of prescription-only controlled medicines, have responsibilities under law. Labeling and Medication Guides caution patients to not transfer the medications prescribed for them to any other person, under penalty of law. It is unlawful for any person to possess controlled substances, including opioid analgesics, without a valid prescription. In addition, it is illegal under federal and state laws to acquire these medications by theft, fraud, or misrepresentation.

Despite all of these legal requirements governing distribution of controlled "prescription drugs"[1] via the closed system, opioid analgesics are diverted from all levels of the pipeline. Once diverted, they become illegally available for sale and non-medical use, which can lead to overdose and death.

[1] It is important to note that some usages of the term "prescription drug" can lead to incorrect conclusions about the source of an abused drug. "Prescription drug" does not necessarily mean a drug that was actually prescribed. When considering a balanced policy approach to abuse or diversion of prescription opioids, determining whether a valid prescription was involved is essential.

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Opioid analgesics are often diverted from the pipeline *before* they are prescribed. For example, criminal diversions of large quantities are reported by manufacturers, distributors, and pharmacies, and often involve armed robberies and night break-ins. Thefts, including employee pilferage, occur from pharmacy supplies in nursing homes and hospitals. There also are numerous criminal activities by organizations and individuals, including some patients, to obtain opioid analgesics unlawfully. These include fraud and misrepresentation, such as "doctor shopping," prescription forgery, alteration of prescription forms, and misuse of Medicare and Medicaid drug coverage. "Script doctors" and "Pill Mills" are illegal activities by rogue physicians who still have the necessary authority to prescribe, or to purchase and dispense, controlled substances. Some of these high volume "prescription" practices, though ultimately found to be illegal, nevertheless have contributed to state patterns of controlled medication consumption. Taken together, these methods of diversion are sometimes referred to as an "industry."

Relatively distinct from overt criminal activities, some physicians and pharmacists prescribe or dispense in a careless or unprofessional manner (which would include practitioners who prescribe more than medically necessary and thus contribute to the volume of unused medications), and are subject to license revocation or other civil penalties defined in federal and state law. Even if opioids are prescribed legitimately, but then are not stored securely, they are vulnerable to diversion through medicine cabinet theft and home burglaries. When people report obtaining opioids from peers or family or from a dispensed prescription, the actual means of diversion from the system remains unknown unless further information is acquired.

There currently is insufficient understanding about the extent to which these numerous sources of diversion contribute to abuse, addiction, overdose, and death. It is obvious that, to effectively address non-medical use of opioid analgesics, a better appreciation is needed about the multiple determinants of diversion by using data and intelligence information to identify specific leaks in the system (which could be communicated through educational programs or public awareness campaigns). Consequently, existing data systems, including those that track theft and drug evidence, burglary, retail drug distribution, prescribing, and health consequences, can be used to inform law enforcement and public health interventions. In this way, sources can be targeted using geographic indicators, just as one would locate the source of the agent in infectious disease control. Once detected, law enforcement or regulatory officials can address the problem with precision. For example, rogue prescribers and pill mills can be identified using information that is available today; intervention would produce immediate reductions in distribution to the retail level in that area, and should take into consideration whether legitimate patients would be affected. Effectively addressing these issues also would be strengthened by broader availability and access to treatment for substance use disorders. Overall, policy or programmatic approaches aimed at only a single diversion source should not be considered sufficient for such a multifaceted issue as diversion.

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PPSG Policy Evaluation Research

This research was designed to help ensure that people with pain who need treatment with controlled medicines are better able to have access, by identifying and assessing balance in current federal and state statutes, regulations, and other official policies. Since the inception of this project in 2000, numerous states have adopted policies to enhance safe and effective pain management while removing regulatory barriers to appropriate treatment. These policies often are modeled after balanced templates developed by the Federation of State Medical Boards. Nevertheless it is possible that new state laws and healthcare regulatory policies aimed at substance abuse could introduce undue requirements, restrictions, or ambiguities that could impede healthcare decision-making and patient care. Examples of current policies affecting pain management are included throughout this report and, especially, in Section IX. Adoption of balanced policy responds to the continued call from international and national authoritative bodies representing legal, regulatory, and healthcare communities to promote the reduction of the non-medical use of prescription medications while at the same time addressing inadequate treatment for debilitating pain.

Most of the policy development activities identified in this report demonstrate state governments' willingness to cooperate and promote safe and effective pain management and avoid unduly restricting access to controlled medications for the people who need them, while taking precautions against exacerbating non-medical use or diversion. The overall aim is a balanced drug control and healthcare regulatory environment that maintains or improves the well-established closed distribution system of drug control and related information systems. To achieve and sustain balance in a dynamic environment, it is necessary to understand and enforce the closed distribution system, preserving the critical distinction between the many patients who use these medications for therapeutic purposes and those whose motivations and activities are outside medicine and the law. Appendix A provides an extensive list of recommended readings, of which the articles by Cicero et al., Coleman, Inciardi et al., and Joranson & Gilson are relevant to this issue.

When balance is achieved, patient care decisions can be based only on clinical circumstances, with individualized treatment approaches that are not hampered by legislative or regulatory barriers. Such an approach could help to allay the concern expressed in a recent editorial in the *Journal of Pain Research*:

> "Why should patients with chronic pain who are prescribed necessary opioids for legitimate medical purposes endure the wrath of policy changes and resultant untreated pain due to criminality of others…?"

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Commentary

To provide the most current information about states' pain policies, the PPSG has now conducted an updated evaluation of policies in effect as of December**,** 2013, resulting in this report (entitled *Achieving Balance in Federal and State Pain Policy: A Guide to Evaluation (CY 2013)* (*Evaluation Guide 2013*)). The evaluation findings relating to policies governing drug control and medical and pharmacy practice (but not nursing practice) were then used to calculate grades for each state for 2013, which are included in a companion report entitled *Achieving Balance in State Pain Policy: A Progress Report Card (CY 2013)* (*Progress Report Card 2013*). Nursing polices are not included as a basis for states' grades at this time because such a foundational change in methodology would make it impossible to compare 2013 grades with those from previous years.

These updated *Evaluation Guides* and *Progress Report Cards* supersede all prior reports.

The *Evaluation Guide 2013* is not a "position statement" about pain policies. Rather, it is the product of an ongoing research program to systematically analyze public policy affecting pain relief and the use of pain medications, and to disseminate the results. While recognizing that states may take different approaches to policy formulation, we assert that there is a long-standing Central Principle that should guide efforts to establish a governmental and regulatory environment that avoids creating barriers to appropriate pain management. Achieving this goal does not mean that all state policies must look alike; rather, the laws that govern controlled medications and practitioners who prescribe and dispense should ensure medication availability for people who legitimately need them for the relief of pain and suffering.

Federal regulations governing prescribing have recently been modified to permit electronic prescribing of controlled substances and the issuance of a series of multiple prescriptions to reduce the number of dosage units dispensed as a time. Although at least partially designed as methods to further control the diversion of medications into illicit markets, it is expected that these changes should have little if any deleterious consequences on appropriate prescribing or effective pain management. In addition, in the last few years a number of states have codified methods to help ensure that controlled substances are issued for legitimate purposes. Such methods include requiring a photo ID when picking up a prescription, requiring an established physician-patient relationship when issuing a prescription, using a written agreement when issuing prescriptions to patients determined to be at increased risk for medication misuse, and creating drug abuse awareness programs. These federal and state examples seem to represent reasonable measures to prevent the non-medical use of controlled medications and, at least at this time, do not seem likely to impose overly burdensome regulatory requirements; if outcomes to the contrary become evident, however, evaluation of such provisions will be reconsidered.

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The national problem of inadequate pain relief has drawn the attention of a variety of professions, including medicine, pharmacy, nursing, social work, law, state law enforcement, and bioethics. Numerous professional, private, and public organizations are developing patient information and professional education resources, and have called for the removal of legislative and regulatory barriers. As an increasing number of individuals and organizations acknowledge the potential influence of some excessively restrictive drug control laws or practice regulations on pain management services and patient care, it is our hope that they will make use of the State Profiles from the *Evaluation Guide 2013*, the *Progress Report Card 2013*, and the many other relevant resources that are provided in this document and elsewhere on the PPSG website at www.painpolicy.wisc.edu.

Of course, there can be pitfalls and unintended consequences when working to achieve more balanced laws, regulations, and other agency policies. Changes in policy can advance or retard progress, depending on the content and clarity of the policy and the extent of collaboration among stakeholders during policy development. In addition, the level of effort devoted to communicating current or new policies to the stakeholders can have a direct impact on awareness, and therefore the influence, of the policy; policy change without implementation, even when the policy's message is clear and positive, may contribute little to influencing actual practice and care. Policy change aimed at the healthcare professions and improving practice should be accompanied by a sustained commitment to repeated dissemination and incorporation into effective professional and public education, guidelines, and patient care standards. Numerous considerations when adopting or changing policies are described in Section IV.

Acknowledgement of Support, Citation, Notes to the Reader

The PPSG remains grateful to the Robert Wood Johnson Foundation for providing resources to produce the first *Evaluation Guide in 2000*, as well as the second *Evaluation Guide* and the first *Progress Report Card* in 2003. The *Evaluation Guides* and *Progress Report Cards* developed in 2006, 2007, and 2008 were supported by "Benchmarking State Policies for Cancer Pain and Palliative Care" (SIRSG-06-095-01) from the American Cancer Society, a grant from Susan G. Komen for the Cure, and through a cooperative agreement with the Lance Armstrong Foundation (now called Livestrong). This current research, and the resulting *Evaluation Guides* and *Progress Report Cards*, was supported by "Improving State Policies for Cancer Pain Management" (Award # NHQOLSGCC 10849) from the American Cancer Society, and through a cooperative agreement with the Livestrong Foundation.

We also wish to thank the numerous professionals (representing healthcare, regulation, and legal areas) who provided thoughtful and valuable feedback throughout the development of this entire series of policy evaluation reports.

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Notes to the Reader

This document is one product of the ongoing policy research program of the Pain & Policy Studies Group. Our purpose for making these data available is to promote education and policy change. We ask that anyone who wishes to use the policy data published herein for the purposes of research seek permission from the PPSG.

Policies are in constant flux, and the results presented herein pertain to policies adopted through December 2013. Also, the material in this report does not represent legal or medical advice. Individuals who need to know the current policy for legal or advocacy purposes should double-check the current status of any policies in question; PPSG is happy to assist individuals in locating the current policies.

This Evaluation Guide, along with its companion Progress Report Card, is available on the PPSG website at www.painpolicy.wisc.edu. Requests, comments, and suggestions are welcome and may be directed to:

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SECTION I: PURPOSE AND AUDIENCE

Purpose

This is the newest edition of *Achieving Balance in Federal and State Pain Policy: A Guide to Evaluation* (*Evaluation Guide 2013*); its purpose, as with all previous editions of the report, is to promote more balanced[2] and consistent U.S. federal and state policy relating to the legitimate use of controlled substances for the medical management of pain generally and specifically in palliative and end-of-life care. This purpose is accomplished by providing an updated evaluation of current federal and state policy[3] using a methodology that was conceptualized, developed, and tested over a 20-year period (Gilson, 2010a; Gilson, Maurer, & Joranson, 2005). The *Evaluation Guide 2013*, used in conjunction with *Achieving Balance in State Pain Policy: A Progress Report Card (CY 2013)*, provides a framework for considering the policies or policy content that could be examined and addressed, as well as identifying language from all other states to guide the development of new and more balanced policies. Balance in policy affecting pain relief can be achieved and maintained if policymakers, healthcare professionals, and regulatory agencies work together and take advantage of the policy resources that are available. In this way, a legislative, regulatory, and practice environment can evolve that supports the relief of pain in all patients, including those who are challenged by cancer, HIV/AIDS, sickle-cell anemia, and other painful conditions.

To accomplish this goal, the *Evaluation Guide 2013*:

(1) includes updated background information about policy issues related to pain, controlled substances, and professional practice (see Appendix A for recommended readings);

(2) provides a description of policy and extra-policy considerations that can affect the implementation of new or revised polices;

(3) explains the Central Principle of Balance and the sources of authority from which it is derived,

(4) describes the criteria that were used to evaluate policy for the presence or absence of provisions that have the potential to either positively or negatively affect pain management;

(5) presents the results of a criteria-based evaluation of identified federal drug control law, and state policies governing drug control and medical and pharmacy practice, that were current as of December, 2013, which offers examples of language that can be used to help guide the content of policy change activities; and

(6) includes a separate section of criteria-based results for all state policies governing advanced practice nursing, including prescribing privileges, which again offers examples of language that can be used to help guide the revision of policy content.

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[2] A thorough description of the concept of *Balance*, as well as a demonstration of the national and international organizations that support this concept, is provided in Section V.

[3] Policy includes federal and state statutes and regulations, as well as other governmental policies issued by state professional licensing agencies (see Section II for a definition of policy types and Section VII for a description of the specific policies evaluated for this report).

SECTION I: PURPOSE AND AUDIENCE

Using Policy Evaluation to Inform Policy Change

Interested parties can use the *Evaluation Guide 2013* to learn about policies affecting pain treatment at the state or federal level and to advise their own evidence-based review of changes that may be needed to achieve policy that promotes safe and effective pain management and availability of needed medications. This document provides the results from a transparent evaluative framework, which can help shape an action plan to remove potential impediments and add positive provisions in federal and state policy.

The individual provisions identified by this evaluation are not weighted or adjusted to reflect their importance or severity. Although it is possible that some provisions may influence practice or care more than others, PPSG (assisted by feedback from external experts) did not believe there was enough information available to warrant the development of a valid weighting protocol. Instead, PPSG recommends that the relative importance of individual provisions be taken into consideration by those who are developing action plans to improve state policy.

In a state where potential impediments have been identified, it may be possible to amend statutes or regulations as soon as warranted. In other cases, it may be prudent to work with professional licensing boards to adopt and disseminate guidelines or policy statements that promote a balanced approach to treating pain. In still other cases, it may be appropriate to initiate a broad-based study of the options to determine priorities and procedures prior to acting (Appendix B presents a discussion of the role of state legislatures and an article about task forces or study commissions that have been established by legislatures). In all cases, policy adoption or improvement must be understood as being only an important step in enhancing effective pain relief – policy must be properly implemented and disseminated to be effectual (Connecticut Cancer Pain Initiative & American Cancer Society New England Division, 2003; Joranson, Gilson, & Nischik, 2002; Gilson, Joranson, & Maurer, 2007). The *Evaluation Guide 2013* is a tool that can be used by government and non-government organizations, as well as policymakers, healthcare professionals, and advocates, to understand the policy content in their state that reinforce the legitimacy of pain management and those that could hinder patient access to effective treatment.

Again, this is an analysis of current policy content, identifying language that conforms to a set of evaluation criteria, and is not meant to be a statement of a "position." It is possible, however, that others may find policy language in addition to what we identified, or may disagree with our interpretation of the language or how we have applied the criteria; PPSG is eager to have comments from other interested parties about the policies in their state.

Audience

The intended audience for the *Evaluation Guide 2013* is individuals or organizations interested in improving policy relevant to pain treatment, palliative care, or end-of-life care, including:

- the Congress and federal agencies
- state legislatures and Attorneys General
- state professional licensing boards
- associations of healthcare professionals
- multidisciplinary advisory councils and task forces
- state or regional pain or palliative care initiatives
- national cancer, HIV/AIDS, pain, and hospice and palliative care foundations
- individual practitioners.

SECTION II: POLICY RESEARCH TERMS

Use of Pain Policy Research Terms

Policy Research Terms

Pain policy refers to federal or state policy that relates to pain management, and is generally found in two categories:

Pain-specific policies directly address pain and its management, such as medical board pain management guidelines.

Pain-related policies do not directly address pain management but contain provisions that could ultimately affect its treatment, such as state acts that address generally the prescribing and dispensing of controlled substances.

Within pain policies are:

Provisions: policy language that was identified as satisfying an evaluation criterion, and include

positive provisions, which are those parts of a policy identified in the evaluation that have the potential to enhance pain management, and

negative provisions, which are those parts of a policy identified in the evaluation that have the potential to impede pain management.

Policy change is the addition or removal of provisions; sufficient policy change in a state will produce a ***grade change*** for that state.

Policy Types

There are several types of policies. For the purpose of this evaluation they are characterized as follows:

Law is a broad term that refers to rules of conduct with binding legal force adopted by a legislative or other government body at the international, federal, state or local levels. Law can be found in treaties, constitutional provisions, decisions of a court, and include both statutes and regulations. The most common laws are the statutes enacted by a legislature, such as an Intractable Pain Treatment Act (IPTA), or those that create prescription monitoring programs or pain advisory councils, or license healthcare facilities.

Regulation is an official policy issued by an agency of the executive branch of government pursuant to statutory authority. Regulations are found in the state administrative code. Regulations have binding legal force and are intended to implement the administrative policies of a statutorily-created agency. For example, regulations issued by licensing boards according to a state's administrative procedures statute govern professional conduct, and establish what conduct is or is not acceptable for those regulated by the agency (such as physicians, pharmacists, and nurses). Regulations of state agencies may not exceed the agency's statutory authority (see Appendix C for further discussion).

Guideline means an officially adopted policy issued by a government agency to express the agency's attitude about, or position on, a particular matter. While guidelines do not have binding legal force, they may help those regulated by an agency to better understand the regulating agency's standards of practice. A number of state medical boards have issued guidelines regarding the medical use of opioid analgesics, which describe conduct the board considers to be within the professional practice of medicine (some pharmacy and nursing boards have issued similar guidelines.) "Guidelines" may also include an officially adopted position statement that appears in a position paper, report, article, letter or agency newsletter.

SECTION III: BACKGROUND ABOUT PAIN RELIEF AND PUBLIC POLICY

Unrelieved Pain Continues to Burden Americans

Pain remains one of the most common physical complaints upon a person's admission into the healthcare system (Burton, Fanciullo, Beasley, & Fisch, 2007; Foley et al., 2005; Freburger et al., 2009; McCarberg, 2010; Peterlin, Rosso, Rapoport, & Scher, 2009; Schug & Chong, 2009; Weiss, Emanuel, Fairclough, & Emanuel, 2001). Pain is prevalent in cancer, especially near the end of life (Paice, 2010; Smith et al., 2010), and in other diseases and conditions such as HIV/AIDS (Breitbart & Cortes-Ladino, 2010; Tsao, Stein, & Dobalian, 2010) and sickle-cell anemia (American Pain Society, 1999; Ballas, 2010); indeed, persistent pain itself is increasingly being recognized as a disease (Institute of Medicine Committee on Advancing Pain Research, 2011). However, insufficient treatment attention often is given to appropriate pain relief, especially when pain is severe or prolonged. In extreme circumstances, pain can impair all aspects of life and sometimes contribute to a person's wish for death (Fishman & Rathmell, 2010; Ilgen et al., 2013; Institute of Medicine Committee on Advancing Pain Research, 2011; Institute of Medicine National Cancer Policy Board, 2001; Wasan, Sullivan, & Clark, 2010). When pain relief is achieved, it can result in improved quality of living for people with prolonged pain and can decrease suffering for people at the end of life (Higginson & Evans, 2010).

International organizations have provided valuable guidance with regard to the implications of health care, and even pain care in particular, as a human right. In 1966, the United Nations (UN) General Assembly's International Covenant on Civil and Political Rights recognized that every person has a right to the highest attainable standard of physical and mental health (United Nations General Assembly, 1966). In more recent years, several international authorities, including the UN Economic and Social Council (ECOSOC)(2010; 2011), the World Health Organization (WHO)(2011a), the World Health Assembly (WHA)(2005), and the Council of Europe (2003) have recognized pain relief as an important public health issue and, indeed, a universal human right (Brennan, Carr, & Cousins, 2007; Cousins, Brennan, & Carr, 2004; Lema, 2012). In the U.S., a recent IOM report (Institute of Medicine Committee on Advancing Pain Research, 2011) also acknowledged the moral imperative of effective pain management, as well as considering it a professional healthcare responsibility.

Many factors can influence the provision of treatment for pain in the U.S., especially when pain is persistent or severe, including clinical domain characteristics related to the healthcare system and healthcare professionals:

(1) **knowledge, beliefs, and attitudes of healthcare professionals** (Breuer, Cruciani, & Portenoy, 2010; Breuer, Fleishman, Cruciani, & Portenoy, 2011; Darer, Hwang, Pham, Bass, & Anderson, 2004; Gardiner et al., 2012; Hirsh, Hollingshead, Matthias, Bair, & Kroenke, 2014; Hollen, Hollen, & Stolte, 2000; Institute of Medicine Committee on Advancing Pain Research, 2011; Joranson & Gilson, 2001; Lin, Alfandre, & Moore, 2007; Lippe, Brock, David, Crossno, & Gitlow, 2010; McCarberg, 2010; McMillan, Tittle, Hagan, Laughlin, & Tabler, 2000; Notcutt & Gibbs, 2010; Nwokeji, Rascati, Brown, & Eisenberg, 2007; Passik, Byers, & Kirsh, 2007; Roth, Burgess, & Mahowald, 2007; Wilson et al., 2013; Wolfert, Gilson, Dahl, & Cleary, 2010),

(2) **patient and family perceptions** (Auret & Schug, 2005; Baker, O'Connor, & Krok, 2014; Cano, Miller, & Loree, 2009; Dawson et al., 2005; Drayer, Henderson, & Reidenberg, 1999; Gunnarsdottir, Donovan, Serlin, Voge, & Ward, 2002; Institute of Medicine National Cancer Policy Board, 2001; Institute of Medicine Committee on Advancing Pain Research, 2011; McCarberg, 2010; McCracken, Hoskins, & Eccleston, 2006; Tolle, Tilden, Rosenfeld, & Hickman, 2000; Ward et al., 1993; Wilson, Lewandowski, & Palermo, 2011),

(3) **the inadequate attention to pain in certain patient populations** (Anderson, Green, & Payne, 2009; Burgess et al., 2014; Campbell et al., 2012; Cintron & Morrison, 2006; Green & Hart-Johnson, 2010; Narayan, 2010; Institute of Medicine Committee on Advancing Pain Research, 2011; Mathur, Richeson, Paice, Muzyka, & Chiao, 2014; Pletcher, Kertesz, Kohn, & Gonzales, 2008; Rolnick et al., 2007; Schwaderer & Itano, 2007; Wieder, DeLaRosa, Bryan, Hill, & Amadio, 2014; Wolfe et al., 2008), and

(4) **restrictive policies governing healthcare practice, as well as concerns about regulatory scrutiny when prescribing controlled substances** (Cancer Pain Management Policy Review Group, 2001c; Gilson, 2010b; Gilson, 2010c; Gilson et al., 2005; Gilson et al., 2007; Institute of Medicine Committee on Advancing Pain Research, 2011; Joranson & Gilson, 2003; McErlean, Triner, & Young, 2006; Miaskowski et al., 2005; National Association of Attorneys General, 2003b; National Association of Attorneys General, 2003a; National Institutes of Health Consensus Development Program, 2002; Quill & Meier, 2006; Taylor, Gostin, & Pagonis, 2008; Tucker, 2001).

Successfully addressing these numerous barriers to pain control will likely require what the IOM Committee on Advancing Pain Research, Care, and Education has termed a "cultural transformation:"

> "[Such a] transformation will lead to a greater awareness of the impact of pain on individuals and society, wider support of efforts to understand and prevent pain, a greater commitment to assessing and treating pain effectively, and enhanced recognition of the highly individual ways in which people experience pain and respond to treatment" (Institute of Medicine Committee on Advancing Pain Research, 2011), p. 1-23).

A variety of pharmacologic and non-pharmacologic treatments exist that can be useful to relieve pain (Bercovitz, Jones, & Harris-Kojetin, 2011; Chou et al., 2009; Cleary, 2007; Delgado et al., 2014; Dworkin et al., 2007) (Foreman, 2014; Fransen & McConnell, 2009; Kerns, Sellinger, & Goodin, 2011; Miaskowski et al., 2005; World Health Organization, 2011a)), and a collaborative or an integrative model of care should be encouraged for all patients (Dobscha et al., 2009; Institute of Medicine Committee on Advancing Pain Research, 2011). Opioid analgesics in the class of morphine have a legitimate medical use (Controlled Substances Act, 1970a) and are indicated for the medical management of moderate or severe pain[4] (World Health Organization, 1996; World Health Organization, 2011a). Although the role of prescription opioids for treating chronic pain from a variety of non-cancer conditions[5] continues to

[4] On April 16, 2014, the FDA approved class-wide labeling changes for all extended-release and long-acting (ER/LA) opioid analgesics – such products are indicated for the "management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate" (http://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm363722.htm).

[5] It is important to clarify that the terms "chronic pain" (Fillingim et al., 2014) or "non-cancer pain" (Webster, 2012) do not represent uniform diagnostic concepts, but rather embody a broad array of disparate conditions that may or may not be responsive to treatment with opioids. Moreover, even the concept of "cancer pain" does not offer as straightforward an interpretation as often assumed. This is especially the case

evolve (Eriksen, Sjogren, Bruera, Ekholm, & Rasmussen, 2006; Warner, 2012), and evidence of effectiveness is derived largely from consensus standards, there seems to be a general agreement that some patients with such pain can be properly treated with opioid therapy (American Academy of Pain Medicine, 2013; Federation of State Medical Boards of the United States Inc., 2013; Fishman, 2012; Group Health Research Institute, 2013; Manchikanti et al., 2012). Ultimately, however, the distinction between "cancer" and "non-cancer" pain does not obviate the need to maintain availability and accessibility of opioids as a therapeutic modality when clinically warranted. Opioids should be available in adequate amounts when determined to be clinically appropriate, especially when pain is severe (Brennan et al., 2007; Katz, McCarberg, & Reisner, 2007; Lohman, Schleifer, & Amon, 2010; World Health Organization, 2011a). Physicians, osteopaths, pharmacists, and nurses (where permitted) must be able, knowledgeable, and confident to prescribe, administer, and dispense opioids according to individual patient needs (Bruehl et al., 2013; Federation of State Medical Boards of the United States Inc., 2013; Payne et al., 2010).

Prescribers of opioid medications should be aware of potential adverse effects, which should be monitored and addressed throughout treatment (American Academy of Pain Medicine, 2013; Federation of State Medical Boards of the United States Inc., 2013; Fishman, 2012). Adverse effects include such common side effects as constipation, sedation, pruritus, nausea, and respiratory depression, as well as the potential for hyperalgesia, sexual dysfunction, changes in hormone levels, immune system changes, and, in some cases, the development of substance dependence and overdose (Chou et al., 2009; Institute of Medicine Committee on Advancing Pain Research, 2011). Although further evidence is needed to determine the extent that many of the more serious risks relate to patients whose medications are taken in prescribed dosage regimens for legitimate medical purposes, especially when the patient does not have a history of substance abuse, practitioners should be knowledgeable about the clinical potential for these issues (American Academy of Pain Medicine, 2013). It is, therefore, incumbent on the prescriber to be able to discuss with the patient the benefits and risks of prolonged opioid treatment and to periodically assess for particular outcomes once treatment is initiated (American Academy of Pain Medicine, 2013; Federation of State Medical Boards of the United States Inc., 2013; Fishman, 2012; Manchikanti et al., 2012; Substance Abuse and Mental Health Services Administration, 2011).

Diversion and Non-Medical Use of Prescription Opioids

In recent years there has been a growing recognition that increases in the availability of prescription opioids indicated for the treatment of moderate or severe pain have co-occurred with more prevalent diversion and non-medical use of these medications (Becker, Tobin, & Fiellin, 2011; Cicero, Inciardi, & Munoz, 2005; Compton & Volkow, 2006; Gilson, Ryan, Joranson, & Dahl, 2004; Inciardi & Cicero, 2009; Novak, Nemeth, & Lawson, 2004; Office of National Drug Control Policy, 2011; Paulozzi, Budnitz, & Xi, 2006; Peindl, Mannelli, Wu, & Patkar, 2007; Volkow & McLellan, 2011; Zacny et al., 2003). Use of diverted opioids can result in harm and even death, and population-based studies have suggested an increased risk of death from overdose with higher opioid doses (Bohnert et al., 2011; Dunn et al., 2010; Gomes, Mamdani, Dhalla, Paterson, & Juurlink, 2011). In fact, unintentional poisoning deaths involving

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for the increasing number of long-term cancer survivors who do not experience pain from the disease but who nevertheless suffer from pain associated with their cancer treatment; the label of "cancer pain" may not sufficiently characterize this scenario (Cheung, Neville, Cameron, Cook, & Earle, 2009).

opioids increased from approximately 4,000 to over 16,500 between 1999 and 2010 (Jones, Mack, & Paulozzi, 2013); published evidence also suggests that opioid-related overdose and deaths often are characterized by diversion activities, a history of substance abuse, polypharmacy, non-medical uses and routes of administration, and previous overdose episodes (Hall et al., 2008). Although it remains unclear whether non-medical use and diversion of opioid medications occurs largely outside the context of legitimate pain management practices, a recent IOM report identifies an important consideration when contemplating the interface between pain and addiction issues (Institute of Medicine Committee on Advancing Pain Research, 2011):

> "…the majority of people with pain use their prescription drugs properly, are not a source of misuse, and should not be stigmatized or denied access because of the misdeeds or carelessness of others" (IOM, 2011, p. 3-27).

A more comprehensive, evidence-based, understanding the methods by which prescription opioids are being diverted from the drug distribution system into illicit channels and unauthorized use is necessary to effectively identify sources of diversion and to address this complex public health problem (Becker et al., 2011; Cicero et al., 2011; Coleman, 2012; Inciardi et al., 2009; Tufts Health Care Institute Program on Opioid Risk Management, 2013).

The federal government has taken a significant step forward in developing a strategy that acknowledges the complexity of this issue and the need for an extensive initiative. In April 2011, the Office of National Drug Control Policy (ONDCP) unveiled its *Prescription Drug Abuse Prevention Plan* (Office of National Drug Control Policy, 2011). This approach represents a federal multi-agency, multi-method, initiative to reduce morbidity and mortality from prescription medications, which involves four domains: (1) Education, (2) tracking and monitoring, (3) proper medication disposal, and (4) enforcement.

It is perhaps not surprising that much attention is given to the education of healthcare practitioners, as well as patients and youths and their parents, about the risks associated with prescription medications (Webster et al., 2011). For practitioners, there will be increased continuing education opportunities and educational curricula in health professional schools about the safe and appropriate use of opioids. Such initiatives will be coupled with new tools to promote effective treatment and methods to assess clinical outcomes. Education of patients and youths and their parents will involve a variety of evidence-based educational campaigns addressing appropriate medication use, safe storage, and disposal, and enhancing awareness of the dangers of misuse and abuse. Also of note, proper medication disposal is a targeted area of intervention because there has been increased awareness in recent years that the volume of unused medications is an important source of diversion and abuse (Flemming, 2010) – the ideas to address this include changing DEA laws regarding disposal (and then establishing community-based disposal programs once the DEA laws have been enacted), providing additional take-back activities, and a public awareness campaign; the DEA's plan to address controlled substances disposal recently has been issued in a Notice of Proposed Rulemaking (Federal Register, 2012), which was created to implement the Secure and Responsible Drug Disposal Act of 2010 (Secure and Responsible Drug Disposal Act, 2010). Subsequent ONDCP *National Drug Control Strategy* reports (2012; 2013) continued to substantiate this strategy.

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The ONDCP strategy is designed to reduce non-medical use of prescription drugs within the broader context that is warranted. This federal initiative conforms to the notion that a more thorough understanding of diversion and abuse is essential to avoid drug control efforts that end up using limited resources that either have little or no benefit in minimizing abuse or diversion or that can actually obstruct the availability of medications for the patients who need them (Joranson & Gilson, 2006; Office of National Drug Control Policy, 2011). See Section IV, the subsection entitled "Recognize Federal and State Policy Initiatives to Reduce Non-Medical Use and Diversion of Prescription Medications that Extend Beyond Prescribing Practices," for a more thorough description of the ONDCP strategy.

Balancing Control and Availability

Because opioid analgesics have both a medical indication and an abuse liability, their prescribing, dispensing, and administration, indeed their very availability in commerce, is governed by a combination of policies, including international treaties and U.S. federal and state laws and regulations. The main purpose of these policies is **drug control:** to prevent diversion and abuse of prescription medications. However, international and federal policies also express clearly a second purpose of drug control, that being **availability**: recognizing that many opioids (referred to in law as narcotic drugs or controlled substances) are necessary for pain relief and that governments must ensure their adequate availability for medical and scientific purposes. When both control and availability are appropriately recognized in public policy, and *implemented* in everyday practice, this is referred to as a **balanced** approach (American Medical Association-Department of Substance Abuse, 1990; Cooper, Czechowicz, Petersen, & Molinari, 1992; Drug Enforcement Administration et al., 2001; Fishman, 2012; Gilson, 2010a; Gilson, Joranson, Maurer, Ryan, & Garthwaite, 2005; Joranson & Dahl, 1989; Office of National Drug Control Policy, 2011; Woodcock, 2009; World Health Organization, 2011a). Section V and Section VI contain a detailed discussion of the concept of Balance, as well as both the international and national support for the imperative to create balanced healthcare policy.

The Federal Food, Drugs and Cosmetic Act (FFDCA) determines which drugs require a prescription. Federal and state laws, including the Controlled Substances Act (CSA), establishes the system of drug control around prescription medications with a potential for abuse (see Types of Policies in Section II) by governing their importation, manufacture, distribution, prescribing, dispensing, and possession. State-licensed and properly registered healthcare practitioners may prescribe, dispense, and administer FDA-approved controlled drugs only for legitimate medical purposes and in the course of professional practice[6] (Code of Federal Regulations, 2003a; Controlled Substances Act, 1970d). To prevent diversion, the CSA establishes a closed system that is similar to a chain of custody, including licensing, security, order forms, record keeping, monitoring, and penalties (Drug Enforcement Administration, 2004; Drug Enforcement Administration, 2006b). Everyone in the supply chain for controlled drugs is expected to have adequate qualifications for effective management of the applicable legal requirements. A valid prescription completes the chain of custody that results in authorized patient access. To be lawfully possessed, the controlled substance must be kept in the original container having the dispenser's label with the required prescription information. It is a violation of federal law to transfer the drug to another person (Controlled Substances Act, 1970e).

[6] The use of opioids to treat opioid addiction is not considered legitimate practice unless accomplished by a specially-registered practitioner according to federal and state laws that regulate this practice.

Section III: Background about Pain Relief and Public Policy

Prescriptions for Schedule II drugs are required to be either in written form or electronic (since 2011), and cannot be refilled; however, there are no federal statutory restrictions on dosages or quantities of drugs prescribed (Drug Enforcement Administration, 2006b; Drug Enforcement Administration, 2007). Federal controlled substances law recognizes that many controlled substances are necessary to maintain public health (Controlled Substances Act, 1970a), and establishes a procedure for ensuring that these medications are adequately available to satisfy prescription demand (Federal Register, 1988b; Gilson, 2010a). In fact, the DEA (Federal Register, 1988a) has issued a strong statement in support of maintaining a sufficient supply of needed medications:

> "The CSA requirement for a determination of legitimate medical need is based on the undisputed proposition that patients and pharmacies should be able to obtain sufficient quantities of methylphenidate, or of any Schedule II drug, to fill prescriptions. A therapeutic drug should be available to patients when they need it. To accomplish this a smooth flow of distribution is required." (emphasis added) (DEA, 1988).

The CSA is not intended to interfere with healthcare practice or with the availability of controlled substances approved under the FFDCA for legitimate medical purposes (Controlled Substances Act, 1970f; Joranson & Gilson, 1994; Noah, 2003). Although the CSA does contain an outdated definition of "addict,"(Controlled Substances Act, 1970b) the definition has little potential to confuse patients using opioids for pain treatment with persons who compulsively use opioids non-medically due to an addictive disease, and is not considered a potential barrier to adequate pain relief (Gilson, 2010c). It should be noted, however, that a definition of "drug dependent person" is present in another federal statute (Public Health and Welfare,), which would apply to any patient receiving medical treatment who has developed a physical dependence on the medication. The complete statutory language is as follows:

> "The term 'drug dependent person' means a person who is using a controlled substance (as defined in section 102 of the Controlled Substances Act [21 USCS § 802]) and who is in a state of psychic or physical dependence, or both, arising from the use of that substance on a continuous basis. Drug dependence is characterized by behavioral and other responses which include a strong compulsion to take the substance on a continuous basis in order to experience its psychic effects or to avoid the discomfort caused by its absence" (emphasis added) (42 USCS § 201).

Thirteen states currently have laws that contain this, or conceptually similar, language and should be repealed to avoid legally encompassing people with pain who are being medically treated with opioids.

State Policies May be More Restrictive

In addition to federal requirements, controlled substances prescribing, dispensing, and administration is governed by the states. States also are responsible for regulating healthcare practice, including medical, osteopathic, pharmacy, and nursing practice. State policies historically have tended not to be as balanced as international and federal policy (Gilson, 2010a; Gilson et al., 2005); unlike federal law (Controlled Substances Act, 1970a), most state laws do not specifically recognize the public health importance of controlled drugs (Gilson, 2010a). In addition, some state laws or other governmental policies restrict prescribing and dispensing of opioids to a greater extent than federal law. Such regulatory requirements can interfere with treatment decisions that should be based on individual needs of the patient and medical expertise, rather than on government mandates and prohibitions (Weinberger, Lawrence III, Henley, Alden, & Hoyt, 2012).

Section III: Background about Pain Relief and Public Policy

Beginning in the mid-1980s, studies by various groups and individuals began identifying regulatory impediments to pain management in state policies (Dahl & Joranson, 1987; Hill, Jr. & Fields, 1989; Joranson & Dahl, 1989; Joranson, 1990; Joranson, 1997; Joranson & Gilson, 1996; Von Roenn, Cleeland, Gonin, Hatfield, & Pandya, 1993). A succession of reports and articles on inadequate pain management identified the possible influence of policy impediments at the state level (Cancer Pain Management Policy Review Group, 2001c; Cancer Pain Management Policy Review Group, 2001a; Fujimoto, 2001; Gilson et al., 2005; Institute of Medicine Committee on Care at the End of Life, 1997; Institute of Medicine Committee on Advancing Pain Research, 2011; Merritt et al., 1998; Miaskowski et al., 2005; National Conference of Commissioners on Uniform State Laws, 1990; National Conference of Commissioners on Uniform State Laws, 1994; National Institutes of Health Consensus Development Program, 2002; Rich, 2000; Tucker, 2001). The American Cancer Society (ACS) (Cancer Pain Management Policy Review Group, 2001c), as well the Institute of Medicine (Institute of Medicine Committee on Care at the End of Life, 1997) and the National Institutes of Health (National Institutes of Health Consensus Development Program, 2002), have called for studies to improve pain management by identifying the legal and regulatory impediments to using opioids for pain relief. In addition, international organizations, such as the International Narcotics Control Board (1996; 2011) and the World Health Organization (1990; 1998a; 2000; 2011a), have called on all countries to identify and address regulatory barriers to cancer pain relief.

Regulatory impediments in state policies, many of which were enacted 20 or more years ago, have included:

- unduly-strict limitations on prescribing and dispensing (including the number of days for which a prescription is valid),
- complete exclusion of people with particular characteristics from receiving prescriptions for pain medications (regardless of treatment feasibility),
- defining “unprofessional conducts” to include “excessive prescribing,” without specifying the standards or criteria used to make such a determination, and
- legal terminology (typically reflecting the federal statutory language cited above) that could confuse physical dependence on opioids used in the course of pain therapy with addiction, which is heavily stigmatized in the U.S. and is associated with illegal activity (Cicero et al., 2005; Gilson, 2010c; Inciardi & Cicero, 2009; Inciardi, Surratt, Kurtz, & Cicero, 2007).

State Policies are Changing

In the last two decades, efforts by a variety of professionals, state pain, cancer, and end-of-life care initiatives, patient groups, and state agencies have begun to reform state pain policy (Gilson, 2007; Gilson, 2010a; Gilson et al., 2005). For example, since the late 1980s there has been a growing number of state pain-specific statutes and regulatory policies, such as medical board guidelines and Intractable Pain Treatment Acts (IPTAs) – by the end of 2013, states had adopted a total of 26 pain statutes, 27 pain regulations, and 49 guidelines or policy statements related to pain, palliative care, or end-of-life care that were relevant to this evaluation. These reform activities often produce more balanced state policies, but in some cases can also create additional restrictions and requirements that have the potential to impede pain management.

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IPTAs are statutes first adopted in Texas in 1989, which are intended to improve access to pain management by providing physicians immunity from regulatory (or sometimes even criminal) sanctions for prescribing opioids to patients with intractable pain. Conversely, many IPTAs also have historically imposed *more* requirements and restrictions on, and have created ambiguities about, opioid prescribing for pain in this context (American Alliance of Cancer Pain Initiatives, 2004). Immunity under an IPTA may not apply to physicians who prescribe to patients whose pain does not satisfy the definition of "intractable pain." Some IPTAs suggest that the use of opioids for "intractable pain" is not within the ordinary practice of medicine, and may have the effect of greater rather than less government regulation over the use of controlled substances to manage pain. In addition, IPTAs typically do not contain clear statements that are aimed at enhancing pain management and access to care. Some states have recognized these characteristics and have worked to remove ambiguities and restrictions from IPTAs. For example, in 2001 Michigan became the first state to delete the term "intractable pain" from its statute, thus making its provisions applicable to pain in general. More recently, both California (the state with the second-oldest IPTA) and Rhode Island repealed a number of restrictive provisions from their IPTAs, including removing the term and definition of "intractable pain;" in 2008, Oregon also repealed the definition of "intractable pain" from its IPTA. By the end of 2012, Ohio and West Virginia legislatures also re-evaluated and modified their IPTA content. The resulting laws now govern the treatment of all types of pain. In addition, in 2006 Arkansas adopted a new IPTA that generally eschewed the numerous instances of restrictive or ambiguous policy language found in past IPTAs. Instead of statutes, however, many states have chosen to develop guidelines or regulations containing language aimed at enhancing pain management.

Beginning in the late 1980s, but especially by the early-to-mid-90s, state medical boards began adopting guidelines and regulations to encourage safe and effective pain management and to address physicians' concern about investigation (Gilson & Joranson, 2002; Gilson et al., 2005; Gilson, Maurer, & Joranson, 2007; Joranson, Gilson, Dahl, & Haddox, 2002). To promote consistency in state medical policy, the Federation of State Medical Boards of the U.S. (the Federation) adopted in 1998 *Model Guidelines for the Use of Controlled Substances for the Treatment of Pain* (*Model Guidelines*) (Federation of State Medical Boards of the United States Inc., 1998). In May 2004, the Federation's House of Delegates unanimously adopted a revision of the *Model Guidelines*, called the *Model Policy for the Use of Controlled Substances for the Treatment of Pain* (*Model Policy*) (Federation of State Medical Boards of the United States Inc., 2004). The revision is substantially similar to the 1998 guidelines, but also encourages state boards to address failure to treat pain as subject to professional discipline, which has been identified as an important need for state policy (World Health Organization, 2003a; Tucker, 2003). In July, 2013, the Federation's House of Delegates approved a thorough content update of this policy, making it specific to opioid therapy for chronic pain (entitled *Model Policy on the Use of Opioid Analgesics in the Treatment of Chronic Pain* (Federation of State Medical Boards of the United States Inc., 2013)) (see http://www.fsmb.org/pdf/pain_policy_july2013.pdf). At this time, at least one healthcare regulatory board (i.e., medical, pharmacy, or nursing board) in 35 states have adopted or adapted the Federation's model templates. The trend to adopt state healthcare regulatory board policy statements on pain management has resulted in overall positive changes in state pain policies (Gilson et al., 2005) and also in efforts to communicate them to practitioners and the public (Gilson et al., 2007; Hoffman, Enders, Pippins, & Segal, 2003).

Section III: Background about Pain Relief and Public Policy

State-level activities to enhance pain management practices and end-of-life care have emerged in the form of task forces, pain commissions, and advisory councils. Many of these bodies have as their goal to improve pain management practices in their state by, in part, evaluating the laws that influence patients' access to adequate pain relief and develop a plan to remove any identified regulatory barriers (Abrams, 2006; Gilson, 2007; Maryland State Advisory Council on Pain Management, 2004; Michigan Department of Consumer & Industry Services, 2002; New York State Public Health Council, 1998). Medical, osteopathic, pharmacy and nursing boards in some states have adopted jointly-prepared guidelines for pain management, palliative care, and end-of-life care (Pain & Policy Studies Group, 2008; Pain & Policy Studies Group, 2013). Improving pain relief, palliative care, or end-of-life care policy also has at various times been the focus of groups such as the Alliance of State Pain Initiatives (ASPI) (formerly the American Alliance of Cancer Pain Initiatives) (Dahl, Bennett, Bromley, & Joranson, 2002), the ACS (Cancer Pain Management Policy Review Group, 2001a; Connecticut Cancer Pain Initiative & American Cancer Society New England Division, 2003), the American Society of Law, Medicine & Ethics (Johnson, 2003), the Institute of Medicine (Institute of Medicine Committee on Care at the End of Life, 1997), the National Association of State Controlled Substances Authorities (1999), the National Association of Attorneys General (2003a), and the National Institutes of Health (National Institutes of Health Consensus Development Program, 2002; National Institutes of Health, 2004).

Conclusion

Collectively, the findings, statements, and formal documents and resolutions from international authorities (e.g., the WHO, INCB, and the ECOSOC), which will be discussed more thoroughly in Section V and Section VI, form a clear and consensual imperative from the highest level of international drug control, healthcare, and regulatory authorities in the world – Government members and health professionals should work together to promote safe and effective pain management, as well as to identify and remove impediments to the adequate availability of opioids for medical purposes. This healthcare objective also has been promoted in recent times by federal and national authoritative sources in the U.S. (e.g., DEA, NAAG, FSMB, and IOM).

Positive change to legislative and regulatory policy, as described within the overall objective of this report, should be acknowledged as one necessary but insufficient mechanism (by itself) to better achieve safe and effective treatment of pain. Further efforts still are needed to address other barriers related to attitudinal or clinical issues or the degree to which policies are implemented in practice, which include the adequate education of healthcare professionals about proper pain management practices, but which are beyond the scope of this report (unless a requirement for such education is contained in a state's legislation or regulations). Taken together, such improvements have the potential to contribute to a clinical practice environment that facilitates, rather than impedes, appropriate pain care and enhanced quality of life.

SECTION IV: ESSENTIAL CONSIDERATIONS FOR IMPROVING PATIENT PAIN CARE

The purpose of this evaluation is to identify relevant language in federal law, as well as in legislation or regulatory policies for every state, that have the potential to influence controlled medication availability and appropriate treatment of patients with pain. It is expected that people seeking to improve their state's policy can use the findings from this evaluation to inform their interactions with and messages for policy-makers, as a means to provide convincing justification for any requests for relevant policy change. A recognized limitation of the method used for this report, however, is that it relates exclusively to "black letter" policy analysis and that it is not always possible to consider the intention or context within which the policy was developed and adopted. This analysis also does not account for numerous other factors that can have an effect on patient care or that can cause a disconnect between the intent of policy content and its perception by healthcare professionals.

This section is meant to provide an awareness of the numerous other policies or policy-related activities, as well as extra-policy influences, which can have critical implications for patient treatment or that can limit the effective implementation of adopted policy.

A. Recognize that Non-Policy Actions or Resources Can Have Important Influences on Clinical Practice and Patient Pain Care

This research analysis relates solely to the content of statutes, regulations, and official regulatory policies that govern drug control as well as medical, pharmacy, and nursing practice. However, there are many resources or activities that are designed to help improve healthcare practice related to pain management, but which ultimately fall outside of the policy realm. Examples include professional and public awareness campaigns or educational initiatives (unless they are mandated or encouraged by state law), the development of institutional standards (unless they are codified in law), and cooperative efforts between state medical societies, pain initiatives, and hospice and palliative care groups.

A prevalent non-policy resource also comprises clinical practice guidelines, including those from national organizations such the American Pain Society and the American Academy of Pain Medicine (Chou et al., 2009), the American Society of Interventional Pain Physicians (Manchikanti et al., 2012), and the American Society for Pain Management Nursing (Oliver et al., 2012). In addition, a recent multidisciplinary clinical practice guideline from the state of Washington, entitled "Interagency Guideline on Opioid Dosing for Chronic Non-Cancer Pain" (Agency Medical Director's Group, 2006) has been perceived as establishing a new practice standard for treating chronic non-cancer pain in the state. The Guideline has received much attention from national pain organizations as a precedent for other states to adopt unduly restrictive treatment standards (American Pain Foundation, 2007; American Pain Society, 2007; Peppin, 2008). At least one state commission issued a position statement to oppose Washington's clinical practice guideline (Oregon Pain Management Commission, 2008), which asserted that the guideline can "…limit care and increase the burden of the patients [physicians] are mandated to assist" and "…dramatically increase the stigma and suffering of people in pain" (Oregon Pain Management Commission, 2008). Such reactions illustrate the belief that implementation of such a guideline could create barriers to patient access to appropriate pain treatment; at this time, other states such as Ohio and Oklahoma have adopted related standards. Despite such concern, and the recognition that overly-restrictive standards should be avoided, this policy evaluation does not apply to clinical practice guidelines and, as a result, this Washington resource was not reviewed.

Section IV: Essential Considerations for Improving Patient Pain Care

Some non-policy actions, though, have recently been mandated through federal law. For example, a 2007 statutory change to the Federal Food, Drug and Cosmetic Act (FFDCA) created a legal obligation for the Food and Drug Administration to require pharmaceutical manufacturers to develop a Risk Evaluation and Mitigation Strategy (REMS) as a method to ensure that the benefits of a medication outweigh its risks, especially when the risks are known to be serious (Federal Food Drug and Cosmetic Act,). Requiring industry to create REMS programs is motivated out of concerns about adverse events such as overdose and use by non-tolerant people, as well as abuse and misuse. This new federal legislation implementing the REMS requirement also explicates that such programs should not interfere with patient care or create a burden on the healthcare system (Federal Food Drug and Cosmetic Act, 2008). Such a legislative provision clearly represents the concept of Balance, and is identified as such through this policy evaluation. However, ever since the concept of REMS has been introduced, there was concern that certain REMS programs could impose onerous prescribing requirements (e.g., practitioner certification, patient registries, etc.) that produce barriers to patient treatment. Nevertheless, the policy-specific evaluation described in this report cannot be applied to the individual REMS programs designed by manufacturers within the FFDCA legislative requirements.

B. Recognize that Unevaluated Policies Can Have Important Influences on Patient Pain Care

Each year a number of state policies are adopted that have the potential to impact patient pain care. These policies govern such issues as:

- physician assistants practice,
- controlled substances scheduling,
- prescribing, dispensing, or administering Schedules III-V controlled substances,
- advance directives or living wills,
- physician-assisted suicide or euthanasia,
- reimbursement of therapeutic interventions,
- worker's compensation,
- controlled medication importation, and
- program grants to state agencies.

Such policies are not evaluated because they fall outside the scope of this policy research methodology (see Section VII). However, descriptive studies of these policies in relation to pain treatment would be valuable.

C. Recognize that the Content of Unadopted Policies (e.g., Bills) Can Warrant Attention Due to Their Potential Influences on Patient Pain Care

This report contains an evaluation of provisions identified in all relevant state policies that were adopted and in effect as of December 31, 2013. Although this represents hundreds of operational policies, it is important to recognize that numerous policy proposals (e.g., bills) are introduced in each state's legislative session that either are not adopted within the timeframe necessary for this research or have failed to become law due to a variety of reasons. The content of these bills nevertheless often provides valuable insights into healthcare issues that are important to legislators.

Section IV: Essential Considerations for Improving Patient Pain Care

Many bills have addressed palliative care, treatment guidelines, practitioner education, and reimbursement for comprehensive pain care, and have been designed to improve patient pain care. A number of bills also have been introduced in an effort to improve public health and safety by reducing prescription medication abuse and diversion, often by restricting medication supply in some way. Such supply limitations can reduce availability of medications needed by people who use them therapeutically for pain relief and to maintain their quality of life. For example, during the last legislative session state lawmakers from across the country frequently sought to impose medication dosage/duration limits through the regulation of Pain Management Clinics, prior authorization, and worker's compensation. In doing so, these bills often contain requirements or restrictions that have the potential to establish barriers to appropriate pain treatment when implemented into practice.

It is through the effective state-level advocacy efforts of organizations, such as the American Cancer Society Cancer Action Network, the State Pain Policy Advocacy Network of the American Academy of Pain Management, and the U.S. Pain Foundation, that many if not most of these bills have failed to become laws. However, such bills are being promulgated consistently and require ongoing resources to educate key stakeholders about the potential unintended consequences if they are passed. By this time, a few states in particular, including Indiana, Massachusetts, Ohio, and Tennessee, have introduced bills that could create substantial treatment barriers to people with pain. Coordinated advocacy activities to respond to these bills, as well as to proposed regulations and guidelines when possible, create opportunities for increased policy-maker awareness that can better ensure the avoidance of future policy impediments. In this way, resulting policies will maintain standards for appropriate treatment while also reducing the potential for prescription medication abuse and diversion.

D. Recognize that Content of a Policy Should Not Undermine the Stated Intent Used to Justify Its Development

It is possible that laws created to improve pain management contain requirements or restrictions that, when implemented in practice, actually can create barriers to effective patient care. Indeed, such requirements may make it difficult to meet the stated intent of the law, which often is established through legislative intent language or in a legislative history description. When such a situation exists, it then becomes incumbent to modify the policy content so that it conforms more closely to its explicit intent.

For example, since promulgation of the state of Washington guidelines, many of the parameters established in the guideline have served as the foundation for the creation of formal legislation and healthcare regulations to govern opioid prescribing for chronic non-cancer pain in Washington. These laws (e.g., those governing medicine, osteopathy, and nursing) are, therefore, relevant to this evaluation. Like the IPTAs described in Section III, the intent of these laws is to improve the provision of safe and effective pain relief. In fact, the finally-adopted healthcare regulation from the Department of Health – Medical Quality Assurance Commission (2012) contains an introductory Intent section that is a largely-verbatim reproduction of the Preamble from the 2004 version of the Federation's Model Policy (Federation of State Medical Boards of the United States Inc., 2004). As a result, these final rules now define inappropriate pain treatment (including nontreatment, undertreatment, overtreatment, and continued use of ineffective treatments) as a departure from principles of quality medical practice, clearly encourage appropriate pain management, as well as recognize that pain relief, including with the medical use of opioids, should be considered elements of legitimate professional practice.

Section IV: Essential Considerations for Improving Patient Pain Care

Despite the positive context established by the adopted medical regulations, concern has been expressed that:

> "…these rules have contributed to significant disruption in the provision of care for people with CNCP [chronic non-cancer pain] in the state of Washington. This may be attributed to inadequate explanation of the rules to prescribers and patients, which resulted in confusion and misunderstanding about their provisions. It is not clear how much of this confusion was generated by the content of the rules themselves…, or to confusion and fear surrounding what some believed they contained…" (American Academy of Pain Management, 2011), p. 1).

Critically, the policy has the force of law and may have liability for those who fail to comply with the requirements. Given this potential legal liability, a number of specific provisions contained in the policy may have contributed to an inaccurate understanding of or heighted concern about the rules, including (1) use of a written prescriber/patient agreement for those judged to be at a high risk of substance abuse, have a history of substance abuse, or have psychiatric comorbidities, (2) establishing a morphine equivalence dosing threshold, (3) requiring certain prescribers to obtain a consultation with a "pain management specialist" under certain circumstances, including exceeding the dosing threshold, and (4) establishing qualifications for prescribers who can serve as adequately-prepared specialist consultants (American Academy of Pain Management, 2011). Determining the reasons for practitioners' concerns, while evaluating whether changes to the rules are warranted (including the types of changes that may be most important), remains essential.

E. Recognize the Potential for Perceptions of Legal or Regulatory Oversight to Override Actual Policy Content

In addition to the numerous requirements inherent in the recent state of Washington rules (see Item D), a comprehensive assessment of the rules conducted by the American Academy of Pain Management (American Academy of Pain Management, 2011) suggests that the confusion and concerns expressed at this point, which could actually impede appropriate treatment of pain, stem more from an inadequate understanding of the legal provisions rather than from the requirements established through these policies. If this assessment is indeed accurate, then addressing this situation is more a matter of enhancing prescribers' awareness of the provisions in the rules, as well as promoting their clinical utility, rather than repealing or replacing the rule. Clearly, inaccuracies and misconceptions surrounding the breadth and mandates of these rules have the potential to facilitate prescribers' concerns about legal sanctions because of a failure to conform to these new standards. In fact, practitioners' concerns about criminal sanctions or regulatory discipline, resulting from misinterpretations about any policy requirement or exaggerated perceptions of legal liability, can hinder appropriate prescribing to an equal extent as actual policy barriers; the consequence on practice can be the same – avoiding prescribing altogether rather than taking the risk of failing to comply with statutory or regulatory obligations.

This situation also is currently exemplified by the implementation of rules governing "Pain Management Clinics" to avoid their becoming "pill mills" (i.e., criminal enterprises issuing prescription controlled substances for purposes that are not legitimate). In fact, recent media coverage of Kentucky's emergency regulations for pain clinics illustrates substantial practitioner concern about complying with the new clinical requirements, including questions about "nighttime admissions to hospitals, Medicare payments, conflicts with informed consent and [prescription drug monitoring program] access" (Wynn, 2012). Such considerations, including whether requirements for facilities also extend to individual practitioners, are potentially relevant in other states with similar laws, such as Florida, Indiana, and Ohio. Any policy considered to be confusing, excessive, or time-burdensome can have the unintended consequence of hampering legitimate practitioners and preventing patients from receiving needed treatment. Again, it is possible that such concerns will diminish as the policy content and implications become more understood, and as efforts are offered to solicit practitioner feedback to prompt further policy evaluation and revision. Until these situations are remedied, however, there is the potential to adversely impact patients with legitimate medical needs.

F. Recognize Federal and State Policy Initiatives to Reduce Non-Medical Use and Diversion of Prescription Medications that Extend Beyond Prescribing Practices

Healthcare professionals and law enforcement members share a responsibility to ensure that prescription pain medications are available to the patients who need them, while also protecting public safety by preventing their abuse and diversion. A balanced approach can be accomplished only when healthcare practitioners who treat pain understand and avoid intentionally contributing to diversion, and when law enforcement members understand and do not interfere with pain management when dealing with diversion (Drug Enforcement Administration et al., 2001). To be effective, drug control measures need to be in place to reduce the potential for prescription medications, which are available for legitimate medical and scientific purposes, to be diverted into illicit channels for non-medical use. Also, importantly, efforts to reduce non-medical drug use and diversion must be more comprehensive than focusing primarily on prescribing and dispensing practices and patient access. Such approaches should target diversion control efforts throughout the entire medication distribution system, including thefts from manufacturers, distributors, and other DEA registrants, employee pilferage, prescription form theft or forgery, and pill mills.

Throughout 2013, a number of states (including Alabama, Colorado, Iowa, North Carolina, Ohio, and Texas) adopted laws governing such diversion- and abuse-control strategies as overdose prevention efforts, medication take-back and security, and medication prescription series. In addition, in 2012 the New York state legislature adopted a statute authorizing creation of a state-wide prescription pain medication awareness program (Public Health Law,). The purpose of this program is to provide educational resources both to the healthcare professional community and to the public about the risks associated with prescription controlled substances. Such an objective is to be accomplished through:

(1) a public media campaign focusing on the harm associated with the non-medical use of prescription medications and the existing resources for their safe disposal, and
(2) the development of education and training courses and materials in medical education, and in residency, fellowship, and continuing education programs.

Section IV: Essential Considerations for Improving Patient Pain Care

All educational programs are to be informed by a professional workgroup comprised of experts in pain management, palliative care, and addiction medicine. Importantly, the governor and leaders of the state Congressional house would be sent on an annual basis a report that documents the effects of the law on deaths and ED admissions from overdose and the use of pre-hospital addiction services. Central to this law is the requirement to "protect and promote the access of patients with a legitimate need for controlled substances" (§3309-a(2)(b)(iv)). It is unfortunate, therefore, that outcomes in the annual report do not address this issue. Demonstrated effectiveness of this legislative approach should lead to further programmatic modification and refinement.

At a national level, an initiative from the Office of National Drug Control Policy's (ONDCP's) broad *Prescription Drug Abuse Prevention Plan*, published in April 2011, promotes Federal, state, and local enforcement activities representing a collaborative and systematic effort to reduce pill mills, doctor-shopping or pharmacy-hopping, and to reduce the volume of unused medications (Office of National Drug Control Policy, 2011). The following list of activities are identified in the report to address these issues:

- "While the administrative process to establish the DEA medication disposal rule is underway, DEA and other Federal agencies shall conduct additional take-back activities. Information about the take-back events shall be distributed to local anti-drug coalitions, HIDTAs, and other organizations (chain pharmacies, boards of pharmacies, boards of medicine, environmental agencies, etc.).
- Once DEA regulations on controlled substance prescription drug disposal have been established, develop and execute a robust public education initiative to increase public awareness and provide education on new methods of safe and effective drug return and disposal.
- Once DEA regulations have been established, engage PhRMA and others in the private sector to support community-based medication disposal programs.
- "ONDCP, the National Methamphetamine and Pharmaceutical Initiative (NMPI), a law enforcement training initiative funded by [High Intensity Drug Trafficking Areas], and DEA will contribute to the curriculum for the pharmaceutical crime investigation and prosecution training program sponsored by [Bureau of Justice Assistance] in 2011. Target training to states with the highest need.
- Increase training to law enforcement and prosecutor groups at national and regional conferences.
- Continue aggressive enforcement actions against pain clinics and prescribers who are not prescribing within the usual course of practice and not for legitimate medical purposes.
- Work with the appropriate groups to write and disseminate a Model Pain Clinic Regulation Law taking into consideration:
    1. registration of these facilities with a state entity;
    2. guidance for rules regarding number of employees, location, hours of operation;
    3. penalties for operating, owning, or managing a non-registered pain clinic;
    4. requirements for counterfeit-resistant prescription pads and reports of theft/loss of such pads;
    5. disciplinary procedures to enforce the regulations; and
    6. a procedure to allow patient records to be reviewed during regular state inspections.
- Increase HIDTA intelligence-gathering and investigation of prescription drug trafficking, and increase joint investigations by Federal, state, and local agencies.
- Identify and seek to remove administrative and regulatory barriers to "pill mill" and prescriber investigations that impair investigations while not serving another public policy goal.
- Expand the use of [Prescription Drug Monitoring Program (PDMP)] data to identify criminal prescribers and clinics by the volume of selected drugs prescribed. Encourage best practices for PDMPs, such as PDMP reporting of such prescribers and clinics to pharmacies, law enforcement, and insurance providers.
- Use PDMP data to identify "doctor shoppers" by their numbers of prescribers or pharmacies. Encourage best practices such as identifying such individuals to their prescribers and pharmacies, law enforcement and insurance providers." (pp. 8-9)

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This initiative truly is a multi-agency, multi-factoral, approach – in addition to the ONDCP, the other organizations designated to be involved in this initiative include the FDA, the DEA, the Department of Justice, the Bureau of Justice Assistance, the High Intensity Drug Trafficking Areas program, the Department of Health and Human Services, and state medical boards. As such, this approach better recognizes and focuses on the intricate nature of non-medical opioid use, extending beyond the practitioner/patient relationship to include clearly criminal behavior. Successfully addressing the multiple means by which prescription medications become available for illicit use, and to do so collaboratively, represents a more auspicious strategy to effectively reduce the national public health problem of non-medical drug use (Becker et al., 2011; Joranson & Gilson, 2006).

G. Recognize Positive Policy Changes as Only the First Step in Improving Pain Management

Overall, improving state policy, like any other single intervention related to the complex issue of pain management, is not usually sufficient in and of itself to accomplish safe and effective pain relief. Constructive policy change does remain, however, a necessary component to achieving a positive professional practice and regulatory environment for treating pain. Policy will have an impact only to the extent that it is communicated and implemented. Even the most positive policy, with no implementation, will have only modest practical value at best. Moreover, as described previously, adopted policy that becomes perceived as burdensome actually can hinder patient care. Structured communication strategies, therefore, often can be a beneficial mechanism for enhancing awareness of new policy requirements. To be most practicable, a new state policy should be disseminated widely and conveyed repeatedly to licensees and the public. Coordinated awareness initiatives, which not only impart information about policy content to relevant audiences but also elicit feedback from those professionals governed by the policy, can be important to ensure an accurate understanding of and effective compliance with practice requirements.

SECTION V: THE CENTRAL PRINCIPLE OF BALANCE

Balance is the Central Principle

Opioid analgesics, such as morphine, have long been used to relieve pain and have been a part of medical practice for centuries. This fact has been recognized in international law aimed at preventing drug abuse and diversion activities. The Single Convention on Narcotic Drugs of 1961 is an international treaty to which most governments, including the U.S., are parties. This Convention[7] establishes a governmental obligated to ensure the availability of narcotic drugs[8] for medical and scientific purposes and to prevent diversion, illicit trafficking, and abuse.

The Central Principle of Balance, used for this and all previous *Evaluation Guides*, is stated as follows:

> The Central Principle of **Balance** represents a dual imperative of governments to establish a system of controls to prevent abuse, trafficking, and diversion of narcotic drugs while, at the same time, ensuring their availability for legitimate medical purposes. While opioid analgesics are controlled drugs, they are also essential drugs and are absolutely necessary for the relief of pain. Opioids, including those in the therapeutic group of morphine, should be accessible to patients who need them for relief of pain. Governments must take steps to ensure the adequate availability of opioids for medical and scientific purposes. These steps include empowering medical practitioners to provide opioids in the course of professional practice, allowing them to prescribe, dispense and administer according to the individual medical needs of patients, and ensuring that a sufficient supply of opioids is available to meet medical demand.
>
> When misused, opioids pose a threat to society; a system of controls is necessary to prevent abuse, trafficking, and diversion, but the system of controls is not intended to diminish the medical usefulness of opioids, nor interfere in their legitimate medical uses and patient care. Indeed, governments have been asked to identify and remove impediments to the availability and legitimate medical use of opioid analgesics.

It is recognized that the adequacy of *controls* to prevent diversion and abuse of controlled substances is also a valid topic for policy evaluation. The evaluation and refinement of federal and state drug *control* policy occurs frequently, but the *Evaluation Guide* is the only systematic criteria-based methodology available for evaluating U.S. drug control policies as they relate to the *availability* and *medical use* of opioids. Thus, the purpose of this guide is to evaluate policies affecting legitimate availability and not drug trafficking and abuse prevention. Critically, however, another component of balance (as indicated above) is that medication availability be limited to medical and scientific purposes – national governments that have difficulty accomplishing this can be considered unbalanced in regard to effective drug control to prevent abuse and diversion (Room & Reuter, 2012); a complementary approach to address the issue of successful drug control would be valuable.

[7] In addition, the Convention on Psychotropic Substances of 1971 establishes a similar imperative for balanced policy concerning psychotropic drug policy.

[8] "Narcotic drugs," which includes opioid analgesics, is now primarily used in legal contexts, such as in reference to the international drug control treaty or relevant laws and will be used throughout this report where the context requires.

SECTION V: THE CENTRAL PRINCIPLE OF BALANCE

The Rational Basis for the Central Principle of Balance

The validity of policy analysis depends on the relevance and credibility of the evaluation criteria (Patton & Sawicki, 1993). Evaluation criteria should be based on principles, determinations, or recommendations that have been accepted by the highest possible authorities in the field.

The following excerpts from international and national legal and medical authorities establish the Central Principle of Balance, the criteria, as well as the imperative to evaluate pain policy (see Table 1 and Table 2).

INTERNATIONAL AUTHORITIES

The Single Convention on Narcotic Drugs of 1961, as amended by the 1972 protocol (United Nations, 1972), stated that:

> *"*the medical use of narcotic drugs continues to be indispensable for the relief of pain and suffering...adequate provision must be made [by governments] to ensure the availability of narcotic drugs for such purposes.*"* (Preamble)
>
> *"*The Parties [national governments] shall take such legislative and administrative measures as may be necessary...to limit exclusively to medical and scientific purposes the production, manufacture...distribution... and possession of drugs.*"* (Article 4(c))
>
> "The Board, in co-operation with Governments, and subject to the terms of this Convention, shall endeavour to limit the cultivation, production, manufacture and use of drugs to an adequate amount required for medical and scientific purposes, to ensure their availability for such purposes and to prevent illicit cultivation, production and manufacture of, and illicit trafficking in and use of, drugs." (Article 9(4))

SECTION V: THE CENTRAL PRINCIPLE OF BALANCE

The International Narcotics Control Board, which implements the Single Convention of Narcotic Drugs, has a long and consistent history of calling for adequate amounts of needed medications:

"One of the objectives of the Single Convention on Narcotic Drugs, 1961, and of that Convention as amended by the 1972 Protocol amending the Single Convention on Narcotic Drugs, 1961, is to ensure the availability of opiates, such as codeine and morphine, that are indispensable for the relief of pain and suffering, while minimizing the possibility of their abuse or diversion." (International Narcotics Control Board, 1989, ¶1)

"…[the Board], in conjunction with WHO, undertook to identify possible medical needs for opiates which were currently not being met for a variety of reasons. Information was gathered from various sources, including drug regulators, health system managers, medical specialists, pharmacists and specialized units within WHO, to determine how countries are assessing their medical needs for opiates, the extent to which those needs are being met, what impediments have arisen, and what short-, medium- and long-term strategies may be deployed to overcome those impediments." (International Narcotics Control Board, 1989, ¶5)

"International drug control treaties not only recognize the dangers associated with abuse of and trafficking in narcotics drugs, but they also recognize that they are indispensable for the relief of pain and suffering…The [INCB], in cooperation with Governments, endeavours to ensure that there is an adequate supply of narcotic drugs for medical and scientific purposes and to limit their production and use only to such purposes in order to prevent illicit narcotic drug production, trafficking and use." (International Narcotics Control Board, 1996, Summary, p. iii)

"The Single Convention on Narcotic Drugs of 1961 as amended by the 1972 Protocol establishes a dual drug control obligation for Governments: to ensure adequate availability of narcotic drugs, including opiates, for medical and scientific purposes, while at the same time preventing the illicit production of, trafficking in and use of such drugs." (International Narcotics Control Board, 1996, ¶1)

"The Board believes that an efficient national drug control regime must involve not only a programme to prevent illicit trafficking and diversion, but also a programme to ensure the adequate availability of narcotic drugs for medical and scientific purposes…Controls should not be such that for all practical purposes they eliminate the availability of narcotic drugs for medical purposes." (International Narcotics Control Board, 1996, ¶48)

*"*The International Narcotics Control Board is the successor to drug control bodies the first of which was established by international treaty over sixty years ago. A series of treaties confer on the Board specific responsibilities. The Board 'shall endeavor to limit the cultivation, production, manufacture and use of drugs to an adequate amount required for medical and scientific purposes' and 'to ensure their availability for such purposes'*."* (International Narcotics Control Board, 1997, Forward, p. iii)

The principal objective of the Single Convention on Narcotic Drugs of 1961 and previous international conventions to limit the use of narcotic drugs to legitimate medical and scientific purposes reflects the consensus among all Governments that the medical use of narcotic drugs continues to be indispensable for the relief of pain and suffering and that adequate provision must be made to ensure the availability of narcotic drugs for such purposes…Adequate availability and limitation were considered by the State parties to the 1961 Convention…as two complementary, not mutually exclusive, aims and were thus incorporated in the control provisions of those Conventions. In adopting such aims, Governments were motivated by two complimentary humanitarian considerations, namely the need to provide optimal help and relief for pain and suffering and the need to protect the individual and society from drug dependence and its detrimental consequences." (International Narcotics Control Board, 2000, (¶1)

"If the underlying principles of the international drug control treaties are correctly and fully implemented, they can provide the necessary international basis for Governments to guarantee the availability of narcotic drugs and psychotropic substances with accepted medical use to all those who need them. Those principles can also provide the necessary mechanism for preventing the inappropriate use and abuse of those narcotic drugs and psychotropic substances. The correct interpretation of the two complementary aims, namely ensuring and at the same time limiting the availability of those controlled drugs which are essential for medical purposes, is gaining wider acceptance." (International Narcotics Control Board, 2000, ¶38)

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"A well-functioning national and international system for managing the availability of narcotic drugs and psychotropic substances has to fulfill, inter alia, the following functions: (a) To provide for relief from pain and suffering by ensuring the safe delivery of the best affordable drugs to those patients who need them and, at the same time, preventing the diversion of drugs for the purpose of abuse;" (International Narcotics Control Board, 2000, ¶41(a))

"The Single Convention is the result of the recognition by the United Nations of the fact that the adequate provision of narcotic drugs for medical purposes is indispensable for the welfare of mankind, as well as of the fact that drug addiction is a worldwide social and economic threat…Therefore, the Single Convention aims to restrict the use of narcotic drugs to medical and scientific purposes and to prevent their diversion and abuse, while at the same time ensuring their availability for legitimate purposes. It includes control measures over the cultivation of plants that serve as sources of raw material of narcotic drugs, provisions regarding the obligations of national authorities in the application of control measures over the production, manufacture, trade, and distribution of narcotic drugs, as well as provisions for the medical treatment and rehabilitation of addicts." (International Narcotics Control Board, 2005, ¶2)

"Another objective of the international drug control treaties is to ensure the availability of narcotic drugs and psychotropic substances for medical treatment and to promote the rational use of controlled drugs." (International Narcotics Control Board, 2006, ¶649)

"The primary objective of the 1961 and 1971 Conventions is to ensure the availability of controlled drugs for medical and scientific purposes and to prevent the non-medical use of those drugs." (International Narcotics Control Board, 2009a, ¶20)

"One of the fundamental objectives of the international drug control treaties is to ensure the availability of narcotic drugs and psychotropic substances for medical and scientific purposes and to promote the rational use of narcotic drugs and psychotropic substances." (International Narcotics Control Board, 2009a, ¶770)

"Ensuring the availability of internationally controlled substances for treatment in accordance with article 9 of the Single Convention on Narcotics Drugs of 1961 (1961 Convention), as amended by the 1972 Protocol, and the preamble of the 1971 Convention on Psychotropic Substances (1971 Convention) is a mandate of the International Narcotics Control Board." (International Narcotics Control Board, 2011, ¶1)

"The conventions established a control regime to serve a dual purpose: to ensure the availability of controlled substances for medical and scientific ends while preventing the illicit production of, trafficking in and abuse of such substances. The 1961 Convention, while recognizing that addiction to narcotic drugs constitutes a serious evil for the individual and is fraught with social and economic danger to humankind, affirms that the medical use of narcotic drugs continues to be indispensable for the relief of pain and suffering and that adequate provision must be made to ensure the availability of narcotic drugs for such purposes…The implementation of the international drug control treaties by parties is monitored by the Board, whose responsibilities under article 9 of the 1961 Convention expressly include the responsibility to ensure the availability of narcotic drugs for medical and scientific purposes." (International Narcotics Control Board, 2011, ¶3)

"The international drug control treaties recognize that narcotic drugs and psychotropic substances are indispensable for medical and scientific purposes. However, despite numerous efforts by the Board and the World Health Organization (WHO), as well as non-governmental organizations, their availability in much of the world remains very limited, depriving many patients of essential medicines. The Board continues to monitor the worldwide availability of narcotic drugs and psychotropic substances and has made their availability one of the main topics of its dialogue with Governments on adequate treaty implementation." (International Narcotics Control Board, 2011, ¶4)

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In fact, a recent document published jointly by the INCB and the WHO, outlining ways to effectively estimate a country's need for controlled medicines, clearly emphasized the importance of medication availability:

> "By becoming parties to these conventions, States accept the obligation to implement in their national legislation the provisions of the [international drug control] conventions…(¶1)…The international drug control conventions were elaborated in recognition of the fact that certain substances, while being of great benefit to mankind, also had the potential to cause harm, such as dependence syndrome. Therefore, the conventions established a control regime that would ensure the availability of controlled substances for medical and scientific purposes while preventing their illicit production, trafficking and abuse…(¶2)…WHO also provides guidance to Governments on policies and legislation on the availability, accessibility, affordability and control of medicines made from controlled substances." (International Narcotics Control Board & World Health Organization, 2012, ¶4)

A WHO Expert Committee (1986) devised and recommended to all governments a simple, medically, and scientifically sound approach to treating cancer pain that depends on the availability of opioids such as codeine and morphine. The WHO Expert Committee on Essential Drugs (1998b) has for many years designated such opioids as morphine and codeine as "essential drugs" (and has continued to today (World Health Organization, 2011b)). "Essential drugs" is defined as:

> "those that satisfy the health care needs of the majority of the population; they should therefore be available at all times in adequate amounts and in the appropriate dosage forms..." (p. 2)

With respect to medical availability in relation to the care of individual patients, the WHO (1996) recognized that:

> "The [Single Convention] also requires the INCB to endeavour to ensure that opioids are available for medical purposes, and to confirm national estimates as quickly as possible…" (p. 48)

In 2000, the WHO (2000) prepared guidelines for evaluating national opioids control policy that also were based on the Central Principle of Balance:

> "These Guidelines can be used by governments to determine whether their national drug control policies have established the legal and administrative framework to ensure the medical availability of opioid analgesics, according to international treaties and the recommendations of the INCB and the WHO… [and] to encourage governments to achieve better pain management by identifying and overcoming regulatory barriers to opioid availability." (pp. 1-2)

Even more recently, the WHO (2004) recognized that:

> "…access to pain relief and palliative care services is often limited, even in high-resource settings, because of…excessive regulation of opioids (p. 3) [and] urges Member States…to ensure the medical availability of opioid analgesics according to international treaties and recommendations of WHO and the International Control Board." (p. 6)

Section V: The Central Principle of Balance

In 2006, the WHO Expert Committee on Drug Dependence addressed the negative impact that overly-restrictive drug control efforts can have on medical availability (World Health Organization, 2006):

> "During the discussions, factors limiting the availability of drugs for medical use were identified, including barriers inadvertently created by the application of laws and regulations. There are countries where stricter measures are applied than are required by the Conventions. This is permissible, as the requirements of the Conventions are minimum requirements. However, the aims of the Conventions are to ensure availability for medical use as well as the prevention of abuse. It should be noted therefore that the Conventions do not require the parties to implement specific licensing for prescribing and dispensing controlled substances for medical use, nor require permits for receiving these substances therapeutically. Applying stricter measures than those required by the Conventions may hamper rational use of medicines. The appropriate national authorities should carefully consider whether any such measure currently in force could be modified to permit access for patients in need…The Committee requested the WHO Secretariat to suggest including on the proposed agenda of the next Committee meeting, a discussion of the impact of scheduling on the balance between medical availability of controlled substances and the prevention of their abuse." (pp. 20-21)

When the WHO created an updated guideline in 2011 for evaluating national policies to ensure the availability and accessibility of controlled medicines, it completed superseded its guideline developed in 2000 specific to national drug control policies governing opioids (World Health Organization, 2011a). The revised WHO guideline, however, continued to be based on the Central Principle of Balance, and even contained the following clarifying statement:

> "The central principle of 'balance' represents a dual obligation of governments to establish a system of control that ensures the adequate availability of controlled substances for medical and scientific purposes, while simultaneously preventing abuse, diversion and trafficking. Many controlled medicines are essential medicines and are absolutely necessary for the relief of pain, treatment of illness and the prevention of premature death. To ensure the rational use of these medicines, governments should both enable and empower healthcare professionals to prescribe, dispense and administer them according to the individual medical needs of patients, ensuring that a sufficient supply is available to meeting those needs. While misuse of controlled substances poses a risk to society, the system of control is not intended to be a barrier to their availability for medical and scientific purposes, nor interfere in their legitimate medical use for patient care." (p. 11)

The 2011 WHO guideline also further elaborates on the dual objectives characterized by the Central Principle of Balance (World Health Organization, 2011a):

> "Countries have a dual obligation with regard to these medicines based on a quadruple imperative, which is based on legal, political, public health and moral grounds. They must ensure that these substances are available for medical purposes and they must protect their populations against abuse and dependence. Indeed, here lies the challenge for both public-health and drug-control authorities. WHO promotes policies that simultaneously strive for minimizing substance abuse and maximizing access for rational medical use. The combination that leads to the maximum public health outcome is the optimum between these two elements, and a policy leading to this optimum can be called a 'balanced policy'." (p. 11)

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The UN Economic and Social Council (ECOSOC) began in 2005 to address the demand for and supply of opioids for medical purposes, including for the treatment of pain.

> *"…*Recognize[s] that the medical use of narcotic drugs, including opiates, is indispensable for the relief of pain and suffering [and]…the need to balance the global licit supply of opiates against the legitimate demand for opiates used to meet medical and scientific needs is central to the international strategy and policy of drug control.*"* (United Nations Economic and Social Council, 2005a, p. 1)
>
> Urges all Governments to continue to contribute to maintaining a balance between the illicit supply of and demand for opiate raw materials used for medical and scientific purposes…" (United Nations Economic and Social Council, 2005a, p. 2)
>
> *"…*Recognizes the importance of improving the treatment of pain, including by the use of opioid analgesics, as advocated by the World Health Organization, especially in developing countries, and calls upon Member States to remove barriers to the medical use of such analgesics, taking fully into account the need to prevent their diversion for illicit use." (United Nations Economic and Social Council, 2005b, p. 2)

More recently, ECOSOC (2010) has been promoting positive action to assure a balanced approach to medication availability:

> *"*Stressing the importance of promoting adequate availability of internationally controlled licit drugs for medical and scientific purposes while preventing their diversion and abuse,*"* (p. 1)
>
> "Affirming that the international drug control conventions seek to achieve a balance between ensuring the availability of narcotic drugs and psychotropic substances under international control for medical and scientific purposes and preventing their diversion and abuse," (p. 1)
>
> "Noting the medical and scientific needs for internationally controlled substances worldwide to be met within a regulatory and legal framework that prevents their diversion and abuse," (p. 2)
>
> "Also noting with appreciation the efforts of non-governmental organizations and civil society in continuing to highlight the importance of the issue of adequate availability of internationally controlled substances for medical and scientific purposes as set out in the international drug control conventions," (p. 3)
>
> "Requests the United Nations Office on Drugs and Crime to continue its efforts to ensure the adequate availability of internationally controlled drugs for medical and scientific purposes, cooperating, as appropriate, through the Access to Controlled Medications Programme of the World Health Organization, while continuing its activities to prevent diversion and abuse;" (p. 4)
>
> "Invites Member States to ensure that the International Narcotics Control Board and the United Nations Office on Drugs and Crime are funded adequately, as appropriate, to support their activities to ensure adequate availability of narcotic drugs and psychotropic substances for medical and scientific purposes, including the development and implementation of guidelines to assist Governments in estimating their requirements for internationally controlled substances and to address the risk of the diversion and abuse of those substances;" (pp. 5-6)

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In the last few years, however, a Discussion Paper was issued (United Nations Commission on Narcotic Drugs, 2011), in anticipation of the 54th session of the Commission on Narcotic Drugs, specific to the adequate availability of medications in conformity to international drug control treaties (i.e., in accordance with the concept of Balance):

> "The reason that opioids are controlled under the international drug control Conventions is the harm associated with misuse and abuse. As the Commission affirmed in Resolution 53/4, the Conventions seek to achieve a balance between ensuring the availability of narcotic drugs and psychotropic substances under international control for medical and scientific purposes and preventing their diversion and abuse. Both sides of this balance — ensuring availability and preventing diversion and abuse — are concerned with the protection and promotion of health and public safety. As the World Health Organization (WHO) states, the public health outcome is "at its maximum" when 'the optimum is reached between maximizing access for rational medical use and minimizing hazardous or harmful use.'" (¶13)
>
> "This recognition of the international drug control Conventions as concerned primarily with health was articulated by the former Executive Director of the United Nations Office on Drugs and Crime (UNODC), in his report to the review of the twentieth special session of the General Assembly, in which he said 'we must bring public health — *the first principle of drug control* — back to centre stage' and 'drug control, and the implementation of the drug Conventions, must proceed with due regard to health and human rights.'" (¶14)
>
> "Opioid analgesics are essential for sufficient pain management, but should never be the only available substance type for the treatment of pain, particularly for the treatment of mild to moderate pain. Both opioid and non-opioid analgesics should be made available for appropriate pain management and their rational use should follow an appropriate clinical assessment, criteria for proportional interventions and pharmacological rules for the integration in a complex therapeutics approach. If appropriately used, opioid medicines are safe and the patients rarely become dependent on opioid analgesia." (¶23)
>
> "The control provisions of the Conventions are designed 1) to ensure that controlled medications are prescribed for legitimate medical purposes and safely reach patients through a controlled distribution chain and 2) to combat illicit manufacture, trade and distribution. They are designed to serve what the INCB has described as the overall goal of a 'well-functioning national and international system for managing the availability of narcotic drugs and psychotropic substances' namely 'to provide relief from pain and suffering by ensuring the safe delivery of the best affordable drugs to those patients who need them and, at the same time, to prevent the diversion of drugs for the purpose of abuse.'" (¶32)

SECTION V: THE CENTRAL PRINCIPLE OF BALANCE

NATIONAL AUTHORITIES

In the U.S., a number of opioid analgesics have been accepted as effective, essential, and legal to be prescribed for human use under the FFDCA.[9] The FFDCA does not specify or recommend maximum dosages or quantity of prescription (Federal Register, 1975; Joranson & Gilson, 1994). Neither does the FFDCA regulate medical practice, a matter that is left to the states (a lower court decision that is referenced in United States v Evers (1981)). At both the federal and state levels, opioid analgesics are regulated as controlled substances because they have a potential for abuse.

Upon adoption of the CSA (1970a), the Congress declared:

> "Many of the drugs included within this subchapter have a useful and legitimate medical purpose and are necessary to maintain the health and general welfare of the American people." (Title 21 §801(1))

Manufacturers are registered by the Department of Justice Drug Enforcement Administration (DEA) (Controlled Substances Act, 1970c), not only to maintain effective controls against diversion but also to:

> "...produce an adequate and uninterrupted supply of these substances..." (Title 21 §823a(1))

An administrative law judge for the DEA (Federal Register, 1988b) declared:

> "The CSA requirement for a determination of legitimate medical need is based on the undisputed proposition that patients and pharmacies should be able to obtain sufficient quantities...of any Schedule II drug, to fill prescriptions. A therapeutic drug should be available to patients when they need it..." (p. 50593)

To clarify that the medical use of opioids for pain management is a legitimate medical purpose, the DEA, which implements the CSA throughout the U.S., declared in a regulation (Code of Federal Regulations, 2003b) that:

> "This section is not intended to impose any limitations on a physician or authorized hospital staff to...administer or dispense narcotic drugs to persons with intractable pain in which no relief or cure is possible or none has been found after reasonable efforts." (Title 21 §1306.07(c))

[9] Reidenberg (Reidenberg, 2006) has urged the healthcare field to discontinue using the term "drug safety," as no prescription medication is absolutely safe and all pose some safety and health risks. Rather, all drugs have adverse effects, which the FDA consider acceptable risks relative to the medication's benefits when used as directed under the supervision of a licensed and registered practitioner.

SECTION V: THE CENTRAL PRINCIPLE OF BALANCE

The *Model Policy on the Use of Opioid Analgesics in the Treatment of Chronic Pain* (Federation of State Medical Boards of the United States Inc., 2013) is an update by the Federation of State Medical Boards of its previous policies from 1998 (Federation of State Medical Boards of the United States Inc., 1998) and 2004 (Federation of State Medical Boards of the United States Inc., 2004) relating more broadly to treatment with controlled substances for pain in general. As with the previous policies, this policy reaffirms the central role of the physician in making decisions about the use of opioids:

> "Physicians should not fear disciplinary action from the Board for ordering, prescribing, dispensing or administering controlled substances, including opioid analgesics, for a legitimate medical purpose and in the course of professional practice, when current best clinical practices are met." (p. 7)

The Federation (Federation of State Medical Boards of the United States Inc., 2013) also stated that:

> "…principles of high-quality medical practice dictate that the people...have access to appropriate, safe and effective pain management...All physicians and other providers should be knowledgeable about assessing patients' pain and function...opioid analgesics are useful and can be essential in the treatment of acute pain that results from trauma or surgery, as well as in the management of certain types of chronic pain, whether due to cancer or non-cancer causes n, and familiar with methods of managing pain. Physicians also need to understand and comply with federal and state requirements for prescribing opioid analgesics... The diagnosis and treatment of pain is integral to the practice of medicine." (p. 7-8)

The National Council of State Boards of Nursing (the Council) issued in 2008 a "Report of Disciplinary Resources Committee," which outlined "Regulatory Implications: The Advanced Practice Registered Nurse in a Pain Management Primary Care Role" (National Council of State Boards of Nursing, 2008). Because Advanced Practice nurses have controlled substances prescribing authority in most states, the Council focused specifically in this unique practice within the nursing profession.

> *"*In providing treatment of pain, the [Advanced Practice Registered Nurse] is charged with the responsibility to diagnose the causes of pain, intervene with a variety of therapies, and evaluate the effectiveness of pain treatment being prescribed. The [Advanced Practice Registered Nurse] is responsible for appropriate, accurate and complete documentation of assessment, treatment of pain, informed consent and ongoing review of efficacy.*"* (p. 132)

The Council also seemed to stress the concept of balance as foundational to nursing professional standards and practice expectations (National Council of State Boards of Nursing, 2008):

> "Promoting pain relief, while at the same time preventing abuse of pain medications, becomes a balancing act. Preventing drug abuse is an important societal goal, but there is consensus by law enforcement agencies, health care practitioners, and patient advocates alike, that it should not hinder patients' ability to receive the care they need and deserve." (p. 133)

SECTION V: THE CENTRAL PRINCIPLE OF BALANCE

A recent Joint Policy Statement from the American Cancer Society Cancer Action Network & Alliance of State Pain Initiatives (2007) also reinforced the concept of balance as an important consideration for policy development:

> "Efforts to prevent diversion and abuse of opioid analgesics are very important and necessary but should not interfere with medical practice and patient care. Policies aimed at preventing drug diversion, regulating professional practice, and improving patient care must be balanced so they do not restrict medical decision-making and the availability of controlled substances for legitimate medical purposes." (p. 1)

The 2011 IOM report, entitled "Relieving Pain in America," contained a statement that directly relates to the principle of balance, within the context of pain as an important public health issue (Institute of Medicine Committee on Advancing Pain Research, 2011):

> "…pain raises societal issues that extend beyond individuals and their suffering. Specifically, the opioid medications that are effective for many people with pain also are subject to misuse and abuse, and ensuring that they are available for those who need them and not available to abusers necessitates cross-governmental efforts at all levels." (p. 2-1)

More than a decade ago, DEA and 21 leading health organizations endorsed a joint statement, *Promoting Pain Relief and Preventing Abuse of Pain Medications: A Critical Balancing Act*, resulting in explicit language promoting balance (Drug Enforcement Administration et al., 2001):

> "Preventing drug abuse is an important societal goal, but there is consensus, by law enforcement agencies, health care practitioners, and patient advocates alike, that it should not hinder patients' ability to receive the care they need and deserve."
>
> "Undertreatment of pain is a serious problem in the United States, including pain among patients with chronic conditions and those who are critically ill or near death. Effective pain management is an integral and important aspect of quality medical care, and pain should be treated aggressively."
>
> "For many patients, opioid analgesics – when used as recommended by established pain management guidelines – are the most effective way to treat their pain, and often the only treatment option that provides significant relief."
>
> "Drug abuse is a serious problem. Those who legally manufacture, distribute, prescribe and dispense controlled substances must be mindful of and have respect for their inherent abuse potential. Focusing only on the abuse potential of a drug, however, could erroneously lead to the conclusion that these medications should be avoided when medically indicated – generating a sense of fear rather than respect for their legitimate properties."

SECTION V: THE CENTRAL PRINCIPLE OF BALANCE

The National Association of Attorneys General (2003b) recognized this joint approach and issued a resolution endorsing a balanced approach to pain management:

> "…there is a consensus among law enforcement agencies, health care practitioners, and patient advocates that the prevention of drug abuse is an important societal goal that can and should be pursued without hindering proper patient care; and…it is crucial that public health, law enforcement, and government officials continue to develop strategies and methods to prevent the abuse and diversion of prescription drugs, while safeguarding the right of those suffering from severe and chronic pain to continue to have access to appropriate medications." (p. 1)

In a separate report that same year, the National Association of Attorneys General (2003a) reconfirmed its commitment to balance by stating that:

> "…the Attorney General should actively promote the concept of balance that legitimate law enforcement goals should be pursued without adversely affecting the provision of quality end-of-life care." (p. 20)

As additional evidence of law enforcement's dedication to a balanced policy initiative, the White House Office of National Drug Control Policy (2011), when issuing a report to address the crisis of prescription drug abuse in the U.S., included the following statements:

> "…any policy response [to the prescription drug abuse problem] must be approached thoughtfully, while acknowledging budgetary constraints at the state and Federal levels. The potent medications science has developed have great potential for relieving suffering, as well as great potential for abuse. There are many examples: acute medical pain treatment and humane hospice care for cancer patients would be impossible without prescription opioids; benzodiazepines are the bridge for many people with serious anxiety disorders to begin the process of overcoming their fears; and stimulants have a range of valuable uses across medical fields. Accordingly, <u>any policy in this area must strike a balance between our desire to minimize abuse of prescription drugs and the need to ensure access for their legitimate use</u>…" (pp. 1-2)
>
> "Research and medicine have provided a vast array of medications to cure disease, ease suffering and pain, improve the quality of life, and save lives. This is no more evident than in the field of pain management. However, as with many new scientific discoveries and new uses for existing compounds, the potential for diversion, abuse, morbidity, and mortality are significant. Prescription drug misuse and abuse is a major public health and public safety crisis. <u>As a Nation, we must take urgent action to ensure the appropriate balance between the benefits these medications offer in improving lives and the risks they pose</u>…" (pp. 1-2)

SECTION VI: THE IMPERATIVE TO EVALUATE FEDERAL AND STATE POLICY FOR BALANCE

Some Drug Control Policies have the Potential to Impede the Use of Opioids for Pain Relief

International and national authorities have called attention to the inadequate treatment of pain and have concluded that this is due, at least in part, to statutes and regulations that may impede the adequate availability and medical use of opioids.

The International Narcotics Control Board (INCB)[10] has, over a number of years, observed that the medical need for opiates in the world was not being fully met. In cooperation with the WHO, the INCB determined that there were a number of reasons for inadequate availability of opiates for pain relief in the world, including unduly restrictive drug control policies:

> "...the reaction of some legislators and administrators to the fear of drug abuse developing or spreading has led to the enactment of laws and regulations that may, in some cases, unduly impede the availability of opiates. The problem may also arise as a result of the manner in which drug control laws and regulations are interpreted or implemented." (International Narcotics Control Board, 1989, Summary, p. 1)
>
> "...legislators sometimes enact laws which not only deal with the illicit traffic itself, but also impinge on some aspects of licit trade and use, without first having adequately assessed the impact of the new laws on such licit activity. Heightened concern with the possibility of abuse may also lead to the adoption of overly restrictive regulations which have the practical effect of reducing availability for licit purposes." (International Narcotics Control Board, 1989, ¶42)
>
> "The most frequently mentioned causes of inadequate opioid availability are restrictive regulations, cumbersome administrative procedures, concerns about diversion and the consequences of inadvertent errors, concerns about iatrogenic addiction, and inadequate or insufficient training of health personnel. The removal of these impediments should be first of all the responsibility of the concerned Governments and that of the medical profession." (International Narcotics Control Board, 1999, ¶31)
>
> "The Board and WHO reviewed documents and studies on the availability of opioid analgesics at the national level and examined the activities undertaken and planned by various bodies to assist Governments in ensuring the availability of those drugs for medical use. The Board and WHO observed that, although there was no shortage of licitly produced opioid analgesic raw materials worldwide and there had been a substantial increase in the global consumption of opioids in the past two decades, access to opioid analgesics continued to be difficult in some countries. The difficulties in having access to opioid analgesics are due to various interrelated factors, such as inadequate medical education and lack of knowledge and skills in pain management, public attitude, regulatory impediments and economic constraints." (International Narcotics Control Board, 2007, ¶210)
>
> "Laws and regulations, and their administration or interpretation, unduly impeded the availability of opiates." (International Narcotics Control Board, 2011, ¶10)

[10] The International Narcotics Control Board is an independent treaty-based body affiliated with the United Nations, which monitors implementation of the Single Convention on Narcotic Drugs of 1961.

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Also, a recent document published jointly by the INCB and the WHO, outlining ways to effectively estimate a country's need for controlled medicines, clearly emphasized the importance of policy influences on medication availability:

> "…the effectiveness of the supply management system depends on a well-functioning legal and policy framework that is based on ensuring the availability and rational use of controlled substances for medical purposes. The lack of such a framework can affect the proper functioning of the supply management cycle and create barriers to the rational use of controlled substances. Fundamental changes to the legal and policy framework are necessary to eliminate such barriers." (International Narcotics Control Board & World Health Organization, 2012, ¶21)
>
> "Although legal and regulatory measures are necessary to prevent the diversion of controlled substances from the distribution system, they should not be a barrier to the availability of such substances for medical purposes." (International Narcotics Control Board & World Health Organization, 2012, ¶36)

The WHO Expert Committee on Cancer Pain Relief and Active Supportive Care (World Health Organization, 1990) issued a special report that addressed the obstacles to meeting medical needs for opioids to relieve cancer pain, and concluded that legislative, regulatory, and administrative impediments exist in various countries, leading to underutilization of opioids. In 2006, the WHO Expert Committee on Drug Dependence identified the negative impact that overly-restrictive drug control policies can have on medical availability (World Health Organization, 2006):

> "During the discussions, factors limiting the availability of drugs for medical use were identified, including barriers inadvertently created by the application of laws and regulations. There are countries where stricter measures are applied than are required by the Conventions. This is permissible, as the requirements of the Conventions are minimum requirements. However, the aims of the Conventions are to ensure availability for medical use as well as the prevention of abuse. It should be noted therefore that the Conventions do not require the parties to implement specific licensing for prescribing and dispensing controlled substances for medical use, nor require permits for receiving these substances therapeutically. Applying stricter measures than those required by the Conventions may hamper rational use of medicines. The appropriate national authorities should carefully consider whether any such measure currently in force could be modified to permit access for patients in need…The Committee requested the WHO Secretariat to suggest including on the proposed agenda of the next Committee meeting, a discussion of the impact of scheduling on the balance between medical availability of controlled substances and the prevention of their abuse." (pp. 20-21)

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By 2011, the WHO had published its Guidelines to promote the availability and accessibility of controlled medications (World Health Organization, 2011a), expanding upon opioid-related guidelines from 2000 (World Health Organization, 2000). The Guidelines emphasized the role of government legislation and policies on public health and welfare:

> "In many countries, national legislation includes provisions stricter than the international drug control conventions require. This is allowed for by the conventions, as far as it is in the opinion of the government 'necessary or desirable for the protection of the public health or welfare'. However, in practice, many stricter provisions do not contribute to a better public or individual health. Therefore, it is important to analyze the effects of any stricter rules on the prevention of diversion, abuse and dependence syndrome and on the availability and accessibility of controlled medicines. Rules (and policies) that do not contribute to the protection of public health or welfare should be eliminated or changed. Rules violating any other international obligation, regardless whether originating from the drug conventions or any other treaty, should be guarded against." (p. 27)
>
> "Such an analysis should be undertaken rule by rule, and cover both legislation and official policy. If a rule provides a barrier for availability and accessibility, but does not contribute to the prevention of abuse, diversion and dependence syndrome, this rule does not contribute to the protection of public health or welfare, and should therefore be either eliminated or changed. In the case where a rule both contributes to prevention and constitutes a barrier for medical use at the same time, alternative ways of providing the same level of prevention without prosing a barrier to rational medical use should be explored. This publication provides a check list that may be used for assessing which rules are overly restrictive and may therefore be in need of correction." (p. 27)

At the same time as the recent INCB and WHO documents, the UN ECOSOC (2011) has identified the potential problems associated with legislative and regulatory barriers in drug control policies.

> "While States are not precluded from adopting measures that are more restrictive than those required by the Conventions if they deem them necessary or desirable to protect public health or welfare, efforts to limit the use of narcotic drugs and psychotropic substances to medical and scientific purposes "must not adversely affect their availability for such purposes". A recent survey conducted by the INCB found that laws and regulations that were unduly restrictive or burdensome were commonly perceived as a significant limitation on availability." (¶36)
>
> "Examples of measures that may impede availability and that are not required by the Conventions include: (a) Limitations on the number of days' supply that may be provided in a single prescription (with too short a period of time allowed); (b) Limitations on doses that may be prescribed in a single prescription (with allowed doses being too low); (c) Excessive limitations on prescription authority, such as only to some categories of medical doctors; (d) Special prescription procedures for opioids, for example, the use of specific prescription forms, which may be difficult to obtain, and/or a requirement that multiple copies of the prescription be maintained; (e) Requirements that patients receive special permission or registration to render them eligible to receive opioid prescriptions; (f) Excessive penalties and prosecutions for unintentional mis-prescription or mishandling of opioids; (g) Arbitrary restrictions on the number of pharmacies permitted to dispense opioid medications; (h) Unreasonable requirements relating to the storage of opioid medications." (¶37)
>
> "These measures, not required by the Convention, do not significantly improve control, but may interfere significantly with accessibility to and availability of essential medicines." (¶38)

Section VI: The Imperative to Evaluate Federal and State Policy for Balance

In the last few years, the International Association for the Study of Pain (IASP) issued a "Declaration of Montreal" declaring that access to safe and effective pain management is a fundamental human right (International Association for the Study of Pain, 2010). Within this Declaration, the IASP recognizes the following situation and obligation:

> "Most countries have no national policy at all or very inadequate policies regarding the management of pain as a health problem, including an inadequate level of research and education." (p. 1)
>
> "There are severe restrictions on the availability of opioids and other essential medications, critical to the management of pain." (p. 1)
>
> "The obligation of governments and all health care institutions, within the scope of the legal limits of their authority and taking into account the health care resources reasonably available, to establish laws, policies, and systems that will help to promote, and will certainly not inhibit, the access of people in pain to fully adequate pain management. Failure to establish such laws, policies, and systems is unethical and a breach of the human rights of people harmed as a result." (p. 1)

In the U.S., the Institute of Medicine (IOM) (Institute of Medicine Committee on Care at the End of Life, 1997; Institute of Medicine National Cancer Policy Board, 2001; Institute of Medicine Committee on Advancing Pain Research, 2011) concluded that there is evidence to support the contention that laws and regulatory policies in the U.S. can discourage the appropriate use of opioids in pain management. In addition, an expert panel of the National Institutes of Health (NIH) (National Institutes of Health Consensus Development Program, 2002) included *"concern about legal or regulatory sanctions for overuse of opioids"* (p. 13) in a list of impediments to effective symptom management in people diagnosed with cancer. A National Consensus Project on Quality Palliative Care (Arnold et al., 2004) identified the need for palliative care programs to be knowledgeable about the legal and regulatory issues surrounding the appropriate prescribing of opioids and other controlled substances.

The American Pain Society (APS) (Miaskowski et al., 2005) recognized the importance of identifying and addressing state laws and regulations that restrict or overly-regulate the prescribing of opioid analgesics for the treatment of pain, as well as the need to train clinicians about these and other practice issues:

> "Regulatory barriers, real or perceived, are often cited as one important reason that cancer pain is inadequately treated…some healthcare professionals continue to report concern about regulatory scrutiny, and some are being held accountable for not providing adequate pain management…It remains a high priority to improve state pain-related policies; education both clinicians and regulators about pain management, substance abuse, and improper diversion of controlled substances; and ensure that enforcement and regulatory actions do not interfere with professional practice and patient care." (p. 7)

The American Cancer Society Cancer Action Network (ACSCAN) (2007) also has identified the potential existence of policy barriers to cancer pain relief:

> "State policies regulating professional practice, prescribing, and patient care vary widely and play a significant role in pain management practice. Most states have a combination of helpful policies that promote pain treatment and restrictive policies that deter adequate pain control by interfering with medical decision-making or even contradicting current medical opinion with outdated provisions." (p. 1)

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In addition, a Joint Policy Statement from ACSCAN and the Alliance of State Pain Initiatives (2007) reiterated the potential impact of policy content on cancer pain treatment:

> "Some state laws or other policies restrict prescribing and dispensing of medications to a greater extent than federal policy and can interfere with medical decisions and expertise." (p. 1)

More recently, the IOM Committee on Advancing Pain Research, Care, and Education, in its report entitled *Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education and Research* (Institute of Medicine Committee on Advancing Pain Research, 2011), reached a similar conclusion:

> "Regulatory and law enforcement policies constrain the appropriate use of opioid drugs. Restrictions in insurance coverage and payment policies, including those of workers' compensation plans, constrain the ability to offer potentially effective treatment." (p. 1-24)

Drug Control Policy Should be Evaluated

Given the historical recognition that governmental and healthcare policies can create barriers to pain care, several international and national authorities have called for studies to identify legal and regulatory impediments to the appropriate use of opioids for pain relief.

Following a review of the reasons for inadequate cancer pain relief, in cooperation with the WHO, the INCB (1989) communicated with governments throughout the world:

> "The use of certain drugs may be directly or indirectly limited by policies or guidelines adopted by Governments or medical associations. The prohibition of the use of a drug to treat one part of the population…or a particular condition may deter use of the drug under any circumstances. The lack of specific guidelines on the use of drugs such as opiates, and on the treatment of certain conditions for which those drugs may be indicated, may contribute to practitioners' reluctance to use such drugs for legitimate medical purposes…" (¶46)
>
> "In some countries the use of certain drugs is limited by the need for special authorizations or by the conditions under which the drugs may be made available. Policies or regulations may dictate or specify the conditions under which a drug may be used and therefore may affect the way in which health professionals conduct a treatment programme." (¶47)
>
> "...Governments should examine the extent to which their health-care systems and laws and regulations permit the use of opiates for medical purposes, identify possible impediments to such use and develop plans of action to facilitate the supply and availability of opiates for all appropriate indications." (¶49(c))

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The INCB reiterated this recommendation in 1996 (International Narcotics Control Board, 1996):

> "The Board believes that an efficient national drug control regime must involve not only a programme to prevent illicit trafficking and diversion, but also a programme to ensure the adequate availability of narcotic drugs for medical and scientific purposes. A national drug control programme should have legislative authority reflecting the provisions of the 1961 Convention, delegation of responsibility for implementation, including administrative responsibility for managing import and export licenses, estimating medical requirements, reporting required statistics and supervising adequate controls over distribution. Controls over the professionals and medical facilities that distribute narcotic drugs should ensure accountability and prevent diversion while making narcotic drugs available to the patients who need them. Controls should not be such that for all practical purposes they eliminate the availability of narcotic drugs for medical purposes." (¶48)
>
> "Governments are invited to consider the following recommendations:…(a) Governments that have not done so should determine whether there are undue restrictions in national narcotics laws, regulations or administrative policies that impede prescribing, dispensing or needed treatment of patients with narcotic drugs, or their availability and distribution for such purposes, and should make the necessary adjustments…(f) Governments should determine whether their national narcotic laws contain elements of the 1961 Convention and the 1972 Protocol that take into account the fact that the medical use of narcotic drugs continues to be indispensable for the relief of pain and suffering and the fact that adequate provision must be made to ensure the availability of narcotic drugs for such purposes and to ensure that administrative responsibility has been established and that personnel are available for the implementation of those laws." (¶51)

In 1999, the INCB further clarified the responsibility of Governments and the healthcare profession to identify and remove a variety of potential barriers to opioid availability for legitimate medical and scientific purposes (International Narcotics Control Board, 1999):

> "The most frequently mentioned causes of inadequate opioid availability are restrictive regulations, cumbersome administrative procedures, concerns about diversion and the consequences of inadvertent errors, concerns about iatrogenic addiction, and inadequate or insufficient training of health personnel. The removal of these impediments should be first of all the responsibility of the concerned Governments and that of the medical profession." (¶31)

More recently, the INCB (2009a) emphasized the imperative to evaluate national drug control policy and administration:

> "WHO, in consultation with the Board, prepared an assistance programme called Access to Controlled Medications Programme. The programme is designed to address impediments to the rational use of opioid analgesics, focusing on regulatory, attitude and knowledge impediments. The Board encourages UNODC to cooperate with WHO in the implementation of the Access to Controlled Medications Programme, with a view to promoting rational use of opioid analgesics by health-care professionals." (¶772 - Recommendation 44)

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In 2011, the INCB again called for governments to ensure the legitimate availability of opioid medications by focusing on the need to improve their policies (International Narcotics Control Board, 2011):

> "Governments should identify impediments to availability of narcotic drugs and psychotropic substances (policy, regulatory, administrative) and take detailed, step-by-step measures to remove those impediments." (¶132(b))
>
> "Governments should determine whether their national narcotics laws contain elements of the 1961 Convention as amended by the 1972 Protocol that take into account the fact that the medical use of narcotic drugs continues to be indispensable for the relief of pain and suffering and the fact that adequate provision must be made to ensure the availability of narcotic drugs for such purposes and to ensure that administrative responsibility has been established and that personnel are available for the implementation of those laws." (¶132(f))
>
> "Governments should determine whether there are undue restrictions in national narcotics laws, regulations or administrative policies that impede the prescribing or dispensing of, or needed medical treatment of patients with, narcotic drugs or psychotropic substances, or their availability and distribution for such purposes, and, should this be the case, make the necessary adjustments." (¶132(g))

Around the same time that the INCB began calling for greater recognition of the influence of policy barriers, the WHO (1990) recommended that governments review their administrative practices for opioid control with a view to simplification so as not to impede legitimate use of opioids by patients:

> "The following steps are necessary to ensure adequate drug availability:
>
> - review of legislation with a view to permitting the importation, manufacture, prescription, stocking, dispensing, and administration of opioids for medical reasons;
> - review of the administrative practices of opioid drug control with a view to their simplification so as not to impede legitimate use of opioids by patients;
> - determination of the probable needs of the country, based on estimates of present consumption plus the "best guess" of needs for the likely number of cancer patients to be treated;
> - review of legislation and practices that may affect the availability of other drugs." (p. 41)

The most recent 2011 WHO Guidelines for ensuring medication availability and accessibility called for governments to review its legislation and administrative requirements to determine the extent of barriers to medication availability (World Health Organization, 2011a). Such a call is similar to that found in WHO opioid-related guidelines from 2000 (World Health Organization, 2000).

> "Guideline 9: Governments should examine their drug control legislation and policies for the presence of overly restrictive provisions that affect delivery of appropriate medical care involving controlled medicines. They should also ensure that provisions aim at optimizing health outcomes and take corrective action as needed. Decisions which are ordinarily medical in nature should be taken by health professionals." (p. 27)

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In addition, the UN ECOSOC (2011) has called for governments to identify and address regulatory barriers in the narcotics control policies:

> "Review and revise national legislation, regulation and policies, in order to ensure that they reflect a balance between ensuring availability and preventing diversion and abuse, including by identifying and removing overly restrictive provisions which unnecessarily impede availability." (¶47(b))

Importantly, the same ECOSOC document (2011) also included recommendations for the UN Office on Drugs and Crime (UNODC) regarding the context of countries' laws or regulations governing the use of opioids for legitimate medical purposes.

> "A central aspect of the work of the UNODC is its normative work assisting States to implement relevant international treaties, including through the development of domestic legislation. UNODC thus has a clear mandate and responsibility to work to assist Member States to implement balanced laws and policies taking into account that different cultures, attitudes, knowledge and experience require individual guidance in such processes." (¶48)
>
> "UNODC will commence a process of examination of its model laws to ensure that they reflect an appropriate balance between the measures to ensure availability of controlled medications for medical and scientific purposes and the measures to reduce illicit manufacture, illicit trade, and diversion. If required, revisions will be made to remove or modify provisions that create impediments to medical and scientific use and do not advance the objectives of the Conventions." (¶49)
>
> "UNODC has long worked proactively to assist Member States to implement the diversion and abuse prevention aspect of their obligations under the drug Conventions. This should be, and will remain, an essential element of UNODC's work, but the Office will also focus equally on all elements necessary to guarantee availability and accessibility with particular attention to avoiding any control measures unintentionally impeding high quality medical treatment." (¶50)

In addition, the World Medical Association (WMA), which has official relations with the WHO and collaborates with health professional associations, governmental and non-governmental agencies, and regional medical associations to provide guidance to physicians, has promoted the involvement of Governments in reviewing and making changes to relevant legislation and regulations that affect adequate availability and accessibility of controlled medicines (World Medical Association, 2011):

> "Lack of education for health professionals in the assessment and treatment of pain and other symptoms, and the unnecessarily restrictive government regulations (including limiting access to opioid pain medications) are two major reasons for [the pain] treatment gap... Countries should review their drug control policies and regulations to ensure that they do not contain provisions that unnecessarily restrict the availability and accessibility of controlled medicines for the treatment of pain. Where unnecessarily or disproportionately restrictive policies exist, they should be revised to ensure the adequate availability of controlled medicines." (pp. 1-3)

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In the U.S., the IOM Committee on Opportunities in Drug Abuse Research (1996) recommended:

> *"...additional research on the effects of controlled substance regulations on medical use and scientific research. Specifically, these studies should encompass the impact of such regulations and their enforcement on prescribing practices and patient outcomes in relation to conditions such as pain...[and]... for patients with addictive disorders."* (p. 259)

Not long afterward, the IOM Committee on Care at the End of Life (1997) called for a:

> *"...review of restrictive state laws, revision of provisions that deter effective pain relief, and evaluation of the effect of regulatory changes on state medical board policies..."* [and] *"reform [of] drug prescription laws, burdensome regulations, and state medical board policies and practices that impede effective use of opioids to relieve pain and suffering."* (p. 198, 267)

In the next decade, the IOM Committee on Cancer Control in Low- and Middle-Income Countries (2007) reiterated this need:

> *"Governments should collaborate with national organizations and leaders to identify and remove barriers to ensure that opioid pain medications, as well as other essential palliative care medicines, are available under appropriate control. The INCB and WHO should provide enhanced guidance and support, and assist governments with this task."* (p. 250)

An NIH expert panel (National Institutes of Health Consensus Development Program, 2002) recognized that:

> *"Regulatory barriers need to be revised to maximize convenience, benefit, and compliance..."* (p. 15)

The ACSCAN (2007) also offered examples of ways to promote balanced policies and better pain management practices:

> *"- Partner with state healthcare regulatory boards (e.g., medical, nursing, pharmacy, osteopathy) to adopt and disseminate guidelines or policy statements encouraging pain management*
>
> *- Remove or amend restrictive or ambiguous language in state statutes and regulations...*
>
> *- Use task forces, advisory councils, and summit meetings involving multidisciplinary experts and stakeholders to examine state policy and plan a strategy for taking action."* (p. 1)

SECTION VII: RESEARCH METHODOLOGY

Overview

This document presents the results of a systematic, criteria-based, evaluation of policies that have been adopted by the federal government, the 50 states, and the District of Columbia. Policies relevant to the care of patients with pain, including with the use of controlled pain medications, comprise the population studied for this research.

The following policies were collected and analyzed for the purpose of this research:

(1) Federal controlled substances statutes and regulations – including the Controlled Substances Act (CSA) and Controlled Substances Regulations (Code of Federal Regulations), and keyword searches conducted of the Federal Food, Drug & Cosmetic Act (FFDCA) and Public Health laws.

(2) State policies[11] governing prescribing and healthcare practice – including statutes and regulations related to controlled substances, and medical, osteopathic, pharmacy, and nursing practice, other governmental policies where present, such as state medical board guidelines and official policy statements, as well as other policies containing language directly mentioning the treatment of pain, such as:

- Policies authorizing or requiring healthcare facilities to assess or treat pain
- Provisions encouraging or requiring medical school education or continuing medical education related to pain management
- Provisions establishing pain commissions, councils, and task forces as governmental vehicles designed to improve pain management and the use of controlled substances (evaluation is based on the objectives stated in policy, and not on the procedures or results of the commission's work)
- Provisions authorizing or requiring regulatory agencies to create and implement rules or guidelines specifically relating to pain management, and communicating these policies to licensees
- Provisions relevant to pain management in statutes and regulations that create and implement state-level drug control databases such as prescription monitoring programs.

Continuing to Apply Current Evaluation Methodology to Pain Management-Related Nursing Policy

Research has demonstrated that practicing nurses possess many of the same concerns as other practitioners about regualtory investigation when their practice involves providing opioids to patients (Hickman, Tolle, & Tilden, 2000; New York State Public Health Council, 1998; Wilken, 2008), and their practice also can be influenced by restrictive state laws (Institute of Medicine Committee on Advancing Pain Research, 2011). To help meet these needs, the National Council of State Boards of Nursing (the Council) issued a brief policy statement adopted on May 18, 2007, entitled "National Council of State Boards of Nursing Statement on the Regulatory Implications of Pain Management" (National Council of State Boards of Nursing, 2007). The purpose of this policy statement was to help facilitate the development of policies and guidelines regarding the regulatory issues raised in the statement, such as

[11] We did not evaluate civil or administrative case law, or language from legislative notes.

recognizing nurse practitioners as an essential component of patients' pain relief, treating pain should be an accepted part of patient care, and establishing the expectation that policies from individual state nursing boards should address pain issues. This policy statement anticipated the Council's document, entitled "Report of Disciplinary Resources Committee" (National Council of State Boards of Nursing, 2008), which is considered their official guideline and policy statement regarding expectations about pain management issues.

As a result of this 2008 statement, a nursing regulatory-related authoritative source now exists to guide policy development or nursing practice regarding pain relief. Such an authoritative source provides support for including nursing board laws and regulations as a component of the PPSG's comprehensive criteria-based evaluations of state policies that can impact pain management, palliative care, and end-of-life care (see Section X).

Data Collection

An electronic legal database (Lexis, from "Lexis-Nexis Research Software") was used to identify and obtain relevant federal and state statutes and regulations in effect as of December, 2013; with this cut-off, over 85% of all states' legislative sessions had ended and no new bills would be introduced. Governmental policies not available through Lexis were collected directly from the relevant state healthcare regulatory agencies. The websites of all medical, osteopathic, pharmacy, and nursing boards were accessed to determine if they contained official guidelines or policy statements that had been adopted by the boards. If the policies were available electronically, they were downloaded – otherwise the medical, osteopathic, pharmacy, and nursing boards were contacted to inquire about and, if necessary, obtain the policies. Lexis also was used to perform a key-word search of all federal and state statutes and regulations for the presence of provisions that have the potential to impact pain management. The term, "pain," was used to search the federal and state laws in their entirety.

Data collection was further supplemented, through various extents, via a variety of methods: (1) reviewing medical, osteopathic, pharmacy, and nursing board newsletters that are available on the internet; (2) reviewing periodic updates from the National Association of State Controlled Substances Authorities; (3) various e-mail list serves; and (4) personal contacts with those who are knowledgeable about policy trends.

Despite these comprehensive data-collection procedures, however, it is possible that relevant policies or provisions were missed. This is especially true if state laws adopted by December, 2013, were not chaptered in Lexis within the time we completed the data collection phase.

SECTION VII: RESEARCH METHODOLOGY

Policy Evaluation

All relevant policies that were available and in force as of December, 2013, were reviewed for this evaluation. A Central Principle has been identified and defined (see Section V), from which 16 evaluation criteria were developed and defined (see Section VIII). Three of the 16 criteria (Criterion #8, Criterion #15, and Criterion #16) were created for provisions that have the potential to affect pain management but that do not fit the specific criteria. Table 1 and Table 2 list citations from the international and national authoritative sources that support the Central Principle and the criteria, as well as the imperative to evaluate pain policy.

After the data collection phase, criteria were applied the to evaluate all the new or revised policies that were identified. Provisions were judged to satisfy the criteria only on the basis of explicitly-stated language ("black letter policy"), not by their implication or intent.[12] For example, the overall intent of a particular policy may be to encourage pain management, but the language of the policy would need to include an explicit statement to that effect to satisfy the relevant criterion (see Criterion #4: "Pain management is encouraged"). In rare instances, a previously-applied criterion was re-assessed to improve consistency of application across states or in response to a re-interpretation of policy language.

Identified provisions, which met any of the criteria, are presented in the Federal and State Profiles section (see Section IX for drug control and medical and pharmacy practice and Section X for nursing practice). If a policy contained repetitive language, so that the same criterion could be satisfied multiple times, we identified only one instance of language that met that criterion. For example, we did not identify repeated mentions of the same prescription requirement in a particular statute or regulation. As a result, when this *Evaluation Guide* is used to revise a policy, the entire policy must be examined to identify all possible occurrences of a provision that should be changed. However, Criterion #8, Criterion #15, and Criterion #16 can be applied more than once to the same policy if the identified language represents different ideas.

The Federal and State Profiles (see Section IX for drug control and medical and pharmacy practice and Section X for nursing practice) contain all relevant provisions extracted from each identified policy. Highlighting and underlining is used to draw attention to the specific language. A "comment" box identifies the criterion that was satisfied by a particular provision, using a positive (+) or negative (-) sign to indicate whether the provision has the potential to enhance (+) or impede (-) pain management. It should be noted that the effect of the provisions on pain management practice or care may vary according to how the provisions are perceived, implemented, or enforced, and is a matter for separate consideration and study (see Section IV for further discussion of issues that can additionally influence patient pain care).

The evaluation of provisions governing controlled substances included only those relevant to Schedule II controlled substances because these are the only controlled medications approved and indicated for moderate to severe pain. For example, a state may have a 5-day prescription validity period for a Schedule II medication, and a 20-day validity period for Schedule III-V medications; only the 5-day limit on Schedule II medications was considered.

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[12] One exception is Criterion #10, which addresses policy language with an implicit message; see Section VIII for the justification for this methodology.

SECTION VIII: THE RESEARCH CRITERIA

The criteria used to evaluate the policies are based on the Central Principle of Balance, and are presented in the following two sections: (1) those that identify positive provisions that may enhance pain management, and (2) those that identify negative provisions that may impede pain management. For this evaluation, balanced policy recognizes the legitimacy of controlled substances prescribing and pain management practice, and is operationalized by having policy with a number of positive provisions and few, if any, negative provisions.

Each criterion is elaborated with relevant conclusions and recommendations from international and national expert bodies.

Criteria Used to Evaluate State Pain Policies

Positive Criteria: Criteria that identify policy language that may enhance safe and effective pain management

# 1	Controlled substances are recognized as necessary for public health
# 2	Pain management is recognized as part of general healthcare practice
# 3	Medical use of opioids is recognized as legitimate professional practice
# 4	Pain management is encouraged
# 5	Practitioners' concerns about regulatory scrutiny are addressed
# 6	Prescription amount alone is recognized as insufficient to determine legitimacy of prescribing
# 7	Physical dependence or analgesic tolerance are *not* confused with "addiction"
# 8	Other provisions that may enhance pain management
	Category A: Issues related to healthcare professionals
	Category B: Issues related to patients
	Category C: Regulatory or policy issues

Negative Criteria: Criteria that identify policy language that may impede safe and effective pain management

# 9	Opioids are relegated as only a treatment of last resort
#10	Medical use of opioids is implied to be outside legitimate professional practice
#11	Physical dependence or analgesic tolerance are confused with "addiction"
#12	Medical decisions are restricted
	Category A: Restrictions based on patient characteristics
	Category B: Mandated consultation for all patients
	Category C: Restrictions regarding quantity prescribed or dispensed
	Category D: Undue prescription limitations
#13	Length of prescription validity is restricted
#14	Practitioners are subject to undue prescription requirements
#15	Other provisions that may impede pain management
#16	Provisions that are ambiguous
	Category A: Arbitrary standards for legitimate prescribing
	Category B: Unclear intent leading to possible misinterpretation
	Category C: Conflicting or inconsistent policies or provisions

SECTION VIII: THE RESEARCH CRITERIA

Part A. Criteria to Identify Provisions That May *Enhance* Pain Management

CRITERION #1: CONTROLLED SUBSTANCES ARE RECOGNIZED AS NECESSARY FOR THE PUBLIC HEALTH

According to the Central Principle of Balance, the purpose of controlled substances laws is to prevent the abuse of drugs (including medications such as opioids) and also to recognize their important contribution to public health when used medically. Controlled substances laws are in addition to, but should not conflict with, the system that regulates the prescribing and dispensing of prescription medications that are approved for human use. This dual purpose of drug control policy should be included in a state's Controlled Substances Act (CSA) (Joranson, 1990; Joranson & Gilson, 1994; National Conference of Commissioners on Uniform State Laws, 1994).

A Government's responsibility to assure adequate availability and accessibility of controlled medicines is codified in its national laws by acknowledging the Single Convention's assertion about the indispensability of these medicines for public health in general and for pain and suffering in particular, and by subsequent INCB statements in support:

> "The Parties, Concerned with the health and welfare of mankind; Recognizing that the medical use of narcotic drugs continues to be indispensable for the relief of pain and suffering and that adequate provision must be made to ensure the availability of narcotic drugs for such purposes…Hereby agree as follows:…" (emphasis added) (United Nations, 1972, Preamble)
>
> "One of the objectives of the Single Convention on Narcotic Drugs, 1961, and of that Convention as amended by the 1972 Protocol amending the Single Convention on Narcotic Drugs, 1961, is to ensure the availability of opiates, such as codeine and morphine, that are indispensable for the relief of pain and suffering, while minimizing the possibility of their abuse or diversion." (International Narcotics Control Board, 1989, ¶1)
>
> "According to WHO projections, two thirds of the estimated 15 million new cancer cases per year will occur in developing countries by the year 2015. Some 70-80 per cent of cancer patients suffer severe pain, whether acute or chronic, in the late stages of the disease. There is broad consensus today that, for the treatment of severe pain related to cancer, opioids, above all morphine, are indispensable due to their affordability and analgesic efficacy." (International Narcotics Control Board, 2000, ¶9)
>
> "Ensuring the availability of internationally controlled substances for treatment in accordance with article 9 of the Single Convention on Narcotics Drugs of 1961 (1961 Convention), as amended by the 1972 Protocol, and the preamble of the 1971 Convention on Psychotropic Substances (1971 Convention) is a mandate of the International Narcotics Control Board…The international drug control treaties recognize that narcotic drugs and psychotropic substances are indispensable for medical and scientific purposes." (International Narcotics Control Board, 2011, ¶1)

The INCB (1996) further acknowledged that:

> "Governments should determine whether their national narcotic laws contain elements of the 1961 Convention and the 1972 Protocol that take into account the fact that the medical use of narcotic drugs continues to be indispensable for the relief of pain and suffering and the fact that adequate provision must be made to ensure the availability of narcotic drugs for such purposes and to ensure that administrative responsibility has been established and that personnel are available for the implementation of those laws." (¶51(f))

The indispensability of controlled medicines, including opioid analgesics, also is reinforced in the narrative of the 2011 WHO Guideline report (2011a), as well as being represented by a specific guideline.

> "Drug control should not be approached as an objective in itself, but as a tool to optimize public health." "One focus should be the prevention of abuse and dependence; the other to avoid collateral harm. The outcomes should be judged both by the harms from abuse it prevents *and the harm it causes through, for example, lack of access*. (emphasis added) (p. 12)
>
> For all of these patients, pain relief should be part of their overall treatment. Oral opioids are key components for the treatment of moderate to severe pain and several are regarded as essential medicines. Paracetamol (acetaminophen), acetylsalicylic acid, non-steroidal anti-inflammatory medicines (NSAIMs) when used alone and weak acting opioids (tramadol, codeine) are usually not effective in the case of moderate to severe pain. NSAIMs can have serious side-effects and should be used with caution on a chronic basis. Despite a century of pharmaceutical chemistry, suitable alternatives to strong opioids for treatment of moderate to severe pain have yet to be found. (p. 14)
>
> "Guideline1: National drug control policies should recognize that controlled medicines are absolutely necessary for medical and scientific purposes. It can be considered as a condition sine-qua-non for enabling and facilitating availability and accessibility of controlled medicines, that national policies are explicit about their objectives. National policies should recognize the necessity of controlled medicines and ensure they put in place policy statements to ensure implementation of the policies. Such statements would include those on improving access to all in need. Moreover, countries may want to establish this in their law, either as an objective or an obligation for the government. This would mirror the imperative stated in the international drug control treaties to make narcotic drugs and psychotropic substances available for medical use." (p. 20)

In 2008, Manfred Nowak and Anand Grover, in their capacities as UN Special Rapporteur, addressed this important topic as a fundamental human right (Nowak & Grover, 2008):

> "The failure to ensure access to controlled medicines for the relief of pain and suffering threatens fundamental rights to health and to protection against cruel inhuman and degrading treatment. International human rights law requires that governments must provide essential medicines – which include, among others, opioid analgesics – as part of their minimum core obligations under the right to health." (p. 2)

Nowak & Grover's human rights position was further illustrated in the 2011 WHO Guideline (World Health Organization, 2011a):

> "Moreover, in 2008, the United Nations' Special Rapporteur on the prevention of torture and cruel, inhuman, or degrading treatment or punishment, and the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, jointly wrote a letter to the CND on human rights aspects of drug control, in which they requested that 'national drug control laws recognize the indispensable nature of narcotic and psychotropic drugs for the relief of pain and suffering, and guarantee adequate availability of those medicines for legitimate medical uses, including opioid analgesics and opioids for substance dependence programmes'." (p. 11)

In the U.S., the National Conference of Commissioners on Uniform State Laws (1990) recognized this principle, stating that:

> "Legitimate use of controlled substances is essential for public health and safety, and the availability of these substances must be assured." (p. 2)

Language from the Federal CSA (1970a) directly relates to this concept:

> "Many of the drugs included within this subchapter have a useful and legitimate medical purpose and are necessary to maintain the health and general welfare of the American people." (Title 21 §801(1))

CRITERION #2: PAIN MANAGEMENT IS RECOGNIZED AS PART OF GENERAL HEALTHCARE PRACTICE

In balanced policy, pain management is considered a fundamental part of healthcare practice. The Single Convention places the relief of pain and suffering within the purview of medicine and science (United Nations, 1972).

The WHO (2011a) has acknowledged that legitimate healthcare practice includes the provision of pain care:

> "Pain is prevalent in almost all medical specialties, including in general practice, palliative care, oncology, internal medicine, haematology and surgery. Patients who are affected include people who have cancer, HIV, sickle-cell disease, or those who have had surgery or accidents…For all of these patients, pain relief should be part of their overall treatment. Oral opioids are key components for the treatment of moderate to severe pain and several are regarded as essential medicines." (pp. 13-14)
>
> "It should be recognized that controlled medicines when used rationally for medical purposes are safe medicines." (p.15)

In addition, the World Medical Association (2011) further substantiates the professional obligation to provide pain management services:

> "Physicians and other health care professionals have an ethical duty to offer proper clinical assessments to patients with pain and to offer appropriate treatment, which may require prescribing medications – including opioid analgesics – as medically indicated." (p. 2)

In the U.S., medical practice is regulated at the state level. Therefore, state medical practice laws should recognize that the diagnosis and treatment of pain is a part of ordinary medical practice. The Federation's *Modern Medical Practice Act* (MMPA) (Federation of State Medical Boards of the United States Inc., 2000) is a model statute to guide the development of state medical practice acts. The MMPA defined "practice of medicine" to include:

> "offering or undertaking to prevent or to diagnose, correct, and/or treat...any disease, illness, pain, wound, fracture, infirmity..." (p. 2)

In addition, the *Model Policy on the Use of Opioid Analgesics in the Treatment of Chronic Pain* adopted by the House of Delegates of the Federation (Federation of State Medical Boards of the United States Inc., 2013) stated:

> "...principles of high-quality medical practice dictate that the people of the State of [name of state] have access to appropriate, safe and effective pain management. The application of up-to-date knowledge and treatment modalities can help to restore function and thus improve the quality of life of patients who suffer from pain, particularly chronic pain…The diagnosis and treatment of pain is integral to the practice of medicine." (p. 7-8)

In 2008, the National Council of State Boards of Nursing (the Council) issued a report containing "regulatory Implications: The Role of the Nurse in Pain management" (National Council of State Boards of Nursing, 2008), which contained the following language:

> "Boards of nursing fully support the nursing role in the thorough assessment, interventions, and effective management of pain." (p. 127)

CRITERION #3: MEDICAL USE OF OPIOIDS IS RECOGNIZED AS LEGITIMATE PROFESSIONAL PRACTICE

This criterion recognizes that a licensed practitioner's appropriate use of opioids for pain management is a legitimate medical purpose and is considered to be within the boundaries of professional practice as long as certain basic requirements are met. As a general rule, laws that govern the medical use of drugs with an abuse liability also are designed to prohibit uses for other than legitimate medical purposes.

SECTION VIII: THE RESEARCH CRITERIA

The Single Convention (United Nations, 1972), the INCB (1996), the WHO (1986; 1990; 1996), the WMA (2011), the U.S. CSA (1970a), the Uniform Controlled Substances Act (National Conference of Commissioners on Uniform State Laws, 1994), the FSMB (2013), the NCSBN (2008), and the NABP (2012) regard the prescribing of opioids, including for pain, as a legitimate professional practice. In addition, some states have adopted policies stating that legitimate professional practice with controlled substances includes the medical use of opioids for pain management.

For example, internationally, the INCB has acknowledged that legitimate healthcare practice includes the use of opioids:

> "International drug control treaties not only recognize the dangers associated with abuse of and trafficking in narcotics drugs, but they also recognize that they are indispensable for the relief of pain and suffering. Narcotic drugs, including opiates, have a variety of medical uses. They are used as an anaesthetic or analgesic, and to treat diarrhea, cough or narcotic addiction, as well as for veterinary, dental and laboratory purposes. The International Narcotics Control Board, in cooperation with Governments, endeavours to ensure that there is an adequate supply of narcotic drugs for medical and scientific purposes and to limit their production and use only to such purposes in order to prevent illicit narcotic drug production, trafficking and use." (International Narcotics Control Board, 1996, Summary, p. iii)

The WHO has recommended that the health professions and all governments adopt an approach for the management of cancer pain that can include the use of opioid analgesics (1986; 2002), and has classified some opioid analgesics as Essential Drugs (World Health Organization, 1998b). For example, the most recent WHO guidelines (World Health Organization, 2011a) recognize that:

> "The majority of substances controlled under the international drug control treaties, notably narcotic drugs and psychotropic substances, have a variety of medical uses. Opioid analgesics, such as codeine and morphine, and antiepileptics, such as lorazepam and phenobarbital, are considered as essential medicines by the World Health Organization." (p.1)
>
> "Pain is prevalent in almost all medical specialties, including in general practice, palliative care, oncology, internal medicine, haematology and surgery. Patients who are affected include people who have cancer, HIV, sickle-cell disease, or those who have had surgery or accidents…For all of these patients, pain relief should be part of their overall treatment. Oral opioids are key components for the treatment of moderate to severe pain and several are regarded as essential medicines." (p.13)
>
> "It should be recognized that controlled medicines when used rationally for medical purposes are safe medicines." (p.15)

The WMA (2011)also has stated that:

> "Physicians and other health care professionals have an ethical duty to offer proper clinical assessments to patients with pain and to offer appropriate treatment, which may require prescribing medications – including opioid analgesics – as medically indicated." (p. 2)

SECTION VIII: THE RESEARCH CRITERIA

In the U.S., the national regulatory organizations representing medicine, nursing, and pharmacy have clearly acknowledged that the prescribing of drugs, which would include controlled substances broadly and opioid analgesics in particular, is part of a practitioner's professional practice:

> "The Board recognizes that opioid analgesics are useful and can be essential in the treatment of acute pain that results from trauma or surgery, as well as in the management of certain types of chronic pain, whether due to cancer or non-cancer causes…The Board will consider the use of opioids for pain management to be for a legitimate medical purpose if it is based on sound clinical judgment and current best clinical practices, is appropriately documented, and is of demonstrable benefit to the patient." (Federation of State Medical Boards of the United States Inc., 2013, p. 7)
>
> "The scope of practice of the APRN [Advanced Practice Registered Nurse] is unique in the nursing profession. The APRN practices as an independent primary care provider in a majority of states, with nearly all states conferring controlled substances prescribing authority upon APRNs, in conjunction with the [Drug Enforcement Administration]. In the role of primary care provider or licensed independent provider (LIP, the APRN is held to a high standard of education and practice in patient care." (National Council of State Boards of Nursing, 2008, p. 132)
>
> "'Practitioner' means an individual currently licensed, registered, or otherwise authorized by the appropriate jurisdiction to prescribe and Administer Drugs in the course of professional practice.." (National Association of Boards of Pharmacy, 2012, p. 15)

CRITERION #4: PAIN MANAGEMENT IS ENCOURAGED

Policies that regulate professional practice or medications can encourage (or discourage) pain management. Those who make public policy can provide leadership, encouragement, and direction for eliminating barriers to pain management by adopting positive statements about the importance of controlling pain.

A number of bodies have adopted clear and positive statements, including the INCB and the WHO at the international level. In fact, the INCB's 1999 *Annual Report* (International Narcotics Control Board, 1999) clarified this point within the context of the Single Conventions:

> "Adequate availability and limitation were considered by the States parties to the 1961 Convention and the 1971 Convention as two complementary, not mutually exclusive, aims and were thus incorporated in the control provisions of those conventions. In adopting such aims, Governments were motivated by two complementary humanitarian considerations, namely the need to provide optimal help and relief for pain and suffering and the need to protect the individual and society from drug dependence and its detrimental consequences." (p.1)

The INCB (2010) more recently highlighted the importance of encouraging pain care, when discussing how countries have successfully implemented programs to improve pain management:

> "…key factors in the successful implementation of [a programme that provides home-based palliative care] include the commitment of the Government to making relief from pain a health-care priority and the education of health-care professionals about the use of opioids and palliative care." (¶101)

Again, the recent update of the WHO guidelines (World Health Organization, 2011a) reiterates this point:

> "Pain in prevalent in almost all medical specialties, including in general practice, palliative care, oncology, internal medicine, haematology and surgery. Patients who are affected include people who have cancer, HIV, sickle-cell disease, or those who have had surgery or accidents. Cancer patients may need pain relief at every stage of the disease. More than two thirds of patients with advanced cancer and about half of all patients with advanced HIV/AIDS will experience moderate to severe pain. In obstetrics, women may need pain relief during labour, surgery and post-surgery. For all of these patients, pain relief should be part of their overall treatment…" (pp. 13-14)

In the U.S. a number of expert bodies have encouraged pain management as well. The American Pain Society (Miaskowski et al., 2005) emphasized that:

> "Because pain is pervasive in cancer, all healthcare professionals who care for patients at any stage of their illness should know how to assess pain, how to treat it, and when to refer to others with more expertise patients whose pain they are unable to manage." (p. x)

The IOM (Institute of Medicine Committee on Care at the End of Life, 1997) stated that:

> "Reliable, excellent care at the end of life is an objective that should be supported, not impeded, by public policy." (p. 206)

A more recent IOM report, specific to transforming pain in America,(Institute of Medicine Committee on Advancing Pain Research, 2011) reiterated the need for better pain management:

> "The ultimate goal of this study is to contribute to improved outcomes for individuals who experience pain and their families. The report builds on and reinforces recommendations regarding ways to improve care, education, and research – and the research enterprise in general – made by the IOM in past reports, as well as by other entities." (p. 55)

The *Model Policy* adopted by the House of Delegates of the Federation (Federation of State Medical Boards of the United States Inc., 2013) recommended that:

> "All physicians and other providers should be knowledgeable about assessing patients' pain and function, and familiar with methods of managing pain." (p. 7)

The report from the Council (National Council of State Boards of Nursing, 2008), relevant to the regulation of nurse practitioners, contained the following statement:

> "Effective treatment of pain requires nurses to be aware of patient needs and to become skillful at the assessment of pain. The nurse needs to be knowledgeable about available treatment options and ordered protocols. Expanding knowledge and emerging new technologies require the nurse to maintain current information about pain management standards and topics relevant to the nurse's practice role." (p. 5)

SECTION VIII: THE RESEARCH CRITERIA

CRITERION #5: PRACTITIONERS' CONCERNS ABOUT REGULATORY SCRUTINY ARE ADDRESSED

Sub-optimal treatment of pain can stem from many factors. One well-recognized factor is healthcare professionals' concerns that their prescribing practices for pain may be construed to be in violation of drug control or professional practice laws because of misunderstanding about the rational use of opioids. For decades physicians have reported being reluctant to prescribe opioids because of concern about the stress, expense, and consequences of being investigated by licensing agencies or, more recently, law enforcement. These fears have profound implications for practitioners' willingness to consider these medications a viable treatment option and, in turn, hinder their adequate availability for patient pain relief (Hoffmann & Tarzian, 2003; National Conference of Commissioners on Uniform State Laws, 1990; Rich, 2005; Richard & Reidenberg, 2005); such reluctance can be based on excessively strict regulations, the *perception* that regulations or enforcement are excessive, a lack of knowledge about the regulations, or a lack of confidence in the use of opioids. A policy that is balanced and able to overcome these concerns should (1) recognize that a concern about regulatory scrutiny exists, (2) clarify that a physician may appropriately prescribe opioids for pain without a risk of disciplinary sanction, and, most importantly, (3) be implemented by the relevant regulatory bodies.

In support of this criterion at the international level, the INCB (1989) observed that there were a number of reasons for inadequate availability, including that:

> "the reaction of some legislators and administrators to the fear of drug abuse developing or spreading has led to the enactment of laws and regulations that may, in some cases, unduly impede the availability of opiates. The problem may also arise as a result of the manner in which drug control laws and regulations are interpreted or implemented." (p. 1)

The INCB (1989) further suggested that:

> "While sanctions are necessary to deal with persons who transgress the law, they should not, as such, constitute an impediment to the prescription or dispensation of opiates in accordance with existing regulations. The vast majority of health professionals exercise their activity within the law and should be able to do so without unnecessary fear of sanctions for unintended violations. Occasions may still arise when a health professional could nevertheless be exposed to legal action for technical violations of the law. This possibility may tend to inhibit the prescribing or dispensing of opiates." (¶43)

In attempting to substantiate this perception, the INCB (in cooperation with the WHO) (1996), studied the reasons for inadequate availability of opioids for pain relief in the world and found the following:

> "...reluctance to prescribe or stock opiates owing to concerns about legal sanctions ranked third (47%)." (p. 4)

As a result, the INCB (1996) requested that all governments in the world:

> "determine whether there are undue restrictions in national narcotics laws, regulations or administrative policies that impede prescribing, dispensing or needed medical treatment...[and]... communicate with health professionals about the legal requirements for prescribing and dispensing narcotic drugs and...provide an opportunity to discuss mutual concerns." (¶51(f) & (g))

SECTION VIII: THE RESEARCH CRITERIA

In a further INCB survey of governments (International Narcotics Control Board, 2009b), which asked about impediments to opioid availability, the item "reluctance to prescribe or stock opiates because of concerns about legal sanctions" was found to rank second in terms of relevance (p. 16).

As early as 1990, the WHO, specifically the WHO Expert Committee on Cancer Pain Relief and Active Supportive Care (World Health Organization, 1990), recognized that:

> "Health care workers may be reluctant to prescribe, stock or dispense opioids if they feel that there is a possibility of their professional licenses being suspended or revoked by the governing authority in cases where large quantities of opioids are provided to an individual, even though the medical need for such drugs can be proved." (p. 39)

To address this issue in a systematic manner, the WHO issued a Guideline in 2000 (World Health Organization, 2000) that was designed to improve national policies and processes related to the appropriate use of controlled medicines, which also included a checklist containing the following question:

> "Has the government identified and addressed concerns of health care professionals about being investigated for prescribing opioids?" (p. 25)

Concern about adverse regulatory or legal actions in response to the medical use of opioids was further highlighted, more than a decade later, in the WHO's updated Guideline for ensuring the global availability and accessibility of controlled medicines (World Health Organization, 2011a):

> "Some countries maintain severe punitive provisions for errors or problems in the prescribing and dispensing of controlled medicines that deter healthcare workers from legitimated prescribing and dispensing of these medicines. The INCB has stated: 'Health professionals … should be able to … [provide opiates] without unnecessary fear of sanctions for unintended violations [including] … legal action for technical violations of the law … [that] may tend to inhibit prescribing or dispensing of opiates.' Unintentional errors that do not result in diversion of controlled medicines or serious health consequences should not be subject to criminal penalties." (p. 28)

Again, the Guideline checklist contained a question related to addressing practitioner concern (World Health Organization, 2011a):

> "Can health professionals be free from fear of investigation, prosecution and disproportionate punishment for minor or unintentional breach of drug control rules?" (p. 56)

Finally, according to a recent report from the Commission on Narcotic Drugs, a prominent regulatory impediment that should be addressed when warranted is health care practitioners' concerns about potentially punitive legal requirements (United Nations Commission on Narcotic Drugs, 2011):

> "Examples of measures that may impede availability and that are not required by the Conventions include:…excessive penalties and prosecutions for unintentional mis-prescription or mishandling of opioids." (¶37(f))

SECTION VIII: THE RESEARCH CRITERIA

In the U.S., the American Medical Association House of Delegates (American Medical Association, 2003) issued a resolution stating that:

> "...physicians who appropriately prescribe and/or administer controlled substances to relieve intractable pain should not be subject to the burdens of excessive regulatory scrutiny, inappropriate disciplinary action, or criminal prosecution. It is the policy of the AMA that state medical societies and boards of medicine develop or adopt mutually acceptable guidelines protecting physicians who appropriately prescribe and/or administer controlled substances to relieve intractable pain before seeking the implementation of legislation to provide that protection..." (p. 1)

The Federation of State Medical Board's (2013) *Model Policy* has clearly stated that:

> "Physicians should not fear disciplinary action from the Board for ordering, prescribing, dispensing or administering controlled substances, including opioid analgesics, for a legitimate medical purpose and in the course of professional practice, when current best practices are met." (p. 7)

The National Council of State Boards of Nursing (2008) report also contained statements recognizing this issue as being important to acknowledge and address:

> "Many health care practitioners, including APRNs, fear being investigated for over-administering or over-prescribing controlled substances for pain. This fear can pose a barrier to effective pain management. Regulatory boards must consider the balance of promoting appropriate pain management against deterring inappropriate use of pain medications. Under-treatment of pain decreases patient functional status, safety, and quality of life." (p. 136)

The DEA (2006a) even issued a policy statement, with the explicit purpose of addressing this barrier, because of the belief that physicians are reluctant to provide legitimate pain treatment due to regulatory or legal liability:

> "One of the chief purposes of this document is to make clear that the longstanding requirement under the law that physicians may prescribe controlled substances only for legitimate medical purposes in the usual course of professional practice should in no way interfere with the legitimate practice of medicine or cause any physician to be reluctant to provide legitimate pain treatment. DEA also wishes to dispel the mistaken notion among a small number of medical professionals that the agency has embarked on a campaign to "target" physicians who prescribe controlled substances for the treatment of pain (or that physicians must curb their legitimate prescribing of pain medications to avoid legal liability)." (p. 52716)

CRITERION #6: PRESCRIPTION AMOUNT ALONE IS RECOGNIZED AS INSUFFICIENT TO DETERMINE LEGITIMACY OF PRESCRIBING

This criterion addresses another specific source of concern about regulatory policy: That duration or amount of drug therapy will be used to judge the propriety of prescribing. The clinical extension of this view is that a prescription can be considered inappropriate merely by exceeding a certain quantity or length of time. Such a determination, however, cannot necessarily be made without understanding the medical context and patient care needs within which the prescribing is taking place (Fishman, 2012). Policies that allow conclusions about treatment appropriateness based solely on amount of medications prescribed would contradict the Central Principle of Balance by failing to conform to current medical and scientific consensus, and may inadvertently contribute to a restrictive regulatory environment for pain management. Indeed, some states have issued policies to clarify that the quantity of medication or the duration of treatment is not sufficient by itself to judge the legitimacy of a practitioner's opioid prescriptions for a pain patient.

The WHO (1996) clearly supported this position:

> "Decisions concerning the type of drug to be used, the amount of the prescription and the duration of therapy are best made by medical professionals on the basis of the individual needs of each patient, and not by regulation." (p. 58)

A justification for this criterion also is implied through the WHO *Ensuring Balance* Guidelines document (World Health Organization, 2011a), which argues for prescription amount or treatment duration being a function of healthcare decision-making based on the particular clinical situation:

> "Guideline 10: Appropriately trained and qualified physicians, and, if applicable, nurses and other health professionals, at all levels of health care should be allowed to prescribe and administer controlled medicines, based on their general professional license, current medical knowledge and good practice without any further license requirements.
> .
> .
> .
> When balancing drug *control* legislation and policies, it is wise to leave *medical* decisions up to those who are knowledgeable on medical issues. Therefore, the amount of medicine prescribed, the appropriate formulation and the duration of treatment should be the practitioner's decision, based on individual patient needs and on sound scientific medical guidance (e.g. national or WHO treatment guidelines)." (pp. 29-30)

In the U.S., this position was recognized by the Food and Drug Administration (FDA) (Federal Register, 1972):

> "Once the new drug is in a local pharmacy after interstate shipment, the physician may, as part of the practice of medicine, lawfully prescribe a different dosage for his patient, or may otherwise vary the conditions of use from those approved in the package insert." (p. 16503)

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The Federation's (2013) *Model Policy* stated:

> "The Board will judge the validity of the physician's treatment of the patient on the basis of available documentation, rather than solely on the quantity and duration of medication administration. The goal is the management of the patient's pain while effectively addressing other aspects of the patient's functioning, including physical, psychological, social and work-related factors, and mitigating risk of misuse, abuse, diversion and overdose." (p.86)

By 2010, the DEA (2010) seemed to continue to support this position:

> "…there are no express federal limits with respect to the quantities of drugs dispensed via a prescription. However, the amount dispensed must be consistent with the requirement that a prescription for a controlled substance be issued only for a legitimate medical purpose by a practitioner acting in the usual course of professional practice." (p. 34)

CRITERION #7: PHYSICAL DEPENDENCE OR ANALGESIC TOLERANCE ARE NOT CONFUSED WITH "ADDICTION"

According to the INCB survey (International Narcotics Control Board, 1996), concern about addiction was the impediment to improving availability and use of opioids most frequently identified by government narcotic control agencies. The use of addiction-related terminology, especially if undefined or defined inaccurately, is fraught with potential for confusing addiction with the physical dependence or tolerance that is common when opioids are used to treat pain (Gilson, 2010c; Gilson & Joranson, 2002; Joranson & Gilson, 2003; Maurer, Gilson, & Joranson, 2008; National Conference of Commissioners on Uniform State Laws, 1990; National Conference of Commissioners on Uniform State Laws, 1994). Policies that continue to use outdated terminology (e.g., habituation, drug dependence, etc.), which is inconsistent with current medical and scientific knowledge, are considered unbalanced.

It is not necessary for state policy to use terms that identify classes of persons such as "addict" or "habitué" and no modern model acts do so. If such terminology appears in current drug control or professional practice policy, they should at least be defined according to the prevailing medical standard for defining "addiction" (Savage et al., 2003).

Early interpretations of the meaning of addiction are incorrect by today's standards, but may have influenced policy that still exists. A 1941 article in the *Journal of the American Medical Association* (Lee, 1941) revealed the prevailing belief about addiction:

> "The use of narcotics in the terminal cancer [patient] is to be condemned if it can possibly be avoided. Morphine and terminal cancer are in no way synonymous. Morphine usage is an unpleasant experience to the majority of human subjects because of undesirable side effects. Dominant in the list of these unfortunate effects is addiction." (p. 217)

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Importantly, since 1950 the WHO has demonstrated an evolution of conceptualizations of "drug addiction," as it was originally termed and defined. ''Drug addiction'' was initially considered the direct and largely inevitable effect of specific substances:

> "Drug addiction…is a state of periodic or chronic intoxication, detrimental to the individual and to society, produced by the repeated consumption of a drug. Characteristics include: (1) an overpowering desire or need (compulsion) to continue taking the drug and to obtain it by any means; (2) a tendency to increase the dose; and (3) a psychic (psychological) and sometimes a physical dependence on the effects of the drug." (World Health Organization, 1950, pp. 6-7)
>
> "There are some drugs, notably morphine and pharmacologically morphine-like substances, whose specific pharmacological action, under individual conditions of time and dose, will always produce compulsive craving, dependence, and addiction in any individual. Addiction will develop sooner in those individuals whose psychological make-up leads them to seek and find escape in the pharmacological action of drugs. Sooner or later there must come a time when the use of the drug cannot be interrupted without significant disturbance, always psychic (psychological) and sometimes physical. With these drugs pharmacological action is paramount, psychological make-up adjuvant. Such drugs cause individual and sociological damage and must be rigidly controlled" (World Health Organization, 1952 (p. 10).
>
> ''a state of periodic or chronic intoxication produced by the repeated consumption of a drug (natural or synthetic). Its characteristics include: (1) an overpowering desire or need (compulsion) to continue taking the drug and to obtain it by any means; (2) a tendency to increase the dose; (3) a psychic (psychologic) and generally a physical dependence on the effects of the drug; (4) detrimental effect on the individual and on society'' (World Health Organization, 1957, pp. 9–10)

In 1964, the WHO replaced the term "addiction" with the term "drug dependence" to reduce stigma. Under this new conceptualization, "drug dependence" was comprised both of a psychic component (psychological dependence) *and* a physical component (an abstinence syndrome) (World Health Organization, 1964). The WHO clarified, however, that the more general term of "drug dependence" did not indicate degree of risk to public health.

In a few more years, in 1969, "drug dependence" was defined centrally as compulsive use despite harm, with neither physical dependence nor tolerance sufficient to define "drug dependence" (or "addiction") (World Health Organization, 1969):

> "Drug dependence. A state, psychic and sometimes also physical, resulting from the interaction between a living organism and a drug, characterized by behavioral and other responses that always include a compulsion to take the drug on a continuous or periodic basis in order to experience its psychic effects, and sometimes to avoid the discomfort of its absence. Tolerance may or may not be present" (p. 6).

This conceptualization has remained relatively consistent to the present time, with the 1993 definition of "drug dependence" representing a biopsychosocial construct (World Health Organization, 1993):

> "A cluster of physiological, behavioral and cognitive phenomena of variable intensity, in which the use of a psychoactive drug (or drugs) takes on a high priority. The necessary descriptive characteristics are preoccupation with a desire to obtain and take the drug and persistent drug-seeking behavior." (p. 5).

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Although in 1998 the WHO replaced the term "drug dependence" with "dependence syndrome, there was no substantive reinterpretation of the 1993 definition (World Health Organization, 1998c); this nomenclature is current as of today.

When considering the occurrence of withdrawal or tolerance within the context of dependence syndrome, however, the WHO Expert Committee on Drug Dependence (World Health Organization, 2003b) has stressed the importance of maintaining a proper perspective about the appropriate relationships among these phenomena:

> "The International Classification of Diseases (ICD) is the most widespread tool used in health epidemiology. While it is correct to say that *withdrawal* and *tolerance* are neither required nor sufficient for a positive diagnosis of *dependence syndrome*, excessive emphasis on this aspect can lead to the misconception that *withdrawal* is unrelated to *dependence*." (p. 19)

Recently, the WHO (2011a) reinforced the importance of national law having clear and up-to-date addiction-related terminology:

> "Guideline 10: Terminology in national drug control legislation and policies should be clear and unambiguous in order not to confuse the use of controlled medicines for medical and scientific purposes with misuse. (p. 28)
>
> Drug control legislation and policy have sometimes contributed to stigmatization of controlled medicines because of the use of inappropriate terminology. Confusion and discrimination relating to terminology can deter doctors from prescribing controlled medicines when it is legitimate to do so; it can also confuse authorities who wish to discriminate between legitimate and illegitimate use. Countries should therefore take steps to review policies to ensure the consistent use of medical terms and remove stigmatizing terminology from their legislation. These guidelines specifically recommend the use of non-stigmatizing terminology. (pp. 28-29)
>
> "… The WHO definition of "dependence syndrome" requires the presence of at least three out of six symptoms, including a strong desire or a sense of compulsion to take the drug and also the neglecting of interests and daily activities because of devotion to the use of psychoactive substances. <u>It is clear that a patient requiring increasing doses of an opioid for pain relief because of pharmacological tolerance due to prolonged treatment does not normally fall into this category. Neither does a patient who develops withdrawal syndrome</u>. (p. 29)
>
> Patients should be referred to in a respectful way; WHO does not therefore recommend the use of "addict" for a patient living with dependence syndrome, as the term is considered to be stigmatizing." (p. 29)

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The UN Economic and Social Council (2011) also issued a Discussion Paper relating to the Commission on Narcotic Drugs, which clarified the distinctions between physiological symptomology and the characteristics that define dependence syndrome:

> "The issue of opioid dependence related to the treatment of pain remains controversial. On the one side, the fear of opioid dependence is discouraging public opinion and also health care personnel in respect to the use of opioid analgesics. On the other side, the evidence concerning dependence in patients affected by pain should be expanded. All persons exposed continuously to opioids develop tolerance and withdrawal, two important, but by themselves not sufficient characteristics to diagnose dependence. Dependence is understood as a bio-psycho-social condition which clusters physiological, behavioural, and cognitive phenomena and their related vulnerability factors. In most cases, patients treated with opioid analgesics for pain do not present the vulnerability characteristics that contribute to inducing a condition of dependence, although they develop tolerance and withdrawal symptoms." (¶26)

In the U.S., expert national medical and regulatory authorities have agreed over time with this distinction:

> "Neither physical dependence nor tolerance should be equated with addiction or substance abuse." (Institute of Medicine Committee on Care at the End of Life, 1997, p. 193)
>
> "…physical dependence and tolerance are expected physiological consequences of extended opioid therapy for pain and in this context do not indicate the presence of addiction." (Federation of State Medical Boards of the United States Inc., 2013, p. 15)
>
> "Opioid tolerance and physical dependence are expected with long-term opioid treatment and should not be confused with psychological dependence ("addiction"). The misunderstanding of these terms in relation to opioid use contributes to ineffective practices in prescribing, administering, and dispensing opioids for cancer pain management and leads to undertreatment. The presence of opioid tolerance and physical dependence does not equate with 'addiction,' which manifests itself as drug abuse behavior." (Miaskowski et al., 2005, p. 55)
>
> "Graduate education and preceptors/mentors can work together to assure that graduate students, novice, and experienced APRNs are exposed to current standards and expectations regarding pain management, the latest research and clinical guidelines, the whole range of therapeutic interventions available to manage pain, and the distinctions between drug dependence and drug addiction." (National Council of State Boards of Nursing, 2008, p. 136)

Moreover, Weissman and Haddox (1989) coined the term "pseudoaddiction" in the late 1980's. This term has come to represent a situation in which a pattern of drug-seeking behavior by a patient who is untreated or is receiving ineffective pain relief is mistaken for addictive behavior by healthcare practitioners (Turk & Okifuji, 2010). Patients' seemingly aberrant preoccupations with obtaining opioids, when incorrectly characterized as illicit drug-seeking or the manifestation of an addictive disease, can result in further denial of the pain treatment services they need (Todd & Miner, 2010). As a result, this is an iatrogenic condition. Clinical efforts may be necessary to differentiate "pseudoaddiction" and from true addiction (Rogak, Starr, Kirsh, & Passik, 2010).

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In 2001, three U.S. national organizations (the American Academy of Pain Medicine, the American Pain Society, and the American Society of Addiction Medicine) (2001) collaborated to prepare a consensus document on the use of key terms related to the use of opioids for the treatment of pain. They drew several conclusions and recommended that organizations use the definitions:

> "Clear terminology is necessary for effective communication regarding medical issues. Scientists, clinicians, regulators, and the lay public use disparate definitions of terms related to addiction. These disparities contribute to a misunderstanding of the nature of addiction and the risk of addiction, especially in situations in which opioids are used, or are being considered for use, to manage pain. Confusion regarding the treatment of pain results in unnecessary suffering, economic burdens to society, and inappropriate adverse actions against patients and professionals." (p. 1)
>
> "Physical dependence, tolerance, and addiction are discrete and different phenomena that are often confused. Since their clinical implications and management differ markedly, it is important that uniform definitions, based on current scientific and clinical understanding, be established in order to promote better care of patients with pain and other conditions where the use of dependence-producing drugs is appropriate, and to encourage appropriate regulatory policies and enforcement strategies." (p. 1)
>
> **Addiction**
>
> Addiction is a primary, chronic, neurobiologic disease, with genetic, psychosocial, and environmental factors influencing its development and manifestations. It is characterized by behaviors that include one or more of the following: impaired control over drug use, compulsive use, continued use despite harm, and craving.
>
> **Physical Dependence**
>
> Physical dependence is a state of adaptation that is manifested by a drug class specific syndrome that can be produced by abrupt cessation, rapid dose reduction, decreasing blood level of the drug, and/or administration of an antagonist.
>
> **Tolerance**
>
> Tolerance is a state of adaptation in which exposure to a drug induces changes that result in a diminution of one or more of the drug's effects over time." (p. 2)

The 2004 (Federation of State Medical Boards of the United States Inc., 2004) and 2013 (Federation of State Medical Boards of the United States Inc., 2013) versions of the Federation's *Model Policy* included these jointly-prepared definitions of Addiction, Physical Dependence, and Tolerance, with slight but non-substantive changes. The definitions also have appeared in the Appendices of the APS/AAPM Guidelines relevant to prescribing opioids for non-cancer pain (Chou et al., 2009) and the IOM "Relieving Pain in America" report (Institute of Medicine Committee on Advancing Pain Research, 2011).

Importantly, a more recent policy statement from the American Society of Addiction Medicine (ASAM) (2011) seems to confirm this conception of the disease of addiction:

> "Addiction is a primary, chronic disease of brain reward, motivation, memory and related circuitry. Dysfunction in these circuits leads to characteristic biological, psychological, social and spiritual manifestations. This is reflected in an individual pathologically pursuing reward and/or relief by substance use and other behaviors." (p. 1)
>
> "Addiction is characterized by inability to consistently abstain, impairment in behavioral control, craving, diminished recognition of significant problems with one's behaviors and interpersonal relationships, and a dysfunctional emotional response." (p. 1)

ASAM's most current definition of "addiction" also was included and referenced in the Federation's updated Model Policy from July 2013 (Federation of State Medical Boards of the United States Inc., 2013).

It also is important to note that a recent policy statement promulgated by the American Academy of Pain Medicine (2013) contains a definition that further substantiates "addiction" as a neurobiological disorder comprising compulsive behavior, lack of control, and impaired quality of life with the development of adverse events. The statement additionally identifies the possibility that people can be incorrectly perceived as addicts, which may in turn become a barrier to effective treatment; this relates to the concept of "pseudoaddiction" described above.

CRITERION #8: OTHER PROVISIONS THAT MAY ENHANCE PAIN MANAGEMENT

This analysis identified several provisions with potential to enhance pain management that were related to the Central Principle of Balance but for which no specific criterion existed. Three categories of policy provisions have the potential to enhance pain management:

Category A: Issues related to healthcare professionals. This category is exemplified by several states recognizing the need for physicians to have flexibility (based on reasonable cause) while adhering to state medical board policy, or encouraging multidisciplinary collaboration when assessing and treating pain (Institute of Medicine Committee on Advancing Pain Research, 2011; Schatman, 2010; Strickland, Huskey, & Brushwood, 2007; Turk & Robinson, 2010). In addition, this criterion is used to identify policy language that recognizes that clinical outcomes of pain management should extend beyond merely pain score and include assessments of patient function parameters and overall quality of life (Fishman, 2012; Irving & Squire, 2010; McCarberg, 2010). Policies that extend beyond addressing practitioners' concerns about regulatory scrutiny (identified by Criterion #5), and attempt to provide additional immunity from criminal prosecution, also meet this criterion. Also, some state legislatures have designed policies to insulate healthcare professionals from criminal liability for their good faith efforts at pain relief when using opioid analgesics, even if the medications are perceived to increase the risk of death; such a standard seems to directly address the myth that opioids hasten death when used for palliative and end-of-life care (Paice, 2010; Sykes & Thorns, 2003). These provisions are created to protect health care practitioners when they attempt to use opioids appropriately.

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Category B: Issues related to patients. This category includes provisions specifically aimed at improving pain management for specific groups of at-risk patients. For example, some state policies exempt people with a terminal illness from restrictive prescription requirements (although the restrictive requirements continue to apply to all other patients), or explicitly recognize that a patient's prior history or current status of drug abuse does not necessarily contraindicate appropriate pain management (Chou et al., 2009; Fine & Portenoy, 2007; Heit & Gourlay, 2010). Also, in some states, patients have the right to request or reject treatment options based on their having received adequate information about pain management and palliative care.

Category C: Regulatory or policy issues. An example of a provision fulfilling this category includes establishing a policy with the clear intent to prevent the abuse or diversion of controlled substances while, at the same time ensuring their availability for legitimate medical and scientific purposes, thereby directly reflecting the Central Principle of Balance. Also, although most laws establishing prescription monitoring programs do not promote Balance or require evaluation of outcomes, some contain statements of Balance or require a report on the program's effectiveness and how it impacts patient care. In a related approach, a number of policies urge practitioners to comply with federal and state laws governing pain management practices, which recognizes increased vulnerability to investigation or discipline for failure to conform to legal requirements. Finally, state laws have established a variety of policy or procedural mechanisms to improve pain management, such as the development of licensing or practice standards for assessing and treating patients' pain.

Part B. Criteria to Identify Provisions That May *Impede* Pain Management

CRITERION #9: OPIOIDS ARE RELEGATED AS ONLY A TREATMENT OF LAST RESORT

Policies consistent with the Central Principle of Balance recognize the need to maintain the availability of medications for legitimate purposes, which includes the appropriate use of opioid analgesics as part of medical practice. Opioids can be used effectively to relieve pain for some painful chronic conditions (American Academy of Pain Medicine, 2013; American Pain Society, 2002; Chou et al., 2009; Federation of State Medical Boards of the United States Inc., 2013; Fishman, 2012; Group Health Research Institute, 2013; Institute of Medicine Committee on Advancing Pain Research, 2011; Miaskowski et al., 2005), especially when such treatment benefits clearly outweigh the risks. However, opioids are not effective for relieving all types of pain, nor are opioids helpful for all patients, and these determinations need to be made throughout the course of treatment (American Academy of Pain Medicine, 2013; Federation of State Medical Boards of the United States Inc., 2013).

Some state policies have asserted that opioid medications are unconditionally a treatment of last resort, to be used *only* after all other methods of treatment have been tried and have failed, regardless of pain severity or other patient care considerations (Gilson, 2010a). Although there is no question that non-pharmacologic and non-opioid treatments are valuable modalities, the decision about when to use a particular treatment, including when to use opioids, should be medical and not governmental and should be based on the requirements of the specific clinical situation (American Academy of Pain Medicine, 2013). Alternative treatment options can and should be attempted first, when such treatments are of greater or equal potential for benefit and possess less risk and when reasonably warranted relative to the clinical circumstances (American Academy of Pain Medicine, 2013; Federation of State Medical Boards of the United States Inc., 2013; Fishman, 2012). State legislators and regulators should avoid promoting an inflexible protocol for the complex and evolving clinical decision-making process concerning the role of opioid therapy.

CRITERION #10: MEDICAL USE OF OPIOIDS IS IMPLIED TO BE OUTSIDE LEGITIMATE PROFESSIONAL PRACTICE

This criterion is the converse of Criterion #2 and Criterion #3, and identifies policy provisions, typically found in state Intractable Pain Treatment Acts, that place the medical use of opioids for pain outside the framework of ordinary professional practice, thereby suggesting the practice may not be legitimate. IPTAs grant legal permission and possible disciplinary immunity for practitioners who prescribe opioid analgesics for "intractable pain" under the conditions of the statute. "Intractable pain" is commonly defined in IPTAs as "a pain state…which *in the generally accepted course of medical practice* no relief or cure of the cause of the pain is possible..." (emphasis added). Because this statement suggests that use of opioids is outside the "generally accepted course of professional practice," some states have determined that physicians need immunity for prescribing. Otherwise, physicians may be subject to discipline, unless the patient's pain is deemed to satisfy the definition of "intractable pain," and all of the conditions of the IPTA are met.

IPTAs are a product of the time in which they were first created in some states, typically in the late 1980s and early 1990s; many physicians felt that their regulatory authorities viewed opioid use for chronic pain as being outside legitimate medical practice, and they worked with legislators to develop IPTAs to protect this practice from disciplinary action by placing it squarely within legitimate medical

practice (Hill, Jr., 1989). A potential consequence of such a policy is that a particular prescribing practice involving controlled substances, which is viewed as outside the IPTA, could be considered a violation of federal and state controlled substances law or regulatory policy. In addition, IPTAs were probably not intended to formalize the use of opioids for pain as being within medical practice only when meeting the IPTA standards. Nevertheless, the resulting IPTA language is ambiguous and appears to be inconsistent with the desirable recognition that pain management, including the use of opioid medications, is, simply stated, part of general medicine and is a legitimate professional practice.

CRITERION #11: PHYSICAL DEPENDENCE OR ANALGESIC TOLERANCE ARE CONFUSED WITH "ADDICTION"

This criterion is the converse of Criterion #7 and, as explained, the incorrect use of addiction-related terms still exists in some policies and has the potential to define pain patients as "addicts." According to definitions used in a number of policies, addiction or drug dependence could be established solely by the presence of physical dependence. As a result, those definitions, when codified in law, can legally classify patients as "drug dependent."

In addition, when outdated or confusing policy terminology is applied in practice, it has the potential to stigmatize relevant patients, restrict prescribing practices, and contribute to inadequate treatment. For example, some states still completely prohibits prescribing to those who "habitually use" controlled substances, although "habitual" is an outdated term that the WHO stopped using more than 40 years ago (see Criterion #12, Category A). Some states have also required that practitioners report "addicts" to a government agency; if physical dependence or analgesic tolerance is interpreted as being synonymous with "addiction," pain patients could be reported even if they do not exhibit compulsive drug use despite harm (see Criterion #14).

The implications of outdated or confusing terminology on patient care, as well as the need to avoid, remove, or modify such language, were directly and thoroughly addressed in the updated WHO Guidelines (World Health Organization, 2011a):

> "Guideline 10: Terminology in national drug control legislation and policies should be clear and unambiguous in order not to confuse the use of controlled medicines for medical and scientific purposes with misuse." (p. 28)
>
> "Drug control legislation and policy have sometimes contributed to stigmatization of controlled medicines because of the use of inappropriate terminology. Confusion and discrimination relating to terminology can deter doctors from prescribing controlled medicines when it is legitimate to do so; it can also confuse authorities who wish to discriminate between legitimate and illegitimate use. Countries should therefore take steps to review policies to ensure the consistent use of medical terms and remove stigmatizing terminology from their legislation. These guidelines specifically recommend the use of non-stigmatizing terminology." (pp. 28-29)
>
> "A further confusion relates to the definition of 'dependence' and 'dependence syndrome'…The WHO definition of 'dependence syndrome' requires the presence of at least three out of six symptoms, including a strong desire or a sense of compulsion to take the drug and also the neglecting of interests and daily activities because of devotion to the use of psychoactive substances. It is clear that a patient requiring increasing doses of an opioid for pain relief because of pharmacological tolerance due to prolonged treatment does not normally fall into this category. Neither does a patient who develops withdrawal syndrome." (p. 29)

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CRITERION #12: HEALTHCARE DECISIONS ARE RESTRICTED

Appropriate patient care decisions should be based on medical expertise and the specific clinical situation created, at least in part, by individual patient characteristics (American Academy of Pain Medicine, 2013; Chou et al., 2009; Federation of State Medical Boards of the United States Inc., 2013; Fishman, 2012; Miaskowski et al., 2005). However, there are a number of occasions in which governmental policy has imposed or continues to impose immutable requirements on practice issues, including the eligibility of patients to receive opioids, the choice of medication, and the amount prescribed or dispensed. Numerous international and national organizations have, since the 1980s, recognized the potential for such barriers to impede patient care, including:

International Narcotics Control Board

> "...the reaction of some legislators and administrators to the fear of drug abuse developing or spreading has led to the enactment of laws and regulations that may, in some cases, unduly impede the availability of opiates. The problem may also arise as a result of the manner in which drug control laws and regulations are interpreted or implemented." (International Narcotics Control Board, 1989, p. 1)
>
> "In some countries the use of certain drugs is limited by the need for special authorizations or by the conditions under which the drugs may be made available. Policies or regulations may dictate or specify the conditions under which a drug may be used and therefore may affect the way in which health professionals conduct a treatment program." (International Narcotics Control Board, 1989, ¶47).
>
> "Laws and regulations, and their administration or interpretation, unduly impeded the availability of opiates." (International Narcotics Control Board, 2011, ¶10)

World Health Organization

> "Decisions concerning the type of drug to be used, the amount of the prescription and the duration of therapy are best made by medical professionals on the basis of the individual needs of each patient, and not by regulation." (World Health Organization, 1996, p. 58)
>
> "In many countries, national legislation includes provisions stricter than the international drug control conventions require. This is allowed for by the conventions, as far as it is in the opinion of the government 'necessary or desirable for the protection of the public health or welfare'. However, in practice, many stricter provisions do not contribute to a better public or individual health. Therefore, it is important to analyze the effects of any stricter rules on the prevention of diversion, abuse and dependence syndrome and on the availability and accessibility of controlled medicines. Rules (and policies) that do not contribute to the protection of public health or welfare should be eliminated or changed. Rules violating any other international obligation, regardless whether originating from the drug conventions or any other treaty, should be guarded against." (World Health Organization, 2011a, p. 27)

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United Nations Commission on Narcotic Drugs

"While States are not precluded from adopting measures that are more restrictive than those required by the Conventions if they deem them necessary or desirable to protect public health or welfare, efforts to limit the use of narcotic drugs and psychotropic substances to medical and scientific purposes "must not adversely affect their availability for such purposes". A recent survey conducted by the INCB found that laws and regulations that were unduly restrictive or burdensome were commonly perceived as a significant limitation on availability." (United Nations Commission on Narcotic Drugs, 2011, ¶36)

International Association for the Study of Pain

"Most countries have no national policy at all or very inadequate policies regarding the management of pain as a health problem, including an inadequate level of research and education…There are severe restrictions on the availability of opioids and other essential medications, critical to the management of pain." (International Association for the Study of Pain, 2010, p. 1)

American Cancer Society

"The American Cancer Society strongly supports the primacy of clinical decision-making between patients and health care providers and opposes any efforts that might have an adverse effect on health care providers' willingness and ability to provide pain medication and pain management when treating patients with cancer and other serious or life-threatening illness. The Society encourages the drug enforcement community to work with the health care community and patient advocates to develop a balanced policy toward controlled substances." (Cancer Pain Management Policy Review Group, 2001c, p. 4)

American Pain Society

"State laws and regulations vary considerably, and many restrict or [overly-] regulate the prescription of opioids for the treatment of pain in ways that federal law does not." (Miaskowski et al., 2005 p. 6)

Institute of Medicine

*"...*review of restrictive state laws, revision of provisions that deter effective pain relief, and evaluation of the effect of regulatory changes on state medical board policies..." [and] "reform [of] drug prescription laws, burdensome regulations, and state medical board policies and practices that impede effective use of opioids to relieve pain and suffering.*"* (Institute of Medicine Committee on Care at the End of Life, 1997) p. 198, 267)

"Based on the discussion in this and other chapters, the committee identified several important barriers to adequate pain care in the United States. These include the magnitude of the problem, provider attitudes and training, insurance coverage, cultural attitudes of patients, geographic barriers, and regulatory barriers." (Institute of Medicine Committee on Advancing Pain Research, 2011, p. 3-34)

National Institutes of Health

*"*Regulatory barriers need to be revised to maximize convenience, benefit, and compliance*…"* (National Institutes of Health Consensus Development Program, 2002, p. 15)

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Four categories of specific policy provisions were identified that have the potential to restrict medical decisions and impede patient care:

Category A: Restrictions based on patient characteristics. Some state statutes and regulations limit the physician from treating certain patient populations with controlled substances (Gilson & Joranson, 2002). For example, some state policies prohibit prescribing to the *class* of patients with an addictive disease, regardless of the type or severity of the pain, practitioner expertise, or other clinical considerations; as expected, implementation of such laws can create significant treatment disparities. Although it is unlawful to use Schedule II opioids for the purpose of maintaining addiction (unless separately registered for this activity pursuant to federal and state law), it remains a legitimate medical purpose to prescribe opioids to a patient with a substance abuse history or an addictive disease if the purpose of prescribing is to relieve pain or other symptoms (Hagen, 2010; Heit & Gourlay, 2010; Walk & Backonja, 2010). Barriers to appropriate treatment, even if such patients may require extra care, monitoring, and consultation with or referral to experts with relevant training to ensure that prescribed medications are being used therapeutically (American Academy of Pain Medicine, 2013) (Federation of State Medical Boards of the United States Inc., 2013; Fishman, 2012; Substance Abuse and Mental Health Services Administration, 2011; 2012), can interfere with the management of those who also have pain from cancer or HIV/AIDS and who may require a controlled medicine to relieve their pain or other symptoms. In some states, efforts to correct this problem have resulted in additional and complex language that may have a net effect of being more, rather than less, restrictive.

Such policy language would not only fail to broadly grant access to treatment to relevant patient groups, but also serve to withhold needed treatment from others. The WHO (World Health Organization, 2011a) recognized the benefit of reducing the occurrence of language that could produce treatment disparities when it appears in a country's legislation or regulatory policies:

> "Guideline 8: Governments should ensure that all population groups without discrimination equally benefit from their policies on the availability and accessibility of controlled medicines for rational medical use and the prevention of diversion, abuse, and dependence syndrome. Non-discrimination is a fundamental principle that runs throughout the entire body of international human rights law. When developing policies and establishing treatment services, governments should not only guard against deliberate discrimination, but also ensure that the policies do not unintentionally lead to discrimination against vulnerable groups. A number of groups, including women, children, the elderly, people in lower income classes, ethnic minorities, prisoners, people living with HIV, sex workers, men who have sex with men, and injecting drug users, are particularly vulnerable and may require a special effort to ensure realistic access to controlled medicines. When designing policies, it should be ensured that such policies and resultant services allow for equal access and availability for these groups and are both gender sensitive and culturally appropriate. Patients who have a history of substances abuse have as much right to be treated for their pain as anybody else, and regulations should not limit their access to essential medicines. It is a medical decision to consider the advantages and disadvantages of different treatment options. The fact that someone has or had opioid dependence syndrome is not a reason to withhold adequate pain management from that person." (p. 26)

A provision that meets this criterion (i.e., one that bars prescribing to certain classes of patients) should be distinguished from a provision that meets Criterion #11, which has the potential to label and stigmatize as "addicts" patients with pain who are using controlled substances and subsequently become tolerant or physically dependent.

Category B: Mandated consultation for all patients. There is no question that physicians should seek consultation when needed (American Academy of Pain Medicine, 2013; Chou et al., 2009; Federation of State Medical Boards of the United States Inc., 2013; Fishman, 2012). However, state policies, especially intractable pain-related laws such as IPTAs, can *require* (without exception) the physician to obtain a consultation from a specialist for every patient with intractable pain as a means to qualify for immunity from discipline before prescribing opioids to that patient, regardless of the clinical situation or practitioner qualifications. Such a requirement may be inappropriate if the practitioner is knowledgeable or has relevant expertise, and appears to excessively regulate pain management and the entire class of patients who have "intractable" pain. Although IPTAs are intended to improve access to pain relief, such policies instead may discourage pain management or limit patient access because of the increased time and administrative burden for the physician, a lack of available consultation resources, as well as the possibility of increased cost for the patient. The same holds true for those consultation requirements that appear in other laws. Also, when a state policy requires a consultation, what is the liability of a physician who prescribes an opioid in the course of treating a patient with pain who does not obtain the consultation?

Category C: Restrictions regarding quantity prescribed or dispensed. Federal drug control or prescribing law limits neither the quantity nor duration of medications prescribed or dispensed, and avoids using these prescription characteristics to determine the legitimacy of treatment of the patient. Some state policies, however, have limited the amount of Schedule II controlled substances that can be prescribed or dispensed at one time, apparently intending to prevent abuse, addiction, and diversion. It is possible that the quantity permitted by a government policy may be insufficient to meet the individual medical needs of patients under all legitimately-occurring circumstances, and could result in inadequate treatment of pain.

For example, more than three decades ago a number of states had imposed a limit such as a "30-day supply or 100 dosage units, whichever is less." A 30-day supply itself seems an adequate prescribing duration to avoid creating a significant treatment barrier[13] (especially given that such a time-frame now is generally reinforced by reimbursement requirements and the extent of co-pays); however, when prescription duration is in conjunction with a limit of 100 dosage units and the phrase "whichever is less," the number of dosage units takes precedence and may be too restrictive depending on the clinical situation. As a result, a state law fulfills this criterion only when historical quantities of 100 or 120 dosage units are mandated and have greater priority than prescription duration of 30 days or greater.

[13] Importantly, although month-long durations of prescribing are not considered a potential substantial impediment to patient care, this should not be interpreted as a recommendation for states so adopt prescription duration standards in controlled substances laws.

SECTION VIII: THE RESEARCH CRITERIA

The WHO reiterated in its 2011 updated Guidelines document (World Health Organization, 2011a) that international drug control treaty does not limit the dose, amount, or duration of prescribing:

> "The conventions do not define the length of a medical prescription or the amount of medicines to be prescribed by a health worker. If a prescription covers only the amount of medicines needed for a limited time span, or if the validity of prescriptions is limited, the patient will need to go frequently to the physician and the pharmacy." (p. 27)

A recent Commission on Narcotic Drugs-related Discussion Paper also included insufficient thresholds on amounts or durations as an important regulatory barrier (United Nations Commission on Narcotic Drugs, 2011):

> Examples of measures that may impede availability and that are not required by the Conventions include:
>
> "(a) Limitations on the number of days' supply that may be provided in a single prescription (with too short a period of time allowed);" (¶37)
>
> "(b) Limitations on doses that may be prescribed in a single prescription (with allowed doses being too low);" (¶37)

Category D: Undue prescription limitations. Some statutes and regulations place additional and excessively strict limits on prescribing or dispensing Schedule II controlled substances for pain management; these conflict with current medical or scientific understanding or standards, and are more restrictive than federal controlled substances policy. For example, some states have required drug holidays as a routine part of prescribing, or appear to disallow off-label prescribing (which is not restricted under federal policy) (Lipman, 2010; Stafford, 2008).

In 1975, the FDA (Federal Register, 1975) clarified its support of off-label prescribing:

> "Certainly, where a physician uses a drug for a use not in the approved labeling, he has the responsibility to be well informed about the drug and to base such use on a firm scientific rationale or on sound medical evidence, and to maintain adequate medical records of the drug's use and effects, but such usage in the practice of medicine is not in violation of the Federal Food, Drug, and Cosmetic Act." (p. 15394).

As recently as May, 2013 (Department of Justice, 2013), off-label prescribing was re-affirmed when considering a case in which Adipex-P was used for weight maintenance:

> "Thus, even if Adipex-P has not been approved by the Food and Drug Administration for marketing for the indication of weight maintenance, this alone would not establish a violation of the CSA's prescription requirement because a physician can lawfully prescribe a drug, including a controlled substance, for an off-label use as long as the physician acts in the usual course of professional practice and has a legitimate medical purpose for doing so." (p. 27999).

SECTION VIII: THE RESEARCH CRITERIA

The FDA (Food and Drug Administration, 1982; Federal Register, 1983) has stated:

> "Once a product has been approved for marketing, a physician may prescribe it for uses or in treatment regimens or patient populations that are not included in approved labeling." (p. 5).
>
> "Once a drug product has been approved for marketing, a physician may, in treating patients, prescribe the drug for uses not included in the drug's approved labeling." (p. 26733).

Finally, in providing guidance to physicians for interpreting product labeling, the 66th edition of the *Physician's Desk Reference* (Thomson Healthcare, 2011) stated:

> "The FDA has also recognized that the FD&C Act does not, however, limit the manner in which a physician may use an approved drug…The FDA also observes that accepted medical practice includes drug use that is not reflected in approved drug labeling." (Foreword).

CRITERION #13: LENGTH OF PRESCRIPTION VALIDITY IS RESTRICTED

In balanced drug control policy, efforts to reduce drug diversion do not interfere with availability of medications to the patient. Federal law and most state laws do not establish a period of validity for a controlled substances prescription (i.e., the number of days within which the prescription must be dispensed following its issue). However, some states, such as Hawaii, have limited the period of validity to as little as 3 days, apparently in an effort to reduce "uncashed," although valid, prescriptions as a possible source of diversion. Although states can adopt stricter requirements than federal law, unrealistically short validity periods can make it difficult for a patient to obtain medications without having to make extraordinary and sometimes expensive arrangements, especially when travel restrictions, slow mail delivery, or other extenuating circumstances exist. Exceeding a prescription's validity period necessitates issuance of a new prescription and likely a return visit to the prescriber. For this evaluation, validity periods of less than two weeks (14 days) are considered potentially restrictive.

The WHO's updated Guidelines document includes overly-restrictive limitations to prescription validity as an example of policy language that Governments should correct (World Health Organization, 2011a):

> "The conventions do not define the length of a medical prescription or the amount of medicines to be prescribed by a health worker. If a prescription covers only the amount of medicines needed for a limited time span, or if the validity of prescriptions is limited, the patient will need to go frequently to the physician and the pharmacy." (p. 27)

SECTION VIII: THE RESEARCH CRITERIA

CRITERION #14: PRACTITIONERS ARE SUBJECT TO UNDUE PRESCRIPTION REQUIREMENTS

Prescription Drug Monitoring Programs (PDMPs) currently are the most prevalent formalized, state-level, drug control programs in the U.S., with 47 states and the District of Columbia now having an operational system and all but Missouri poised to have one functional in the near future. The PDMP's primary purpose is to provide law enforcement, as well as prescribers and dispensers, with information on "doctor shoppers," "scammers," and dishonest practitioners. Historically, PDMPs were characterized by the requirement that prescribers use government-issued prescription forms when prescribing controlled substances in certain schedules (usually only medications in Schedule II and, occasionally, benzodiazepines) (see Table 3). Several studies of these programs showed that, after they go into effect, the prescribing of those drugs being monitored declined notably along with a corresponding increase in the prescribing of drugs in lower (a not as restricted) schedules that may be less clinically effective for the patient's condition (Ross-Degnan, Simoni-Wastila, Brown, Mah, & Cosler, 2004; Simoni-Wastila et al., 2004; Simoni-Wastila & Tompkins, 2001; Wagner et al., 2003; Wastila & Bishop, 1996). Despite such observational evidence, representatives of PDMPs have maintained that these programs are not intended to interfere with medical practice (Alliance of States with Prescription Monitoring Programs, 1999; Drug Enforcement Administration - Office of Diversion Control, 1998), and that precautions are taken to avoid interference. Indeed, recent state laws adopted to authorize creation of a PDMP include the goal of ameliorating the programs' impact on legitimate prescribing.

Even given these occurrences, concern was expressed that PDMP requirements for government forms for Schedule II medications could have a "chilling effect" on physician prescribing because of the implied risk of being investigated for "excessive" or "inappropriate" prescribing by government officials who may not understand medical uses of controlled substances for varying needs of individual patients (Cancer Pain Management Policy Review Group, 2001b; Fishman, Papazian, Riches, & Gilson, 2004). As a result, physicians have reported that they did not obtain the government prescription forms because of the burden of ordering, re-ordering and maintaining security. In California, for example, it has been shown that over half of all licensed physicians did not have the prescription forms necessary to prescribe the selected controlled substances, so that a physician would not be able to prescribe an opioid for severe pain when necessary (Fujimoto, 2001). Although special government-required prescription forms also are said to have the advantage of reducing forgeries, it seems that this objective could be similarly achieved through the use of tamper-resistant security forms.

The WHO Expert Committee on Cancer Pain Relief and Active Supportive Care (World Health Organization, 1990) has addressed the issue of special government prescription forms:

> "Record-keeping and authorization requirements should not be such that, for all practical purposes, they eliminate the availability of opioids for medical purposes. Multiple-copy prescription programmes are cited as means of reducing careless prescribing and 'multiple doctoring' (patients registering with several medical practitioners in order to obtain several prescriptions for the same, or similar, drugs). There is some justification for thus (sic), but the extent to which these programmes restrict or inhibit the prescribing of opioids to patients who need them should also be questioned." (p. 39)

The World Health Assembly (World Health Assembly, 2005) echoed this approach, recognizing the need to:

> "ensure the medical availability of opioid analgesics according to international treaties and recommendations of WHO and the International Narcotics Control Board and subject to an efficient monitoring and control system." (p. 3)

In the U.S., the National Association of Attorneys General (National Association of Attorneys General, 2003b), while acknowledging the public health implications of both drug abuse and inadequate pain management, encouraged states to:

> "Ensure that…programs or strategies implemented to reduce abuse of prescription pain medication are designed with attention to their potential impact on the legitimate use of prescription drugs." (p. 2)

A few years later, the ACSCAN (American Cancer Society Cancer Action Network, 2007) recommended a similar approach to:

> "Ensure that policies establishing prescription monitoring programs avoid language that interferes with medical practice." (p. 1)
>
> "…ensure that [PDMPs] are balanced and do not interfere with pain management for cancer patients and survivors." (p. 1)

All states with PDMPs currently utilize Electronic Data Transfer (EDT) systems in conjunction with their program (Brushwood, 2003; Clark, Eadie, Kreiner, & Strickler, 2012), either alone or in combination with a government-required form or a security form (with both types of forms covering multiple schedules of drugs). Although there are few sources of definitive data on this subject, it is considered an improvement to eliminate the requirement that physicians use a government-issued prescription form for a single drug schedule (Alliance of States with Prescription Monitoring Programs, 2010), and that EDT alone is less intrusive to physicians' prescribing and can help to identify errant prescribers and doctor shoppers (American Cancer Society Cancer Action Network, 2008; Clark et al., 2012; National Alliance for Model State Drug Laws, 2002). Several states recently have chosen to require that physicians use prescription forms that are printed on security paper when prescribing any controlled substance, but such forms are not government-issued.

Given the aforementioned considerations, a state's PDMP law that requires the physician to use a government-issued prescription form only for Schedule II controlled substances is considered potentially restrictive, because of the stigmatization of this important class of medications and because research suggests that the use of government issued special forms can impede appropriate prescribing. PDMPs that utilize EDT technology to monitor multiple schedules of controlled substances (National Association of Boards of Pharmacy, 2012), either with a regular prescription form or with a security form, do not satisfy this criterion at this time due to a lack of published studies examining their effect on prescribing.

SECTION VIII: THE RESEARCH CRITERIA

This criterion also applies to special requirements that healthcare professionals must follow only for patients receiving prescriptions for Schedule II controlled substances. An example includes the requirement that practitioners report to a government agency the names of patients being prescribed Schedule II medications. When practitioners are required to report to a government agency either patients receiving opioids or "addicts," this has the potential to affect patients being treated for pain, especially in a state where physical dependence is legally classified as being synonymous with "addiction."

CRITERION #15: OTHER PROVISIONS THAT MAY IMPEDE PAIN MANAGEMENT

This analysis identified several additional provisions that are related to the Central Principle of Balance and that have the potential to impede pain relief, but were not sufficiently specific to fulfill an individual criterion. For example, a state's law has created a standard in which deviation from specific clinical practice guidelines constitutes "unprofessional conduct," which seems to impose a professional liability based on guidelines created only to provide guidance about clinical practice issues. If implemented, such requirements could subject practitioners to undue scrutiny and have the potential to seriously disrupt legitimate treatment and patient care.

CRITERION #16: PROVISIONS THAT ARE AMBIGUOUS

This analysis identified several provisions having the potential to impede pain management due to ambiguity of language. Ambiguous provisions were identified by considering whether the language would be clear to a person (professional or lay) who only reads the words of the provision to understand its meaning, absent any available corresponding information from legislative intent, case law, or other interpretive sources.

Three categories of policy provisions have the potential to create ambiguity:

Category A: Arbitrary standards for legitimate prescribing. This category is exemplified primarily by several states establishing a standard for unprofessional conduct (for physicians, osteopaths, or pharmacists) as the prescribing, dispensing, administering, or distribution of a prescription drug or controlled substance in an "excessive" manner or in "amounts greater than medically necessary." Left undefined, these terms may contribute to practitioners' uncertainty about what specific standard determines the legitimacy of a particular prescribing practice and who sets that standard. As another example, a state's law requires pharmacists to refuse to fill a prescription if potential harm is anticipated or if it is not in the patient's best interest; however, this requirement could become a barrier if the pharmacist determined potential harm based solely on the quantity of the prescription, and there is no indication how the determination that a prescription is not in the patient's "best interest" would be supported.

Category B: Unclear intent leading to possible misinterpretation. This category includes vague statutory or regulatory language that can make it difficult for practitioners to understand the explicit meaning of the policy provision or the specific actions that the policy requires or prohibits. A prevalent example of this category is as follows: It seems that physicians would not qualify for statutory immunity when prescribing controlled substances without having tried and failed other treatments, regardless of pain severity or other clinical considerations that could justify their appropriate initial use (see rationale for this in Criterion #9) (Chou et al., 2009). Such provisions typically are fulfilled by definitions contained in Intractable Pain Treatment Acts, which have been created to provide immunity to physicians who prescribe controlled substances to relieve such pain. "Intractable pain" is generally defined as a pain state in which no relief or cure in possible or *none has been found after reasonable efforts*; it seems logical, therefore, that "reasonable efforts" do not include the use of controlled substances outside the context of this law. As a result, although the policy provides immunity for prescribing opioids to patients with a history of failed treatments, it would seem to exclude opioid treatment for patients even when they present initially with severe pain or other issues that may justify opioid therapy. Such language only fulfilled this criterion when identified in the context of an immunity provision.

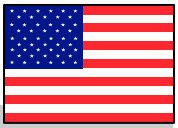
Category C: Conflicting or inconsistent policies or provisions. This category includes provisions in a state's pain policies that appear to contradict or do not conform to other policy provisions, thereby creating conflicting requirements. Such inconsistencies can occur between different policies (typically statutes and the regulations that implement them), or even for provisions in the same policies. A characteristic set of provisions, historically contained in many IPTAs, recognize that it is legitimate medical practice to prescribe opioids to treat pain in patients with an addictive disease, but at the same time provides no authority to physicians who prescribe to persons using controlled substances for non-therapeutic purposes who may have an addictive disease; this establishes a seemingly contradictory treatment standard that can make interpretation unclear. In addition, there are a number of instances where statutory language conflicts with specific requirements created in regulations to implement the statute.

SECTION IX: RESULTS – PROFILES OF FEDERAL AND STATE PAIN POLICIES GOVERNING DRUG CONTROL AND MEDICAL AND PHARMACY PRACTICE

Alabama
Alaska
Arizona
Arkansas
California
Colorado
Connecticut
Delaware
District of Columbia
Florida
Georgia
Hawaii
Idaho
Illinois
Indiana
Iowa
Kansas
Kentucky
Louisiana
Maine
Maryland
Massachusetts
Michigan
Minnesota
Mississippi
Missouri
Montana
Nebraska
Nevada
New Hampshire
New Jersey
New Mexico
New York
North Carolina
North Dakota
Ohio
Oklahoma
Oregon
Pennsylvania
Rhode Island
South Carolina
South Dakota
Tennessee
Texas
Utah
Vermont
Virginia
Washington
West Virginia
Wisconsin
Wyoming

Federal

FEDERAL



STATUTES

- CONTROLLED SUBSTANCES ACT
  Title 21. Food and Drugs; Chapter 13. Drug Abuse Prevention and Control

- PUBLIC HEALTH AND WELFARE
  Title 42. Public Health and Welfare

REGULATIONS

- CONTROLLED SUBSTANCES REGULATIONS
  Title 21. Food and Drugs

- PUBLIC HEALTH
  Title 42. The Public Health

- PUBLIC WELFARE
  Title 45. Public Welfare

OTHER GOVERNMENTAL POLICIES

No policies found

RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES

- VETERANS' BENEFITS
  Title 38. Veterans' Benefits

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FEDERAL

STATUTES

Food and Drugs

21 USCS § 355-1

§ 355-1. Risk evaluation and mitigation strategies

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(f) Providing safe access for patients to drugs with known serious risks that would otherwise be unavailable.

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(5) Evaluation of elements to assure safe use. The Secretary, through the Drug Safety and Risk Management Advisory Committee (or successor committee) of the Food and Drug Administration, shall--

(A) seek input from patients, physicians, pharmacists, and other health care providers about how elements to assure safe use under this subsection for 1 or more drugs may be standardized so as not to be--

(i) unduly burdensome on patient access to the drug; and

(ii) to the extent practicable, minimize the burden on the health care delivery system;

(B) at least annually, evaluate, for 1 or more drugs, the elements to assure safe use of such drugs to assess whether the elements--

(i) assure safe use of the drug;

(ii) are not unduly burdensome on patient access to the drug; and

(iii) to the extent practicable, minimize the burden on the health care delivery system; and

(C) considering such input and evaluations--

(i) issue or modify agency guidance about how to implement the requirements of this subsection; and

(ii) modify elements under this subsection for 1 or more drugs as appropriate.

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21 USCS § 801

§ 801. Congressional findings and declarations: controlled substances

The Congress makes the following findings and declarations:

(1) Many of the drugs included within this title have a useful and legitimate medical purpose and are necessary to maintain the health and general welfare of the American people.

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21 USCS § 801a

§ 801a. Congressional findings and declarations: psychotropic substances

The Congress makes the following findings and declarations:

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(3) In implementing the Convention on Psychotropic Substances, the Congress intends that, consistent with the obligations of the United States under the Convention, control of psychotropic substances in the United States should be accomplished within the framework of the procedures and criteria for classification of substances provided in the Comprehensive Drug Abuse Prevention and Control Act of 1970. This will insure that (A) the availability of psychotropic substances to manufacturers, distributors, dispensers, and researchers for useful and legitimate medical and scientific purposes will not be unduly restricted; (B) nothing in the Convention will interfere with bona fide research activities; and (C) nothing in the Convention will interfere with ethical medical practice in this country as determined by the Secretary of Health, Education, and Welfare [Secretary of Health and Human Services] on the basis of a consensus of the views of the American medical and scientific community.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a responsibility to determine the impact of the REMS program both on safe drug use and patient care.

(+) *CRITERION1:*
Controlled substances are necessary for public health

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Represents the principle of Balance, which states that the regulation of controlled substances should not interfere with legitimate medical use.

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STATUTES

Public Health and Welfare

42 USCS § 201

§ 201. Definitions

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(q) The term "drug dependent person" means a person who is using a controlled substance (as defined in section 102 of the Controlled Substances Act [*21 USCS § 802*]) and who is in a state of psychic or physical dependence, or both, arising from the use of that substance on a continuous basis. Drug dependence is characterized by behavioral and other responses which include a strong compulsion to take the substance on a continuous basis in order to experience its psychic effects or to avoid the discomfort caused by its absence.

(-) *CRITERION 11:*
Physical dependence or analgesic tolerance confused with "addiction"

42 USCS § 280g-3

§ 280g-3. Controlled substance monitoring program

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(j) Studies and reports.
(1) Implementation report.
(A) In general. Not later than 180 days after the date of enactment of this section [enacted Aug. 11, 2005], the Secretary, based on a review of existing State controlled substance monitoring programs and other relevant information, shall determine whether the implementation of such programs has had a substantial negative impact on--
(i) patient access to treatment, including therapy for pain or controlled substance abuse;

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(2) Progress report. Not later than 3 years after the date on which funds are first appropriated under this section, the Secretary shall--
(A) complete a study that--
(i) determines the progress of States in establishing and implementing controlled substance monitoring programs under this section;
(ii) provides an analysis of the extent to which the operation of controlled substance monitoring programs have reduced inappropriate use, abuse, or diversion of controlled substances or affected patient access to appropriate pain care in States operating such programs;

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(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT*:* Establishes mechanisms to determine whether the prescription monitoring programs impede the appropriate medical use of controlled substances.

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STATUTES

Public Health and Welfare

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (program of research) to ensure that pain management is a broad initiative throughout the NIH.

42 USCS § 284q

§ 284q. Pain research

(a) Research initiatives.
(1) In general. The Director of NIH is encouraged to continue and expand, through the Pain Consortium, an aggressive program of basic and clinical research on the causes of and potential treatments for pain.
(2) Annual recommendations. Not less than annually, the Pain Consortium, in consultation with the Division of Program Coordination, Planning, and Strategic Initiatives, shall develop and submit to the Director of NIH recommendations on appropriate pain research initiatives that could be undertaken with funds reserved under section 402A(c)(1) [*42 USCS § 282a(c)(1)*] for the Common Fund or otherwise available for such initiatives.
(3) Definition. In this subsection, the term "Pain Consortium" means the Pain Consortium of the National Institutes of Health or a similar trans-National Institutes of Health coordinating entity designated by the Secretary for purposes of this subsection.

(b) Interagency Pain Research Coordinating Committee.
(1) Establishment. The Secretary shall establish not later than 1 year after the date of the enactment of this section [enacted March 23, 2010] and as necessary maintain a committee, to be known as the Interagency Pain Research Coordinating Committee (in this section referred to as the "Committee"), to coordinate all efforts within the Department of Health and Human Services and other Federal agencies that relate to pain research.

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(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (Interagency Pain Research Coordinating Committee) to ensure that pain management research is a broad initiative throughout the Department of Health and Human Services and other Federal agencies.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (practitioner education and training) to ensure that pain management is an essential part of patient care.

42 USCS § 294i

§ 294i. Program for education and training in pain care

(a) In general. The Secretary may make awards of grants, cooperative agreements, and contracts to health professions schools, hospices, and other public and private entities for the development and implementation of programs to provide education and training to health care professionals in pain care.

(b) Certain topics. An award may be made under subsection (a) only if the applicant for the award agrees that the program carried out with the award will include information and education on--
(1) recognized means for assessing, diagnosing, treating, and managing pain and related signs and symptoms, including the medically appropriate use of controlled substances;
(2) applicable laws, regulations, rules, and policies on controlled substances, including the degree to which misconceptions and concerns regarding such laws, regulations, rules, and policies, or the enforcement thereof, may create barriers to patient access to appropriate and effective pain care;
(3) interdisciplinary approaches to the delivery of pain care, including delivery through specialized centers providing comprehensive pain care treatment expertise;
(4) cultural, linguistic, literacy, geographic, and other barriers to care in underserved populations; and
(5) recent findings, developments, and improvements in the provision of pain care.

(c) Evaluation of programs. The Secretary shall (directly or through grants or contracts) provide for the evaluation of programs implemented under subsection (a) in order to determine the effect of such programs on knowledge and practice of pain care.

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(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a responsibility to determine the impact of the educational component of this program on pain management and patient care.

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FEDERAL

STATUTES

Public Health and Welfare

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Clarifies for physicians that there is an important distinction between physician-assisted suicide and prescribing controlled substances for pain relief; this language identifies a clinical misperception that is pervasive in end-of-life care and attempts to lessen its impact on patient treatment.

42 USCS § 14402

§ 14402. Restriction on use of Federal funds under health care programs

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(b) Construction and treatment of certain services. Nothing in subsection (a), or in any other provision of this Act (or in any amendment made by this Act), shall be construed to apply to or to affect any limitation relating to--

(1) the withholding or withdrawing of medical treatment or medical care;

(2) the withholding or withdrawing of nutrition or hydration;

(3) abortion; or

(4) the use of an item, good, benefit, or service furnished for the purpose of alleviating pain or discomfort, even if such use may increase the risk of death, so long as such item, good, benefit, or service is not also furnished for the purpose of causing, or the purpose of assisting in causing, death, for any reason.

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FEDERAL

CODE OF FEDERAL REGULATIONS

Food and Drugs

21 CFR 1306.04

§ 1306.04 Purpose of issue of prescription.

(a) A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription. An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of section 309 of the Act (21 U.S.C. 829) and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.

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(+) *CRITERION 3:*
Opioids are part of professional practice

CODE OF FEDERAL REGULATIONS

Public Health

42 CFR 8.2

§ 8.2 Definitions.

The following definitions apply to this part:

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Opiate addiction is defined as a cluster of cognitive, behavioral, and physiological symptoms in which the individual continues use of opiates despite significant opiate-induced problems. Opiate dependence is characterized by repeated self-administration that usually results in opiate tolerance, withdrawal symptoms, and compulsive drug-taking. Dependence may occur with or without the physiological symptoms of tolerance and withdrawal.

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(+) *CRITERION 7:*
Physical dependence or analgesic tolerance are not confused with "addiction"

2012

Pain & Policy Studies Group
University of Wisconsin Carbone Cancer Center
Madison, Wisconsin

FEDERAL

CODE OF FEDERAL REGULATIONS

Public Welfare

45 CFR 1643.4

§ 1643.4 Applicability.

(a) Nothing in § 1643.3 shall be interpreted to apply to:

(1) The withholding or withdrawing of medical treatment or medical care;

(2) The withholding or withdrawing of nutrition or hydration;

(3) Abortion;

(4) The use of items, goods, benefits, or services furnished for purposes relating to the alleviation of pain or discomfort even if they may increase the risk of death, unless they are furnished for the purpose of causing or assisting in causing death;

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(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Clarifies for physicians that there is an important distinction between physician-assisted suicide and prescribing controlled substances for pain relief; this language identifies a clinical misperception that is pervasive in end-of-life care and attempts to lessen its impact on patient treatment.

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Madison, Wisconsin

FEDERAL

STATUTES

Veteran's Benefits

38 USCS § 7327

§ 7327. Centers for research, education, and clinical activities on complex multi-trauma associated with combat injuries

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(c) Requirements for centers. To be designated as a center under this section, a facility shall--

(1) be a regional lead center for the care of traumatic brain injury;

(2) be located at a tertiary care medical center and have on-site availability of primary and subspecialty medical services relating to complex multi-trauma;

(3) have, or have the capacity to develop, the capability of managing impairments associated with combat injuries;

(4) be affiliated with a school of medicine;

(5) have, or have experience with, participation in clinical research trials;

(6) provide amputation care and rehabilitation;

(7) have pain management programs;

(8) provide comprehensive brain injury rehabilitation; and

(9) provide comprehensive general rehabilitation.

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(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (pain management programs) for VA centers to ensure that pain management is an essential part of patient care.

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Madison, Wisconsin

ALABAMA

STATUTES

- CONTROLLED SUBSTANCES ACT
  Title 20. Food, Drugs, and Cosmetics; Chapter 2. Controlled Substances

- MEDICAL PRACTICE ACT
  Title 34. Professions and Businesses; Chapter 24. Physicians and Other Practitioners of Healing Arts;
  Article 3. Physicians and Osteopaths
  Article 8. Licensing and Registration of Physicians and Osteopaths

- PAIN MANAGEMENT ACT (*Part of Medical Practice Act*)
  Title 34. Professions and Businesses; Chapter 24. Physicians and Other Practitioners of Healing Arts

- PHARMACY PRACTICE ACT (*No provisions found*)
  Title 34. Professions and Businesses; Chapter 23. Pharmacists and Pharmacies

- INTRACTABLE PAIN TREATMENT ACT
  No policy found

REGULATIONS

- CONTROLLED SUBSTANCES REGULATIONS (*Part of Pharmacy Board Regulations*) (*No provisions found*)
  Alabama Uniform Controlled Substances Regulations; Chapter 680-X-3

- MEDICAL BOARD REGULATIONS
  Alabama Board of Medical Examiners; Chapter 540-X

- PHARMACY BOARD REGULATIONS (*No provisions found*)
  Alabama Board of Pharmacy; Chapter 680-X

OTHER GOVERNMENTAL POLICIES

No policies found

RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES

- HOSPICES
  Alabama State Board of Health; Alabama Department of Public Health; Chapter 420-5-17: Hospices

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Madison, Wisconsin

ALABAMA

STATUTES

Controlled Substances Act

Code of Ala. § 20-2-2

§ 20-2-2. Definitions

When used in this chapter, the following words and phrases shall have the following meanings, respectively, unless the context clearly indicates otherwise:

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(20) Practitioner.

a. A physician, dentist, veterinarian, scientific investigator, or other person licensed, registered, or otherwise permitted to distribute, dispense, conduct research with respect to, or to administer a controlled substance in the course of professional practice or research in this state.

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(+) *CRITERION 3:*
Opioids are part of professional practice

STATUTES

Medical Practice Act

Code of Ala. § 34-24-50

§ 34-24-50. "Practice of medicine or osteopathy" defined

The "practice of medicine or osteopathy" means:

(1) To diagnose, treat, correct, advise or prescribe for any human disease, ailment, injury, infirmity, deformity, pain or other condition, physical or mental, real or imaginary, by any means or instrumentality;

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(+) *CRITERION 2:*
Pain management is part of healthcare practice

2013

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Madison, Wisconsin

ALABAMA

STATUTES

Pain Management Act

Code of Ala. § 34-24-606

§ 34-24-606. Training requirements.

Each physician serving as the medical director at a practice location shall meet at least one of the following requirements:

(1) Successful completion of a residency program in physical medicine and rehabilitation, anesthesiology, addiction medicine, neurology, neurosurgery, family practice, preventive medicine, internal medicine, surgery, orthopedics, or psychiatry approved by the Accreditation Council for Graduate Medical Education (ACGME) or the American Osteopathic Association Bureau of Osteopathic Specialists (AOABOS).

(2) Board certification in physical medicine and rehabilitation, anesthesiology, addiction medicine, neurology, neurosurgery, family practice, preventive medicine, internal medicine, surgery, orthopedics, or psychiatry approved by the American Board of Medical Specialties (ABMS) or the American Osteopathic Association Bureau of Osteopathic Specialists (AOABOS).

(3) Specialty certification in pain management, pain medicine, hospice and palliative medicine, geriatric medicine, rheumatology, hematology, medical oncology, gynecologic oncology, infectious disease, pediatric hematology-oncology, or pediatric rheumatology recognized by the American Board of Medical Specialties or the American Osteopathic Association Bureau of Osteopathic Specialists.

(4) Board certification by the American Board of Pain Medicine.

(5) Board certification by the American Board of Interventional Pain Physicians.

(6) At least one of the following:

a. Completion of 40 in-person, live participatory AMA PRA Category 1 Credit or AOA Category 1-A credits in the area of pain management completed within three years of implementation of this article or prior to serving as a medical director for the practice location, whichever of them is most recent.

b. Completion of a board approved course of medical education in the area of prescribing controlled substances completed within three years of implementation of this article or prior to serving as medical director for the practice location, whichever of them is most recent, and completion of 40 in-person, live participatory AMA PRA Category 1 Credit or AOA Category 1-A credits in the area of pain management within three years of commencement of service as medical director.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (mandatory medical curriculum) to provide physicians information/education about pain management.

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University of Wisconsin Carbone Cancer Center
Madison, Wisconsin

ALABAMA

REGULATIONS

Medical Board Regulations

§ 540-X-4-.08

540-X-4-.08 Guidelines for the Use of Controlled Substances for the Treatment of Pain

(1) Preamble.

(a) The Board recognizes that principles of quality medical practice dictate that the people of the State of Alabama have access to appropriate and effective pain relief. The appropriate application of up-to-date knowledge and treatment modalities can serve to improve the quality of life for those patients who suffer from pain as well as to reduce the morbidity and costs associated with untreated or inappropriately treated pain. The Board encourages physicians to view effective pain management as a part of quality medical practice for all patients with pain, acute or chronic, and it is especially important for patients who experience pain as a result of terminal illness. All physicians should become knowledgeable about effective methods of pain treatment as well as statutory requirements for prescribing controlled substances.

(b) Inadequate pain control may result from physicians' lack of knowledge about pain management or an inadequate understanding of addiction. Fears of investigation or sanction by federal, state, and local regulatory agencies may also result in inappropriate or inadequate treatment of chronic pain patients. Accordingly, these guidelines have been developed to clarify the Board's position on pain control, specifically as related to the use of controlled substances, to alleviate physician uncertainty and to encourage better pain management.

(c) The Board recognizes that controlled substances, including opioid analgesics, may be essential in the treatment of acute pain due to trauma or surgery and chronic pain, whether due to cancer or non-cancer origins. Physicians are referred to the *U.S. Agency for Health Care and Research Clinical Practice Guidelines* for a sound approach to the management of acute pain (Acute Pain Management Guideline Panel. Acute Pain Management: Operative or Medical Procedures and Trauma. Clinical Practice Guideline. AHCPR Publication No. 92-0032. Rockville, Md. Agency for Health Care Policy and Research. U.S. Department of Health and Human Resources, Public Health Service. February 1992.) and cancer-related pain (Jacox A, Carr DB, Payne R. et al. Management of Cancer Pain. Clinical Practice Guideline No. 9. AHCPR Publication No. 94-0592. Rockville, Md. Agency for Health Care Policy and Research, U.S. Department of Health and Human Resources, Public Health Service. March 1994). The medical management of pain should be based upon current knowledge and research and include the use of both pharmacologic and non-pharmacologic modalities. Pain should be assessed and treated promptly, and the quantity and frequency of doses should be adjusted according to the intensity and duration of the pain. Physicians should recognize that tolerance and physical dependence are normal consequences of sustained use of opioid analgesics and are not synonymous with addiction.

(d) The Board is obligated under the laws of the State of Alabama to protect the public health and safety. The Board recognizes that inappropriate prescribing of controlled substances, including opioid analgesics, may lead to drug diversion and abuse by individuals who seek them for other than legitimate medical use.

(e) Physicians should not fear disciplinary action from the Board or other state regulatory or enforcement agency for prescribing, dispensing, or administering controlled substances, including opioid analgesics, for a legitimate medical purpose and in the usual course of professional practice. The Board will consider prescribing, ordering, administering, or dispensing controlled substances for pain to be for a legitimate medical purpose if based on accepted scientific knowledge of the treatment of pain or if based on sound clinical grounds. All such prescribing must be based on clear documentation of unrelieved pain and in compliance with applicable state or federal law.

(+) *CRITERION 2:*
Pain management is part of healthcare practice

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Identifies the potential impact of important barriers on the provision of effective pain care.

(+) *CRITERION 7:*
Physical dependence or analgesic tolerance are not confused with "addiction"

(+) *CRITERION 3:*
Opioids are part of professional practice

(+) *CRITERION 4:*
Encourages pain management

(+) *CRITERION 5:*
Addresses fear of regulatory scrutiny

2013

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Madison, Wisconsin

ALABAMA

REGULATIONS

Medical Board Regulations

[CONTINUED]

(f) Each case of prescribing for pain will be evaluated on an individual basis. The Board will not take disciplinary action against a physician for failing to adhere strictly to the provisions of these guidelines, if good cause is shown for such deviation. The physician's conduct will be evaluated to a great extent by the treatment outcome, taking into account whether the drug used is medically and/or pharmacologically recognized to be appropriate for the diagnosis, the patient's individual needs - including any improvement in functioning - and recognizing that some types of pain cannot be completely relieved.

(g) The Board will judge the validity of prescribing based on the physician's treatment of the patient and on available documentation, rather than on the quantity and chronicity of prescribing. The goal is to control the patient's pain for its duration while effectively addressing other aspects of the patient's functioning, including physical, psychological, social and work-related factors. The following guidelines are not intended to define complete or best practice, but rather to communicate what the Board considers to be within the boundaries of professional practice.

(2) Guidelines. The Board has adopted the following guidelines when evaluating the use of controlled substances for pain control:

(a) Evaluation of the Patient. A complete medical history and physical examination must be conducted and documented in the medical record. The medical record should document the nature and intensity of the pain, current and past treatments for pain, underlying or coexisting diseases or conditions, the effect of the pain on physical and psychological function, and history of substance abuse. The medical record should also document the presence of one or more recognized medical indications for the use of a controlled substance.

(b) Treatment Plan. The written treatment plan should state objectives that will be used to determine treatment success, such as pain relief and improved physical and psychosocial function, and should indicate if any further diagnostic evaluations or other treatments are planned. After treatment begins, the physician should adjust drug therapy to the individual medical needs of each patient. Other treatment modalities or a rehabilitation program may be necessary depending on the etiology of the pain and the extent to which the pain is associated with physical and psychosocial impairment.

(c) Informed Consent and Agreement for Treatment. The physician should discuss the risks and benefits of the use of controlled substances with the patient, persons designated by the patient, or with the patient's surrogate or guardian if the patient is incompetent. The patient should receive prescriptions from one physician and one pharmacy where possible. If the patient is determined to be at high risk for medication abuse or have a history of substance abuse, the physician may employ the use of a written agreement between physician and patient outlining patient responsibilities including

1. urine/serum medication levels screening when requested
2. number and frequency of all prescription refills; and
3. reasons for which drug therapy may be discontinued (i.e. violation of agreement)

(d) Periodic Review. At reasonable intervals based upon the individual circumstance of the patient, the physician should review the course of treatment and any new information about the etiology of the pain. Continuation or modification of therapy should depend on the physician's evaluation of progress toward stated treatment objectives such as improvement in patient's pain intensity and improved physical and/or psychosocial function, i.e., ability to work, need of health care resources, activities of daily living, and quality of social life. If treatment goals are not being achieved, despite medication adjustments, the physician should re-evaluate the appropriateness of continued treatment. The physician should monitor patient compliance in medication usage and related treatment plans.

[CONTINUED ON NEXT PAGE]

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Acknowledges the need for treatment flexibility for physicians to respond to individual clinical circumstances, as long as their prescribing maintains the standards of good medical practice.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Encourages healthcare professionals to incorporate in their practice the evaluations of, and discussions with patients about, the potential benefits and risks of treatment with opioids, which can better ensure a clinical indication of such treatment so that opioids will be used for medical purposes.

(+) *CRITERION 6:*
Prescription amount alone does not determine legitimacy

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Recognizes that the goal of pain treatment should include improvements in patient functioning and quality of life.

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Madison, Wisconsin

ALABAMA

REGULATIONS

Medical Board Regulations

[CONTINUED]

(e) Consultation. The physician should be willing to refer the patient as necessary for additional evaluation and treatment in order to achieve treatment objectives. Special attention should be given to those pain patients who are at risk for misusing their medications and those whose living arrangement pose a risk for medication misuse or diversion. The management of pain in patients with a history of substance abuse or with a comorbid psychiatric disorder may require extra care, monitoring, documentation, and consultation with or referral to an expert in the management of such patients.

(f) Medical Records. The physician should keep accurate and complete records to include:

1. the medical history and physical examination;
2. diagnostic, therapeutic and laboratory results;
3. evaluations and consultations;
4. treatment objectives;
5. discussion of risks and benefits;
6. treatments;
7. medications (including date, type, dosage, and quantity prescribed);
8. instructions and agreements; and
9. periodic reviews.

Records should remain current, and be maintained in an accessible manner, and readily available for review.

(g) Compliance with Controlled Substances Laws and Regulations. To prescribe, dispense, or administer controlled substances, the physician must be licensed in the state, and comply with applicable federal and state regulations. Physicians are referred to *the Physicians Manual of the U.S. Drug Enforcement Administration* and applicable state regulations for rules governing controlled substances.

(3) Definitions. For the purposes of these guidelines, the following terms are defined as follows:

(a) Acute pain. Acute pain is the normal, predicted physiological response to an adverse chemical, thermal, or mechanical stimulus and is associated with surgery, trauma and acute illness. It is generally time-limited and is responsive to opioid therapy, among other therapies.

(b) Addiction. Addiction is a neurobehavioral syndrome with genetic and environmental influences that results in psychological dependence on the use of substances for their psychic effects and is characterized by compulsive use despite harm. Addiction may also be referred to by terms such as "drug dependence" and "psychological dependence." Physical dependence and tolerance are normal physiological consequences of extended opioid therapy for pain and should not be considered addiction.

(c) Analgesic Tolerance. Analgesic tolerance is the need to increase the dose of opioid to achieve the same level of analgesia. Analgesic tolerance may or may not be evident during opioid treatment and does not equate with addiction.

(d) Chronic Pain. A pain state which is persistent and in which the cause of the pain cannot be removed or otherwise treated. Chronic pain may be associated with a long-term incurable or intractable medical condition or disease.

(e) Pain. An unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage.

(f) Physical Dependence. Physical dependence on a controlled substance is a physiologic state of neuro-adaptation which is characterized by the emergence of a withdrawal syndrome if drug use is stopped or decreased abruptly, or if an antagonist is administered. Physical dependence is an expected result of opioid use. Physical dependence, by itself, does not equate with addiction.

(g) Pseudoaddiction. Pattern of drug-seeking behavior of pain patients who are receiving inadequate pain management that can be mistaken for addiction.

(h) Substance Abuse. Substance abuse is the use of any substance(s) for non-therapeutic purposes; or use of medication for purposes other than those for which it is prescribed.

(i) Tolerance. Tolerance is a physiologic state resulting from regular use of a drug in which an increased dosage is needed to produce the same effect or a reduced effect is observed with a constant dose.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Encourages healthcare professionals to understand and follow federal and state laws governing their practice, which can better ensure that practitioners follow the *balanced* approach represented by federal law and the laws in many states.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY B:
Issues related to patients

COMMENT:
Acknowledges that a patient's prior history or current status of drug abuse does not necessarily contraindicate appropriate pain management.

2013

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University of Wisconsin Carbone Cancer Center
Madison, Wisconsin

ALABAMA

REGULATIONS

Hospices

Ala. Admin. Code r. 420-5-17-.06

420-5-17-.06 Personnel.

Each hospice care program shall utilize personnel to provide services that have appropriate training and qualifications for the services that they provide. Any staff member, including a volunteer, who functions in a professional capacity shall meet the standards applicable to that profession, including but not limited to, possessing applicable license, registration, or certification, if required by law, and practicing within the applicable scope of practice.

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(2) Each hospice care program shall have a policy which provides for orientation and ongoing education programs for its personnel, including volunteers that is consistent with acceptable standards of hospice practice which emphasizes:

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(h) Licensed nurses, in addition, shall be trained in pain and symptom management.

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(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (policy) for hospices to ensure that pain management is an essential part of patient care.

2013

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Madison, Wisconsin

ALASKA

STATUTES

- CONTROLLED SUBSTANCES ACT
  Title 11. Criminal Law; Chapter 71. Controlled Substances

  Title 17. Food and Drugs; Chapter 30. Controlled Substances

- MEDICAL PRACTICE ACT (*No provisions found*)
  Title 8. Businesses and Professions; Chapter 64. Medicine

- PHARMACY PRACTICE ACT
  Title 8. Businesses and Professions; Chapter 80. Pharmacists and Pharmacies

- INTRACTABLE PAIN TREATMENT ACT
  No policy found

REGULATIONS

- CONTROLLED SUBSTANCES REGULATIONS
  No policy found

- MEDICAL BOARD REGULATIONS (*No provisions found*)
  Title 12. Professional Regulations; Part 1. Boards and Commissions Subject to Centralized Licensing; Chapter 40. State Medical Board

- PHARMACY BOARD REGULATIONS (*No provisions found*)
  Title 12. Professional Regulations; Part 1. Boards and Commissions Subject to Centralized Licensing; Chapter 52. Board of Pharmacy

OTHER GOVERNMENTAL POLICIES

No policies found

RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY KEY WORD SEARCHES

- HOSPICE AGENCIES
  Title 7. Health and Social Services; Part 1. Administration; Chapter 12. Facilities and Local Units; Article 7. Hospice Agencies

ALASKA

STATUTES

Controlled Substances Act

Alaska Stat. § 11.71.900

Sec. 11.71.900. Definitions

In this chapter, unless the context clearly requires otherwise,

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(19) "practitioner" means

(A) a physician, dentist, veterinarian, scientific investigator, or other person licensed, registered, or otherwise permitted to distribute, dispense, conduct research with respect to, or to administer or use in teaching or chemical analysis a controlled substance in the course of professional practice or research in the state;

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(+) CRITERION 3:
Opioids are part of professional practice

STATUTES

Pharmacy Practice Act

Alaska Stat. § 08.80.480

Sec. 08.80.480. Definitions

In this chapter, unless the context otherwise requires,

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(28) "practitioner" means an individual currently licensed, registered, or otherwise authorized by the jurisdiction in which the individual practices to prescribe and administer drugs in the course of professional practice;

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(+) CRITERION 3:
Opioids are part of professional practice

2013

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University of Wisconsin Carbone Cancer Center
Madison, Wisconsin

ALASKA

REGULATIONS

Hospice Agencies

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT*:* Establishes a mechanism (inpatient care) for hospices to ensure that pain management is an essential part of patient care.

7 Alaska Admin. Code 12.316

7 AAC 12.316. Scope of service: full-service hospice agency

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(d) The hospice agency shall arrange for short-term inpatient care if home care is not feasible for pain control, symptom management, and respite purposes. The agency shall ensure that any short-term inpatient care is provided in a licensed facility that is most appropriate to meet the client's needs.

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7 Alaska Admin. Code 12.338

7 AAC 12.338. Hiring, orientation, and training

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(e) A full-service hospice agency shall provide an educational program that offers a comprehensive overview of hospice philosophy and hospice care. The agency shall provide a minimum of 18 hours of education within a one-year period for each direct service provider delivering hospice care. The four hours of orientation training required under (b) of this section may be counted as part of the 18 hours required under this subsection. The educational program must include at least the following subjects:

(1) hospice philosophy;

(2) family dynamics;

(3) pain and symptom management;

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(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT*:* Establishes a mechanism (educational program) for hospices to ensure that pain management is an essential part of patient care.

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Madison, Wisconsin

ARIZONA

STATUTES

- CONTROLLED SUBSTANCES ACT
  Title 36. Public Health and Safety; Chapter 27. Uniform Controlled Substances Act

- MEDICAL PRACTICE ACT (*No provisions found*)
  Title 32. Professions and Occupations; Chapter 13. Medicine and Surgery

- OSTEOPATHIC PRACTICE ACT (*No provisions found*)
  Title 32. Professions and Occupations; Chapter 17. Osteopathic Physicians and Surgeons

- PHARMACY PRACTICE ACT
  Title 32. Professions and Occupations; Chapter 18. Pharmacy

- INTRACTABLE PAIN TREATMENT ACT
  No policy found

REGULATIONS

- CONTROLLED SUBSTANCES REGULATIONS (*Part of Pharmacy Board Regulations*) (*No provisions found*)
  Title 4. Professions and Occupations; Chapter 23. Board of Pharmacy;
  Article 10. Uniform Controlled Substances and Drug Offenses

- MEDICAL BOARD REGULATIONS (*No provisions found*)
  Title 4. Professions and Occupations; Chapter 16. Arizona Medical Board

- OSTEOPATHIC BOARD REGULATIONS (*No provisions found*)
  Title 4. Professions and Occupations; Chapter 22. Board of Osteopathic Examiners in Medicine and Surgery

- PHARMACY BOARD REGULATIONS (*No provisions found*)
  Title 4. Professions and Occupations; Chapter 23. Board of Pharmacy

OTHER GOVERNMENTAL POLICIES

- MEDICAL BOARD GUIDELINE
  Arizona Medical Board. *Guidelines for the Use of Controlled Substances for the Treatment of Chronic Pain*. Agency Substantive Policy Statement #7. Adopted: June 2003.

- OSTEOPATHIC BOARD GUIDELINE
  Arizona Board of Osteopathic Examiners in Medicine and Surgery. *Guidelines: The Prescribing of Controlled Substances for the Treatment of Pain Management*. Adopted: January 22, 2000.

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Madison, Wisconsin

ARIZONA

RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY KEY WORD SEARCHES

- PRESCRIPTION MONITORING PROGRAM

  Title 36. Public Health and Safety; Chapter 28. Controlled Substances Prescription Monitoring Program

- HEALTH SERVICES

  Title 9. Health Services; Chapter 10. Department of Health Services: Health Care Institutions: Licensing; Article 2. Hospitals

  Title 9. Health Services; Chapter 20. Department of Health Services: Behavioral Health Service Agencies: Licensure; Article 8. Hospices; Hospice Inpatient Facilities

  Title 9. Health Services; Chapter 20. Department of Health Services: Behavioral Health Service Agencies: Licensure; Article 10. Opioid Treatment

Pain & Policy Studies Group
University of Wisconsin Carbone Cancer Center
Madison, Wisconsin

ARIZONA

STATUTES

Controlled Substances Act

A.R.S. § 36-2501

§ 36-2501. Definitions

A. In this chapter, unless the context otherwise requires:

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5. "Drug dependent person" means a person who is using a controlled substance and who is in a state of psychic or physical dependence, or both, arising from the use of that substance on a continuous basis. Drug dependence is characterized by behavioral and other responses which include a strong compulsion to take the substance on a continuing basis in order to experience its psychic effects or to avoid the discomfort caused by its absence.

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(-) *CRITERION 11:*
Physical dependence or analgesic tolerance confused with "addiction"

STATUTES

Pharmacy Practice Act

A.R.S. § 32-1901

§ 32-1901. Definitions

In this chapter, unless the context otherwise requires:

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70. "Practitioner" means any physician, dentist, veterinarian, scientific investigator or other person licensed, registered or otherwise permitted to distribute, dispense, conduct research with respect to or administer a controlled substance in the course of professional practice or research in this state, or any pharmacy, hospital or other institution licensed, registered or otherwise permitted to distribute, dispense, conduct research with respect to or administer a controlled substance in the course of professional practice or research in this state.

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(+) *CRITERION 3:*
Opioids are part of professional practice

Pain & Policy Studies Group
University of Wisconsin Carbone Cancer Center
Madison, Wisconsin

ARIZONA

OTHER GOVERNMENTAL POLICY

Medical Board Guideline

Use of Controlled Substances for the Treatment of Chronic Pain

This substantive policy statement is advisory only. A substantive policy statement does not include internal procedural documents that only affect the internal procedures of the agency and does not impose additional requirements or penalties on regulated parties or include confidential information or rules made in accordance with the Arizona administrative procedure act. If you believe that this substantive policy statement does impose additional requirements or penalties on regulated parties you may petition the agency under Arizona Revised Statutes section 41-1033 for a review of the statement.

ARIZONA MEDICAL BOARD

9545 East Doubletree Ranch Road, Scottsdale, Arizona 85258

GUIDELINES FOR THE USE OF CONTROLLED SUBSTANCES FOR THE TREATMENT OF CHRONIC PAIN (SPS 7)

(+) ***CRITERION 4:*** ***Encourages pain management***

(+) ***CRITERION 2:*** ***Pain management is part of healthcare practice***

The Arizona Medical Board ("Board") strongly urges physicians to view effective pain management as a high priority in all patients, including children and the elderly. Pain should be assessed and treated promptly, effectively and for as long as pain persists. The medical management of pain should be based on up-to-date knowledge about pain, pain assessment and pain treatment. Pain treatment may involve the use of several drug and nondrug treatment modalities, often in combination. For some types of pain the use of drugs is emphasized and should be pursued vigorously; for other types, the use of drugs is better de-emphasized in favor of other therapeutic modalities. Physicians should have sufficient knowledge or consultation to make such judgments for their patients.

(+) ***CRITERION 3:*** ***Opioids are part of professional practice***

Drugs, in particular the opioid analgesics, are considered the cornerstone of treatment for pain associated with trauma, surgery, medical procedure and cancer. Physicians are referred to the U.S. Agency for Health Care Policy and Research Clinical Practice Guidelines as a sound yet flexible approach to the management of these types of pain.

The prescribing of opioid analgesics for other patients with intractable non-cancer pain also may be beneficial, especially when efforts to remove the cause of pain or to treat it with other modalities have been unsuccessful. For the purposes of these guidelines, intractable pain is defined as:

A pain state in which the cause of the pain cannot be removed or otherwise treated and which in the generally accepted course of medical practice no relief or cure of the cause of the pain is possible or none has been found after reasonable efforts including, but not limited to, evaluation by the attending physician and surgeon and one or more physicians and surgeons specializing in the treatment of the area, system or organs of the body perceived as the source of the pain.

(+) ***CRITERION 5:*** ***Addresses fear of regulatory scrutiny***

Therefore, these guidelines are an attempt to communicate to physicians who prescribe opioids for intractable pain not to fear disciplinary action from this Board for prescribing or administering controlled substances in the course of treatment of a person for intractable pain. Also, physicians should use sound clinical judgment, and care for their patients according to the following principles of responsible professional practice.

I. STATUTORY ABILITY TO DEVELOP GUIDELINES

Pursuant to Arizona Revised Statutes § 32-1403(A)(3), the Board may develop and recommend standards governing the profession in Arizona.

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(CONTINUED)

II. GUIDELINES FOR PATIENT CARE WHEN PRESCRIBING CONTROLLED SUBSTANCES FOR CHRONIC PAIN

A) Pain Assessment
Pain assessment should occur during initial evaluation, after each new report of pain, at appropriate intervals after each pharmacological intervention, and at regular intervals during treatment. Unless a patient is terminally ill and death is imminent (in which case the diagnosis is usually evident and diagnostic evaluations may be of little value and discomforting to the patient), the evaluation should include:

1. Medical history, including the presence of a recognized medical indication for the use of a controlled substance, the intensity and character of pain, and questions regarding substance abuse;

2. Corroboration of medical history by reviewing patient's medical records and/or speaking with patient's former physicians. Patients frequently seek out a new prescribing physician after their previous prescribing physician has terminated them for non-compliance, substance abuse, and/or drug diversion;

3. Psycho-social assessment, which may include but is not limited to:

a. The patient's understanding of the medical diagnosis, expectations about pain relief and pain management methods, concerns regarding the use of controlled substances, and coping mechanisms for pain;
b. Changes in mood which have occurred secondary to pain (i.e., anxiety, depression); and
c. The meaning of pain to the patient and his/her family.

4. Physical examination, including a neurologic evaluation and examination of the site of pain.

5. Urine drug screen, testing for commonly abused street drugs as well as prescription pain drugs that are known abused or diverted drugs. Such screening will help identify drug abusers and drug diverters.

B) Treatment Plan
A treatment plan should be developed for the management of chronic pain and state objectives by which therapeutic success can be evaluated, including:

1. Pain relief;

2. Improved physical functioning;

3. Proposed diagnostic evaluations (i.e., blood tests, radiologic, psychological and social studies such as CAT and bone scans, MRI and neurophysiologic examinations such as electromyography); and

4. Analysis of inclusion and exclusion criteria for opioid management: Inclusion criteria includes a clear diagnosis consistent with symptoms, all reasonable alternative therapies have been explored; the patient is reliable and communicates well, there has been informed consent or a treatment agreement signed; Potential exclusion criteria include a history of chemical dependency, major psychiatric disorder, chaotic social situation, or a planned pregnancy.

(CONTINUED ON NEXT PAGE)

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT*:* Recognizes that the goals of pain treatment should include improvements in patient functioning and quality of life.

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(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Encourages healthcare professionals to incorporate in their practice the evaluations of, and discussions with patients about, the potential benefits and risks of treatment with opioids, which can better ensure a clinical indication of such treatment so that opioids will be used for medical purposes.

(CONTINUED)

C) Informed Consent
The physician should advise the patient, guardian, or designated surrogate of the risks and benefits of the use of controlled substances. The patient should be counseled on the importance of regular visits, the impact of recreational drug use, the number of physicians and pharmacies used for prescriptions, taking medications as prescribed, etc.

The physician and the patient should enter into a pain treatment contract that specifically states the patient's required compliance with the treatment plan and what the consequences of non-compliance, misuse and abuse will be. It is particularly important that patients understand that they will be discontinued from the prescribed controlled substances, in a safe manner, should it be revealed that they are abusing or diverting drugs.

D) Ongoing Assessment
The assessment and treatment of chronic pain mandates continuing evaluation, and if necessary, modification and/or discontinuation of opioid therapy. If clinical improvement does not occur, the physician should consider the appropriateness of continued opioid therapy, and consider a trial of alternative pharmacologic and nonpharmacologic modalities.

E) Consultation
The physician should refer the patient as necessary for additional evaluation to achieve treatment objectives. Physicians should recognize patients requiring individual attention, in particular, patients whose living situations pose a risk for misuse or diversion of controlled substances. In addition, the prescription of controlled substances to patients with a history of substance abuse requires extra care, monitoring, and documentation, and may also require consultation with an addiction medicine specialist.

F) Documentation
The physician must maintain adequate, accurate and timely records regarding items A-E from above. "Adequate Records," pursuant to A.R.S. °32-1401(2), "means legible records containing, at a minimum, sufficient information to identify the patient, support the diagnosis, justify the treatment, adequately document the results, indicate advice and cautionary warnings provided to the patient, and provide sufficient information for another practitioner to assume continuity of the patient's care at any point in the treatment." Specific to chronic pain patients, the documentation should include:

1. The medical history and physical examination;
2. Related evaluations and consultations, treatment plan and objectives;
3. Evidence of discussion regarding informed consent;
4. Prescribed medications and treatments;
5. Periodic reviews of treatments and patient response; and
6. Any physician-patient agreements or contracts.

G. Counting and Destroying Medication
The physician may desire to see and count a patient's medication to determine if the patient is taking the medication as prescribed. The patient should display and count the medication in front of the physician. Under no circumstance should the physician touch a patient's controlled substances. If the medication must be destroyed, the patient should flush the medication down the toilet in the physician's presence. The physician should document this fact in the patient's chart.

(CONTINUED ON NEXT PAGE)

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY B:
Issues related to patients

COMMENT:
Acknowledges that a patient's prior history or current status of drug abuse does not necessarily contraindicate appropriate pain management.

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(+) ***CRITERION 8:***
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Encourages healthcare professionals to understand and follow federal and state laws governing their practice, which can better ensure that practitioners follow the *balanced* approach represented by federal law and the laws in many states.

(CONTINUED)

H. Post-Dated Prescriptions

Post-dated prescriptions are illegal in the State of Arizona. Therefore, physicians may not issue post-dated prescriptions.

I. Referral of Patients with Active Substance Abuse Problems

Patients discovered to have an active substance abuse problem should be referred to either a detoxification and rehabilitation program or to an appropriate maintenance program for addicts.

III. COMPLIANCE WITH LAWS AND REGULATIONS

A. Prescribing Controlled Substances

To prescribe controlled substances, physicians must comply with all applicable laws, including the following:

1. Possess a valid current license to practice medicine in the State of Arizona; and
2. Possess a valid and current controlled substances Drug Enforcement Administration registration for the schedules being prescribed.

B. Dispensing Controlled Substances

To dispense controlled substances, physicians must comply with all applicable laws, including the following:

1. Possess a valid current license to practice medicine in the State of Arizona;
2. Possess a valid and current controlled substances Drug Enforcement Administration registration for the schedules being prescribed;
3. Comply with Arizona Revised Statutes § 32-1491, et seq. and A.A.C. R4-16-201 through R4-16-205; and
4. Comply with 22 CFR 1306.07(a) if controlled substances are dispensed for detoxification.

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Osteopathic Board Guideline

ARIZONA BOARD OF OSTEOPATHIC EXAMINERS IN MEDICINE AND SURGERY

GUIDELINES: THE PRESCRIBING OF CONTROLLED SUBSTANCES FOR THE TREATMENT OF PAIN MANAGEMENT

INTRODUCTION:
The Arizona State Board of Osteopathic Examiners in Medicine and Surgery recognizes that Principles of quality medical practice dictate that the people of the State Of Arizona have access to appropriate and effective pain relief. The appropriate application of up-to-date knowledge and treatment modalities can serve to improve the quality of life for those patients who suffer from pain as well as reduce the morbidity and costs associated with untreated or inappropriately treated pain.

The Board encourages physicians to view effective pain management as part of quality medical practice for all patients with pain, acute or chronic, and it is especially important for those patients who experience pain as a result of terminal illness. All physicians should become knowledgeable about effective methods of pain relief as well as statutory requirements for Prescribing controlled substances.

Physicians should not fear disciplinary action from the Board or other state regulatory or Enforcement agencies for Prescribing, dispensing, or administering controlled substances, Including opioid analgesics in the usual course of professional practice. The Board will consider prescribing, ordering, administering, or dispensing controlled substances for pain to be for a Legitimate medical purpose if based on accepted scientific knowledge of the treatment of pain or If based on sound clinical grounds. All such prescribing must be based on clear documentation of unrelieved pain and in compliance with applicable state and/or federal law.

The Board will judge the validity of prescribing based on the physician's treatment of the patient and on the available documentation. The goal is to control the patient's pain for its duration while effectively addressing other aspects of the patient's functioning, including physical, psychological, social and work-related factors. The following guidelines are not intended to define the complete or best practice, but rather to communicate what the Board considers to be with in the boundaries of professional practice.

PURPOSE:
The purpose of these guidelines regarding the prescribing of controlled substances for the treatment of pain is to establish criteria to be considered by the Board in consideration of allegations of unprofessional conduct. The Board's objective is for these Guidelines to recognize but to not interfere with the medical use of controlled substances for pain relief, while continuing to address the issue of prescribing that may contribute to drug abuse and diversion. These guidelines are general recommendations. Each case involving the prescription of controlled substances for pain management will be judged on all factors related to that patient. These guidelines were created to provide the Board and the Licensed osteopathic medical community a basis in which to provide quality medical care to the citizens of the State of Arizona.

Guidelines:
The Board has adopted the following guidelines when evaluating the use of controlled substances for pain control.

1. Pain Assessment:
A. Medical History
A comprehensive history should include a review of pertinent lab and diagnostic test that have already been performed. The initial evaluation of the pain complaint should include characteristics such as intensity, character, frequency, location, duration, and precipitating and relieving factors, underlying or co-existing diseases or conditions.

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(+) *CRITERION 2:*
Pain management is part of healthcare practice

(+) *CRITERION 5:*
Addresses fear of regulatory scrutiny

(+) *CRITERION 6:*
Prescription amount alone does not determine legitimacy

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT*:* Represents the principle of Balance, which states that the regulation of controlled substances should not interfere with legitimate medical use.

(+) *CRITERION 4:*
Encourages pain management

(+) *CRITERION 3:*
Opioids are part of professional practice

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Recognizes that the goal of pain treatment should include improvements in patient functioning and quality of life.

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It should also include a thorough analgesic medication history, including current and previous prescription medications, over-the-counter medications, natural remedies and illicit drug use.

It should also include an evaluation of physical function. This should focus on pain associated disabilities, including activities of daily living.

B. Psycho-social Assessment

Evaluation should also include assessment of the patient's mood with particular concern regarding anxiety or depression. The physician should assess whether the patient understands the diagnosis. One should also evaluate the patient's expectations about pain relief and pain management methods. The patient may have reservations about the use of controlled substances. The physician should question the patient about their coping mechanisms for pain. This also includes assessment of the patient's social networks, including any dysfunctional family relationships.

C. Physical Exam

Physical exams should focus on the neuromuscular system, search for neurological impairment, weakness, hyperalgesia, allodynia, or parathesias.

One should assess the musculoskeletal system with attention to the palpation of tenderness, Inflammation, deformity, trigger points, and physical function.

2. Treatment Plan:
A. Pain Relief
A treatment plan should be developed for the management of chronic pain. Consideration should also be given to different treatment modalities, such as a formal pain rehabilitation program, the use of behavioral strategies, the use of non-invasive techniques, or the use of medications. The assessment of pain should occur, not only during the initial exam, but also after each new reportive pain, at the appropriate intervals, after each pharmacological intervention and at regular intervals during treatment.

B. Improved Physical Functioning

A quantitative assessment of pain should be recorded by the use of a standard pain scale and pain log. Patients with chronic pain and their caregivers should be instructed on the use of the pain log with regular intervals for pain intensity, medication use, response to treatment, and associated activities.

A qualitative assessment of the treatment plan should include the evaluation of the patient's ability to function productively in society.

3. Informed Consent:
Advise the chronic pain patient or guardian of the risks and the benefits of the use of controlled substances as well as alternatives to that treatment. They should be counseled on the importance of regular visits, the impact of recreational drug use, avoiding the use of multiple pharmacies and physicians for prescriptions and taking medication as directed. A contract should be signed outlining the patient's responsibilities, if appropriate.

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(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Encourages healthcare professionals to incorporate in their practice the evaluations of, and discussions with patients about, the potential benefits and risks of treatment with opioids, which can better ensure a clinical indication of such treatment so that opioids will be used for medical purposes.

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4. On-going Assessment:
Patients with chronic pain should be re-assessed regularly. The frequency of follow-up should be a function of the pain syndrome and potential for adverse effects of treatment. The physician may consider discontinuing the use or modifying medications if the patient is experiencing side effects that are not tolerable, if clinical improvement does not occur, or if the physician notes non – compliance. The clinician should watch for signs of narcotic use for inappropriate indications like anxiety or depression. Requests for early refills should prompt an evaluation of tolerance to the medication, progression of disease or inappropriate behavioral factors.

5. Consultation and Referral – Optimal Treatment requires a team approach
Psychiatrists, psychologists, pain management specialists are available and should be part of the treatment team specifically in the more complex patient.

6. Documentation:
Documentation is essential for supporting the evaluation. The clinician should include the reason for prescribing controlled substances. The clinician should also document the overall pain management treatment plan, any consultations received, and a periodic review of the status of the patient. The clinician should also include medications and treatments including the date, type, dosage and quantity prescribed.

7. Medical Record – in accordance with A.R.S.§ 32-1800 (2) and A.R.S. § 12-2291(4)
Physician should develop and maintain complete records to include:

Medical history and physical examination
Diagnostic, therapeutic, and lab results;
Evaluations and consultations;
Treatment objectives;
Discussion of risks and benefits;
Treatment;
Medication (include date, type, dose and quantity)
Instructions and agreements; and
Periodic reviews

Records should be accessible and ready for review.

COMPLIANCE WITH LAWS AND REGULATIONS:

Treating physician must possess a valid and current license to practice medicine in the State of Arizona.

A. Possess a Valid and current controlled substances drug enforcement registration for the schedules being prescribed.

B. If drugs are dispensed from the office, the physician must comply with the Arizona State Statutes.

C. If controlled substances are provided for detoxification, the physician should comply with the Arizona State Statutes.

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(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Recognizes the need for a multidisciplinary approach to pain management.

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Definitions

For the purpose of these guidelines, the following terms are defined as follows:

Acute Pain
Acute pain is the normal, predicted physiological response to an adverse chemical, thermal, mechanical or neurological stimulus and is associated with surgery, trauma and acute illness. It is generally time-limited and is responsive to opioid therapy, among other therapies.

Addiction
Addiction is a neurobehavioral syndrome with genetic and environmental influences that result in psychological dependence on the use of substances for the psychic effects and is characterized by compulsive use despite harm. Addiction may also be referred to by terms such as "drug dependence" and "psychological dependence." Physical dependence and tolerance are normal physiological consequences of extended opioid therapy for pain and should not be considered addiction.

(+) CRITERION 7: Physical dependence or analgesic tolerance are not confused with "addiction"

Analgesic Tolerance
Analgesic tolerance is the need to increase the dose of opioid to achieve the same level of analgesia. Analgesic tolerance may or may not be evident during opioid treatment and does equate with addiction.

Chronic Pain
A pain state which is persistent and in which the cause of the pain cannot be removed or otherwise treated. Chronic pain may be associated with long term incurable or intractable medical condition or disease.

Pain
An unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage.

Physical Dependence
Physical dependence on a controlled substance is a physiologic state of neuro-adaptation which is characterized by the emergence of a withdrawal syndrome if drug use is stopped or decreased abruptly, or if an antagonist is administered. Physical dependence is an expected result of opioid use. Physical dependence, by itself does not equate with addiction.

Pseudo-addiction
Pattern of drug-seeking behavior of pain patients who are receiving inadequate pain management that can be mistaken for addiction.

Substance Abuse
Substance abuse is the use of any substance(s) for non-therapeutic purposes or use of medication for purposes other than those for which it is prescribed.

Tolerance
Tolerance is a physiologic state resulting from regular use of a drug in which an increased dosage is needed to produce the same effect, or a reduced effect is observed with a constant dose.

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STATUTES

Controlled Substances Prescription Monitoring Program

A.R.S. § 36-2602

§ 36-2602. Controlled substances prescription monitoring program; contracts; retention and maintenance of records

A. The board shall adopt rules to establish a controlled substances prescription monitoring program. The program shall:

1. Include a computerized central database tracking system to track the prescribing, dispensing and consumption of schedule II, III and IV controlled substances that are dispensed by a medical practitioner or by a pharmacy that holds a valid license or permit issued pursuant to title 32. The database shall include data from the department of health services that identifies residents of this state who possess a registry identification card issued pursuant to chapter 28.1 of this title. The tracking system shall not interfere with the legal use of a controlled substance for the management of severe or intractable pain.

2. Assist law enforcement to identify illegal activity related to the prescribing, dispensing and consumption of schedule II, III and IV controlled substances.

3. Provide information to patients, medical practitioners and pharmacists to help avoid the inappropriate use of schedule II, III and IV controlled substances.

4. Be designed to minimize inconvenience to patients, prescribing medical practitioners and pharmacies while effectuating the collection and storage of information.

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(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Represents the principle of Balance, which states that the regulation of controlled substances should not interfere with legitimate medical use.

REGULATIONS

Health Services: Hospitals

A.A.C. § R9-10-217

R9-10-217. Pharmaceutical Services

An administrator shall require that:

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14. If pain medication is administered to a patient, documentation in the patient's medical record includes:

a. An assessment of the patient's pain before administering the medication; and

b. The effect of the pain medication administered;

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(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (documentation in medical records) for hospitals to ensure that pain management is an essential part of patient care.

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REGULATIONS

Health Services: Hospice & Hospice Inpatient Facilities

A.A.C. § R9-10-808

R9-10-808. Hospice Services

A. A hospice licensee shall provide a hospice service:
1. Through an employee of the hospice, a volunteer for the hospice, or an agency or individual under contract with the hospice to provide a hospice service;
2. Specified in a patient's plan of care; and
3. Twenty-four hours a day, seven days a week as necessary to meet the needs of a patient and the patient's family.

B. A hospice licensee shall provide the following hospice services:
1. Physician services that are within the scope of practice of a physician, provided by a physician;
2. Nursing services that are within the scope of practice of a nurse, provided by:
a. A registered nurse; or
b. An individual:
i. Licensed or certified under A.R.S. Title 32, Chapter 15 and 4 A.A.C. 19; and
ii. Operating under the direction of a registered nurse;
3. Pharmaceutical services, including the administration of drugs or biologicals, provided according to *R9-10-809*;
4. Dietary counseling services, including menu planning and the designation of the kind and amount of food appropriate for a patient, provided by a registered dietitian approved to work as a dietitian by the American Dietetic Association's Commission on Dietetic Registration;
5. Home health aide services provided:
a. Through a home health agency licensed under 9 A.A.C. 10, Article 1 and Article 11; or
b. By a qualified individual authorized to provide nursing assistant services under A.R.S. Title 32, Chapter 15;
6. Homemaker services, provided by a qualified individual;
7. Occupational therapy services provided by an occupational therapist licensed under and operating within the scope of practice authorized by A.R.S. Title 32, Chapter 34 and 4 A.A.C. 43;
8. Physical therapy services provided by a physical therapist licensed under and operating within the scope of practice authorized by A.R.S. Title 32, Chapter 19 and 4 A.A.C. 24;
9. Social services, including advocacy, referral, problem-solving, and intervention functions related to personal, family, business, and financial issues, provided by a social worker;
10. Speech and language pathology services provided by a speech and language pathologist licensed under and operating within the scope of practice authorized by A.R.S. Title 36, Chapter 17 and 9 A.A.C. 16;
11. Spiritual counseling services, consistent with a patient's customs, religious preferences, cultural background, and ethnicity, provided by a qualified individual;
12. Volunteer services, supervised by a designated hospice staff member;
13. Counseling services other than spiritual and dietary counseling, provided by a qualified individual; and
14. Inpatient services as defined in *R9-10-801* provided to a patient for respite purposes, pain control, or symptom management.

C. A hospice licensee shall ensure that the following services are provided to a patient's family:
1. Hospice respite services at the patient's residence or through inpatient services;
2. Bereavement counseling, including social and emotional support, provided by a qualified individual for at least one year after the death of the patient; and
3. Counseling determined by the interdisciplinary group to be:
a. Necessary while the patient is receiving services from the hospice, and
b. Related to the patient's illness.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a responsibility for hospice facilities to ensure that pain management is an essential part of patient care.

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REGULATIONS

Health Services: Opioid Treatment

A.A.C. § R9-20-1002

R9-20-1002. Administration

A program sponsor shall ensure that:

1. The program sponsor designates a physician to serve as medical director and to have authority over all medical aspects of opioid treatment;

2. Written policies and procedures are developed, implemented, complied with, and maintained at the agency and include:

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g. A requirement that a client who is physiologically dependent as a result of chronic pain receives consultation with or a referral for consultation with a medical practitioner who specializes in chronic pain;

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A.A.C. § R9-20-1004

R9-20-1004. Assessment and Treatment Plan

A program sponsor shall ensure that:

1. Except as provided in this Section, a client receives an assessment conducted according to the requirements in R9-20-209(A), (B)(2), (C), and (D);

2. An assessment is conducted by a behavioral health professional or a behavioral health technician; and

3. Assessment information is documented in the client record within seven working days after completing initiating or updating the assessment and includes:

a. A description of the client's presenting issue;

b. An identification of the client's behavioral health symptoms and the behavioral health issue or issues that require treatment;

c. A list of the medical services, including medication, needed by the client, as identified in the physical examination conducted under R9-20-1003(E);

d. Recommendations for further assessment or examination of the client's needs;

e. Recommendations for treatment needed by the client, such as counseling;

f. Recommendations for ancillary services or other services needed by the client;

g. The signature and date signed, or documentation of the refusal to sign, of the client or the client's guardian or agent or, if the client is a child, the client's parent, guardian, or custodian; and

h. The signature, professional credential or job title, and date signed of:

i. The staff member conducting and developing the assessment; and

ii. If the assessment was completed by a behavioral health technician, the behavioral health professional approving the assessment.

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(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY B:
Issues related to patients

COMMENT:
Acknowledges that a patient's prior history or current status of drug abuse does not necessarily contraindicate appropriate pain management.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (written policies and procedures) for OTP staff to refer opioid-maintained patients who have chronic pain for treatment of their pain.

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ARKANSAS

STATUTES

- CONTROLLED SUBSTANCES ACT
  Title 5. Criminal Offenses; Subtitle 6. Offenses Against Public Health, Safety, or Welfare; Chapter 64. Controlled Substances

  Title 20. Public Health and Welfare; Subtitle 4. Food, Drugs, and Cosmetics; Chapter 64. Alcohol and Drug Abuse; Subchapter 2. Uniform Narcotic Drug Act

- MEDICAL PRACTICE ACT *(No provisions found)*
  Title 17. Professions, Occupations, and Businesses; Subtitle 3. Medical Professions; Chapter 95. Physicians and Surgeons

- INTRACTABLE PAIN TREATMENT ACT (*Part of Medical Practice Act*)
  Title 17. Professions, Occupations, and Businesses; Subtitle 3. Medical Professions; Chapter 95. Physicians and Surgeons; Subchapter 7. Treatment of Chronic Intractable Pain

- OSTEOPATHIC PRACTICE ACT *(No provisions found)*
  Title 17. Professions, Occupations, and Businesses; Subtitle 3. Medical Professions; Chapter 91. Osteopaths

- PHARMACY PRACTICE ACT *(No provisions found)*
  Title 17. Professions, Occupations, and Businesses; Subtitle 3. Medical Professions; Chapter 92. Pharmacists and Pharmacies

REGULATIONS

- CONTROLLED SUBSTANCES REGULATIONS
  007. Department of Health; 07. Pharmacy Services and Drug Control (Bureau of Health Resources)

- MEDICAL BOARD REGULATIONS
  060. State Medical Board

- OSTEOPATHIC BOARD REGULATIONS
  No policy found

- PHARMACY BOARD REGULATIONS *(No provisions found)*
  070. Board of Pharmacy

OTHER GOVERNMENTAL POLICIES

No policies found

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ARKANSAS

RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY KEY WORD SEARCHES

- HOMICIDE
  Title 5. Criminal Offenses; Subtitle 2. Offenses Against the Person; Chapter 10. Homicide

- HEALTH FACILITY SERVICES
  007. Department of Health; 05. Health Facility Services

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ARKANSAS

STATUTES

Controlled Substances Act

(+) *CRITERION 3:*
Opioids are part of professional practice

A.C.A. § 5-64-101

§ 5-64-101. Definitions

As used in this chapter:

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(21) "Practitioner" means:

(A) A physician, dentist, veterinarian, scientific investigator, or other person licensed, registered, or otherwise permitted to distribute, dispense, conduct research with respect to, or to administer a controlled substance in the course of professional practice or research in this state;

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ARKANSAS

STATUTES

Intractable Pain Treatment Act

A.C.A. § 17-95-701 – § 17-95-707

§ 17-95-701. Title

This subchapter shall be known and may be cited as the "Chronic Intractable Pain Treatment Act".

§ 17-95-702. Findings

The General Assembly finds that:

(1) Pain management plays an important role in good medical practice;

(2) Physicians should recognize the need to make pain relief accessible to all patients with chronic intractable pain; and

(3) Physicians should view pain management as a regular part of their medical practice for all patients with chronic intractable pain.

§ 17-95-703. Definitions

As used in this subchapter:

(1) "Board" means the Arkansas State Medical Board;

(2) "Chronic intractable pain" means a pain state for which the cause of the pain cannot be removed or otherwise treated and for which no relief or cure has been found after reasonable efforts by a physician;

(3) (A) "Dangerous or controlled drugs" means drugs used for pain relief, including, but not limited to:

(i) Opioids; and

(ii) Other drugs classified under schedules II, III, IV, or V by the United States Food and Drug Administration.

(B) "Dangerous or controlled drugs" does not include any substance the prescription of which is illegal under federal law;

(4) "Disciplinary action" means any remedial or punitive sanctions imposed on a licensed physician by the board;

(5) "Patient" means a person seeking medical diagnosis and treatment; and

(6) "Physician" means a licensee of the Arkansas State Medical Board.

[CONTINUED ON NEXT PAGE]

(+) *CRITERION 4:*
Pain management is encouraged

(+) *CRITERION 2:*
Pain management is part of healthcare practice

(-) *CRITERION 16:*
Provisions that are ambiguous

CATEGORY B
Unclear intent leading to possible misinterpretation

COMMENT: Although similar language is used in Federal regulation, in the context of this statute this definition suggests that physicians would qualify for the immunity and, thus, relief from concerns about regulatory scrutiny provided by this statute only if they prescribe opioids after other treatments have been tried and failed, regardless of other clinical considerations.

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STATUTES

Intractable Pain Treatment Act

[CONTINUED]

§ 17-95-704. Arkansas State Medical Board -- Treatment -- Prohibitions

(a) (1) A physician shall not be subject to disciplinary action by the Arkansas State Medical Board solely for prescribing dangerous or controlled drugs for the relief of chronic intractable pain.

(2) (A) (i) Any allegation of improper prescribing determined to require a board hearing shall be referred to the Pain Management Review Committee before any board hearing or action.

(ii) (a) However, in exceptional limited substantive instances requiring immediate action to protect the public health, an emergency action under § 25-15-211(c) may be implemented.

(b) The implementation of an emergency action under § 25-15-211(c) shall in no way be used by the board to circumvent, void, supplant, or otherwise limit the role of the committee as provided in this subchapter.

(B) The board shall provide the committee all necessary documentation for the review process in a timely manner.

(3) The board shall direct the committee to use the criteria under subsections (d) and (e) of this section to review a physician's conduct in regard to prescribing, administering, ordering, or dispensing pain medications and other drugs necessary to treat chronic intractable pain.

(4) (A) If the board determines that an allegation or a question regarding a physician's prescribing does not justify a board hearing, in lieu of a board hearing, the board may refer a physician to the committee for review and recommendations to the board.

(B) The review and recommendations under subdivision (a)(4)(A) of this section shall not adversely affect the physician's license or licensure status.

(b) The board shall:

(1) Make reasonable efforts to notify health care providers under its jurisdiction of the existence of this subchapter;

(2) Inform any health care provider licensed by the board and investigated regarding the provider's practices in the management of pain of the existence of this subchapter; and

(3) (A) In a disciplinary hearing, present opinion evidence from a full-time active practice physician in direct patient care who is knowledgeable in pain management.

(B) The physician has the right to present testimony from a full-time active practice physician in direct patient care who is knowledgeable in pain management.

(c) (1) In lieu of a finding of gross and ignorant malpractice, the board after a hearing may incrementally impose sanctions as follows:

(A) Monitor prescribing habits of the physician not to exceed six (6) months;

(B) Require the physician to voluntarily surrender his or her United States Drug Enforcement Agency license to the board for a specified period of time not to exceed three (3) months;

(C) Suspend the physician's license, stay the suspension, and require monitoring of prescribing habits;

(D) Revoke the physician's license, stay revocation, and require monitoring of the physician's prescribing habits for a specified time; and

(E) Revoke the physician's license for serious violations of statutes and regulations.

[CONTINUED ON NEXT PAGE]

(+) *CRITERION 5:*
Addresses fear of regulatory scrutiny

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT*:* Establishes a responsibility to communicate to practitioners about immunity from board discipline for pain management prescribing practices**.**

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT*:* Establishes a mechanism (Pain Management Review Committee) to review allegations of improper prescribing against physicians for treating intractable pain before disciplinary determinations are made.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT*:* Establishes a mechanism (using opinions from physicians involved in direct care of patients with pain) to decide allegations against physicians for treating intractable pain.

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STATUTES

Intractable Pain Treatment Act

[CONTINUED]

(2) With a finding of severe violation of statutes and regulations, the board may initially impose the more severe sanctions.

(3) At any level of sanction, the board may require continuing medical education hours in proper prescribing habits.

(d) Based upon evaluation and management of a patient's individual needs, a physician may:

(1) Treat a patient who develops chronic intractable pain with a dangerous or controlled drug to relieve the patient's pain;

(2) Continue to treat the patient for as long as the pain persists;

(3) Treat the pain by managing it with dangerous or controlled drugs in amounts or combinations that may not be appropriate for treating another medical condition;

(4) Administer large doses of dangerous or controlled drugs for pain management if the benefit of relief outweighs the risk of the large dose; and

(5) Administer a large dose of a dangerous or controlled drug even if its use may increase the risk of death if the purpose is not to cause or assist in a patient's death.

(e) A physician may not:

(1) Prescribe or administer dangerous or controlled drugs intended to manage chronic intractable pain to treat a patient for chemical dependency on drugs or controlled substances;

(2) Prescribe or administer dangerous or controlled drugs to a person the physician knows to be using drugs for nontherapeutic purposes;

(3) Prescribe or administer dangerous or controlled drugs to a person for other than legitimate medical purposes; or

(4) (A) Cause or assist in causing the suicide, euthanasia, or mercy killing of any individual.

(B) However, causing or assisting in causing the suicide, euthanasia, or mercy killing of any individual does not include prescribing, dispensing, or administering medical treatment for the purpose of alleviating pain or discomfort even if that use may increase the risk of death so long as the treatment is not furnished for the purpose of causing or assisting in causing the death of the individual.

[CONTINUED ON NEXT PAGE]

(+) *CRITERION 3:*
Opioids are part of professional practice

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Clarifies for physicians the important distinction between physician-assisted suicide and prescribing controlled substances for pain relief; this language identifies a clinical misperception that is pervasive in end-of-life care and attempts to lessen its impact on patient treatment, and the practitioners who provide it.

(+) *CRITERION 6:*
Prescription amount alone does not determine legitimacy

(-) CRITERION 12:
Medical decisions are restricted

CATEGORY A:
Restrictions based on patient characteristics

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STATUTES

Intractable Pain Treatment Act

[CONTINUED]

§ 17-95-705. Pain Management Review Committee -- Membership -- Duties

(a) There is created the Pain Management Review Committee, appointed by the Arkansas State Medical Board.

(b) The committee shall consist of five (5) members who are full-time active physicians in direct patient care, two (2) of whom may be board-certified pain management specialists and three (3) of whom may be physicians with significant pain management in their practices or with a degree in pharmacy, appointed by the board from a list provided by the Arkansas Osteopathic Medical Association, the Arkansas Medical Society, and the Arkansas Pain Society.

(c) The committee shall:

(1) Have committee representation from the Arkansas Osteopathic Medical Association, the Arkansas Medical Society, and the Arkansas Pain Society to develop guidelines for investigations of complaints regarding conduct in violation of this subchapter;

(2) Review complaints on an individual patient-needs basis regarding physicians treating chronic intractable pain in violation of this subchapter; and

(3) (A) Provide an objective critique to the board for board determination in a timely manner and if so determined, before the board's disciplinary hearing.

(B) In order to ensure a fair, impartial, and objective board hearing, no board member shall be:

(i) Present while the committee reviews allegations of improper prescribing; or

(ii) Involved in any way in the committee's deliberations.

§ 17-95-706. Scope

This subchapter does not condone, authorize, or approve mercy killing or euthanasia, and no treatment authorized by this subchapter may be used for mercy killing or euthanasia.

§ 17-95-707. Immunity -- Criminal prosecution

No physician shall be subject to criminal prosecution for prescribing or administering controlled substances under appropriate criteria in the course of treatment of a person for chronic intractable pain.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (Pain Management Review Committee) to review allegations of improper prescribing against physicians for treating intractable pain based on the individual clinical needs of the patient.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (immunity) to protect physicians treating intractable pain from criminal prosecution.

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ARKANSAS

REGULATIONS

Controlled Substances Regulations

007 07 CARR 001

001. CONTROLLED SUBSTANCES

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ARTICLE II.
RULES AND REGULATIONS

Section I. Registration.

Every Practitioner defined as follows shall obtain a registration from the Federal Drug Enforcement Administration (D.E.A.), Department of Justice unless exempted by Law.

A. A physician, podiatric physician, osteopathic physician, dentist, veterinarian, optometrist, scientific investigator, researcher, mid-level practitioner, or other persons licensed, registered, or otherwise permitted to prescribe, dispense, distribute, administer or conduct research with respect to controlled substances in the course of professional practice or research in Arkansas;

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007 07 CARR 005

005. PRESCRIPTION DRUG MONITORING PROGRAM

Section I Authority.

The following regulations have been hereby promulgated pursuant to *Arkansas Code Annotated § 20-7-613.*

Section II Purpose.

The purpose of these regulations is to protect the state health system and the citizens of Arkansas by:

(1) enhancing patient care by providing prescription monitoring information that will ensure legitimate use of controlled substances in health care, including palliative care, research, and other medical pharmacological uses;

(2) helping curtail the misuse and abuse of controlled substances;

(3) assisting in combating illegal trade in and diversion of controlled substances; and

(4) enabling access to prescription information by practitioners, law enforcement agents, and other authorized individuals and agencies and to make prescription information available to practitioners, law enforcement agents, and other authorized individuals and agencies in other states.

(+) *CRITERION 3:*
Opioids are part of professional practice

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Represents the principle of Balance, which states that the regulation of controlled substances should not interfere with legitimate medical use.

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REGULATIONS

Medical Board Regulations

060 00 CARR 001

001 Arkansas Medical Practices Regulations

REGULATION NO. 2

The Arkansas Medical Practices Act authorizes the Arkansas State Medical Board to revoke or suspend the license issued by the Board to practice medicine if the holder thereof has been found guilty of grossly negligent or ignorant malpractice.

"Malpractice" includes any professional misconduct, unreasonable lack of skill or fidelity in professional duties, evil practice, or illegal or immoral conduct in the practice of medicine and surgery.

It shall include, among other things, but not limited to:
1. Violation of laws, regulations, and procedures governing payment to physicians for medical services for eligible public assistance recipients and/or other third party payment programs.
2. Participation in any plan, agreement, or arrangement which compromises the quality or extent of professional medical services or facilities at the expense of the public health, safety, and welfare.
3. Practicing fraud, deceit, or misrepresentation in the practice of medicine.
4. The prescribing of excessive amounts of controlled substances to a patient including the writing of an excessive number of prescriptions for an addicting or potentially harmful drug to a patient.
5. The prescribing of Schedule II controlled substances by a physician for his own use or for the use of his immediate family.
6. *The treatment of pain with dangerous drugs and controlled substances is a legitimate medical purpose when done in the usual course of medical practice. If the provisions as set out below in this Resolution are met, and if all drug treatment is properly documented, the Board will consider such practices as prescribing in a therapeutic manner, and prescribing and practicing medicine in a manner consistent with public health and welfare.

However, a physician who prescribes **narcotic agents Schedule 2, 3, 4, and 5, excluding Schedule 4 Propoxyphene products and to include the schedule drugs Talwin, Stadol, and Nubain, on a long term basis (more than six (6) months) for a patient with pain not associated with malignant or terminal illness will be considered exhibiting gross negligence or ignorant malpractice unless he or she has complied with the following:

a. The physician will keep accurate records to include the medical history, physical examination, other evaluations and consultations, treatment plan objective, informed consent noted in the patient record, treatment, medications given, agreements with the patient and periodic reviews.
b. The physician will periodically review the course of schedule drug treatment of the patient and any new information about etiology of the pain. If the patient has not improved, the physician should assess the appropriateness of continued prescribing of scheduled medications or dangerous drugs, or trial of other modalities.
c. The physician will obtain written informed consent from those patients he or she is concerned may abuse controlled substances and discuss the risks and benefits of the use of controlled substances with the patient, his or her guardian, or authorized representatives.
d. The physician will be licensed appropriately in Arkansas and have a valid controlled substance registration and comply with the Federal and State regulations for the issuing of controlled substances and prescriptions, more especially the regulations as set forth in 21 Code of Federal Regulations Section 1300, et sequence.

[CONTINUED ON NEXT PAGE]

(+) *CRITERION 2:*
Pain management is part of healthcare practice

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Encourages healthcare professionals to incorporate in their practice the evaluations of, and discussions with patients about, the potential benefits and risks of treatment with opioids, which can better ensure a clinical indication of such treatment so that opioids will be used for medical purposes.

(-) *CRITERION 16:*
Provisions that are ambiguous

CATEGORY A:
Arbitrary standards for legitimate prescribing

COMMENT: Although it is reasonable to expect physicians to avoid contributing to diversion, "excessive" implies there is a known standard, but the standard is not specified.

(+) *CRITERION 3:*
Opioids are part of professional practice

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT*:* Encourages healthcare professionals to understand and follow federal and state laws governing their practice, which can better ensure that practitioners follow the *balanced* approach represented by federal law and the laws in many states.

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REGULATIONS

Medical Board Regulations

[CONTINUED]

7. A licensed physician engaging in sexual contact, sexual relations or romantic relationship with a patient concurrent with the physician-patient relationship; or a licensed physician engaging in the same conduct with a former patient, if the physician uses or exploits trust, knowledge, emotions or influence derived from the previous professional relationship, shows a lack of fidelity of professional duties and immoral conduct, thus exhibiting gross negligence and ignorant malpractice. A patient's consent to, initiation of, or participation in sexual relationship or conduct with a physician does not change the nature of the conduct nor the prohibition.
8. **Requiring minimum standards for establishing physician/patient relationships. A physician exhibits gross negligence if he provides and/or recommends any form of treatment, including prescribing legend drugs, without first establishing a proper physician/patient relationship.

A. For purposes of this regulation, a proper physician/patient relationship, at a minimum requires that:
1. The physician performs a history and physical examination of the patient adequate to establish a diagnosis and identify underlying conditions and/or contraindications to the treatment recommended/provided, OR personally knows the patient and the patient's general health status through an "ongoing" personal or professional relationship, AND THAT
2. Appropriate follow-up be provided, when necessary, at medically necessary intervals.

B. For the purposes of this regulation, a proper physician/patient relationship is deemed to exist in the following situations:
1. When treatment is provided in consultation with, or upon referral by, another physician who has an ongoing relationship with the patient, and who has agreed to supervise the patient's treatment, including follow up care and the use of any prescribed medications.
2. On-call or cross-coverage situations.

C. Exceptions -- Recognizing a physician's duty to adhere to the applicable standc of care, the following situations are herby excluded from the requirement of this regulation:
1. Emergency situations where the life or health of the patient is in danger or imminent danger.
2. Simply providing information of a generic nature not meant to be specific to an individual patient.

060 00 CARR 001

001 Arkansas Medical Practices Regulations
REGULATION NO. 19. PAIN MANAGEMENT PROGRAMS

A. Physicians operating a pain management program for specific syndromes...that is headache, low back pain, pain associated with malignancies, or temporomandibular joint dysfunctions...are expected to meet the standards set forth in this section or in fact be in violation of the Medical Practice Act by exhibiting gross negligence or ignorant malpractice.
B. Definitions:
1. Chronic Pain Syndrome: Any set of verbal and/or nonverbal behaviors that: (1) involves the complaint of enduring pain, (2) differs significantly from a person's premorbid status, (3) has not responded to previous appropriate medical and/or surgical treatment, and (4) interferes with a person's physical, psychological and social and/or vocational functioning.
2. Chronic Pain Management Program provides coordinated, goal-oriented, interdisciplinary team services to reduce pain, improving functioning, and decrease the dependence on the health care system of persons with chronic pain syndrome.

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REGULATIONS

Medical Board Regulations

[CONTINUED]

C. The following standards apply to both inpatient and outpatient programs and the physician should conform to the same.

1. There should be medical supervision of physician prescribed services.

2. A licensee should obtain a history and conduct a physical examination prior to or immediately following admission of a person to the Chronic Pain Management Program.

3. At the time of admission to the program, the patient and the physician should enter into a written contract stating the following:

a. The presenting problems of the person served.

b. The goals and expected benefits of admission.

c. The initial estimated time frame for goal accomplishment.

d. Services needed.

D. In order to provide a safe pain program, the scope and intensity of medical services should relate to the medical care needs of the person served. The treating physician of the patient should be available for medical services. Services for the patient in a Chronic Pain Management Program can be provided by a coordinated interdisciplinary team of professionals other than physicians. The members of the core team, though each may not serve every person should include:

a. A Physician.

b. A clinical psychologist or psychiatrist.

c. An occupational therapist.

d. A physical therapist.

e. A rehabilitation nurse.

E. A physician managing a Chronic Pain Management Program to a patient should meet the following criteria:

1. Three years experience in the interdisciplinary management of persons with chronic pain.

2. Participation in active education on pain management at a local or national level.

3. Board certification in a medical specialty or completion of training sufficient to qualify for examinations by members of the American Board of Medical Specialties.

4. Two years experience in the medical direction of an interdisciplinary Chronic Pain Program or at least six (6) months of pain fellowship in an interdisciplinary Chronic Pain Program.

The Physician must have completed and maintained at least one (1) of the following:

5. Attendance at one (1) meeting per year of a regional and national pain society.

6. Presentation of an abstract to a regional national pain society.

7. Publication on a pain topic in a peer review journal.

8. Membership in a pain society at a regional or national level.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Recognizes the need for a multidisciplinary approach to pain management.

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STATUTES

Homicide

Ark. Stat. Ann. § 5-10-106

§ 5-10-106. Physician-assisted suicide

(a) (1) As used in this section, "physician-assisted suicide" means a physician or health care provider participating in a medical procedure or knowingly prescribing any drug, compound, or substance for the express purpose of assisting a patient to intentionally end the patient's life.

(2) However, "physician-assisted suicide" does not apply to a person participating in the execution of a person sentenced by a court to death by lethal injection.

(b) It is unlawful for any physician or health care provider to commit the offense of physician-assisted suicide by:

(1) Prescribing any drug, compound, or substance to a patient with the express purpose of assisting the patient to intentionally end the patient's life; or

(2) Assisting in any medical procedure for the express purpose of assisting a patient to intentionally end the patient's life.

(c) Upon conviction, any physician or health care provider violating subsection (b) of this section is guilty of a Class C felony.

(d) Nothing in this section prohibits a:

(1) Physician or health care provider from carrying out an advanced directive or living will; or

(2) Physician from prescribing any drug, compound, or substance for the specific purpose of pain relief.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Clarifies for physicians the important distinction between physician-assisted suicide and prescribing controlled substances for pain relief; this language identifies a clinical misperception that is pervasive in end-of-life care and attempts to lessen its impact on patient treatment, and the practitioners who provide it.

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REGULATIONS

Health Facility Services

007 05 CARR 007

007. HOSPICE IN ARKANSAS

Section 1: Preface.

These rules and regulations have been prepared for the purpose of establishing criteria for minimum standards for the licensure operation and maintenance of hospices in Arkansas that is consistent with current trends in patient care practices. By necessity they are of a regulatory nature but are considered to be practical minimal design and operational standards for these facilities. These standards are not static and are subject to periodic revisions in the future as new knowledge and changes in patient care trends become apparent. However, it is expected that facilities will exceed these minimum requirements and that they will not be dependent upon future revisions in these standards as a necessary prerequisite for improved services. Hospices have a strong moral responsibility for providing optimum patient care and treatment for the terminally ill and their families.

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Section 21: Short-Term Inpatient Care.

Inpatient care shall be available for pain control, symptom management, respite purposes, and shall be provided in licensed facilities, as stated below:

A. Inpatient Care for Symptom Control

Inpatient care for pain control and symptom management shall be provided in one of the following:

1. A hospice that meets the requirements for providing inpatient care directly as specified in the Section, 22 "Inpatient Direct Care."

2. A hospital or a Skilled Nursing Facility (SNF).

3. Each shift shall include a registered nurse on site to supervise and provide direct patient care.

B. Inpatient Care for Respite Purposes

Inpatient care for respite purposes shall be provided by one of the following:

1. A hospice that meets the requirements for providing inpatient care directly as specified in the Section, "Inpatient Direct Care", Section 22.

2. A hospital, skilled nursing facility (SNF), or nursing facility (NF).

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(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT*:* Establishes a responsibility for healthcare facilities to ensure that pain management is an essential part of patient care.

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CALIFORNIA

STATUTES

- CONTROLLED SUBSTANCES ACT
  Health and Safety Code; Division 10. Uniform Controlled Substances Act

- MEDICAL PRACTICE ACT
  Business and Professions Code; Division 2. Healing Arts; Chapter 5. Medicine

- INTRACTABLE PAIN TREATMENT ACT (*Part of Medical Practice Act*)
  Business and Professions Code; Division 2. Healing Arts; Chapter 5. Medicine; Section 2241.5

- OSTEOPATHIC PRACTICE ACT (*No provisions found*)
  Business and Professions Code
  Appendix; II. Osteopathic Act
  Division 2. Healing Arts; Chapter 5. Medicine
  Article 4.5 Osteopathic Requirements for Licensure;
  Article 21. Provisions Applicable to Osteopathic Physicians and Surgeons

- PHARMACY PRACTICE ACT (*No provisions found*)
  Business and Professions Code; Division 2. Healing Arts; Chapter 9. Pharmacy

- PAIN PATIENT'S BILL OF RIGHTS
  Health and Safety Code; Division 106. Personal Health Care (Including Maternal, Child, and Adolescent); Part 4.5

- EFFECT ON INTRACTABLE PAIN TREATMENT ACT; BILL OF RIGHTS
  Health and Safety Code; Division 106. Personal Health Care (Including Maternal, Child, and Adolescent); Part 4.5

REGULATIONS

- CONTROLLED SUBSTANCES REGULATIONS (*Part of Pharmacy Board Regulations*) *(No provisions found)*
  Title 16. Professional and Vocational Regulations; Division 17. California State Board of Pharmacy; *Article 6. Dangerous Drugs*

- MEDICAL BOARD REGULATIONS (*No provisions found*)
  Title 16. Professional and Vocational Regulations; Division 13. Medical Board of California

- OSTEOPATHIC BOARD REGULATIONS (*No provisions found*)
  Title 16. Professional and Vocational Regulations; Division 16. Osteopathic Medical Board of California

- PHARMACY BOARD REGULATIONS (*No provisions found*)
  Title 16. Professional and Vocational Regulations; Division 17. California State Board of Pharmacy

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OTHER GOVERNMENTAL POLICIES

- MEDICAL BOARD POLICY STATEMENT

  California Medical Board. "A Statement by the Medical Board." *Action Report*. Vol. 50, pp. 4-5. July 1994.

- MEDICAL BOARD GUIDELINE

  California Medical Board. "Guideline for Prescribing Controlled Substances for Intractable Pain." *Action Report*. Vol. 87, pp. 1, 4-6. October 2003. Adopted: August 2, 2003; Revised: 2007.

RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY KEY WORD SEARCHES

- REPORTS OF INJURIES

  Penal Code; Part 4. Prevention of Crimes and Apprehension of Criminals; Title 1. Investigation and Control of Crimes and Criminals; Chapter 2. Control of Crimes and Criminals; Article 2. Reports of Injuries

- LEGAL END-OF-LIFE CARE OPTIONS

  Health and Safety Code; Division 1. Administration of Public Health; Part 1.8. End-of-Life Care

- HEALTH FACILITY LICENSING

  Health and Safety Code; Division 2. Licensing Provisions; Chapter 2. Health Facilities; Article 1. General

- HOSPICE SERVICES

  Title 28. Managed Health Care; Division 1. The Department of Managed Health Care; Chapter 2. Health Care Service Plans; Article 8. Self-Policing Procedures

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STATUTES

Controlled Substances Act

Cal Health & Saf Code § 11156

§ 11156. Prohibited prescription, or dispensation to, addict or other user; Exception

(a) Except as provided in *Section 2241 of the Business and Professions Code*, no person shall prescribe for, or administer, or dispense a controlled substance to, an addict, or to any person representing himself or herself as such, except as permitted by this division.

(b) (1) For purposes of this section, "addict" means a person whose actions are characterized by craving in combination with one or more of the following:

(A) Impaired control over drug use.
(B) Compulsive use.
(C) Continued use despite harm.

(2) Notwithstanding paragraph (1), a person whose drug-seeking behavior is primarily due to the inadequate control of pain is not an addict within the meaning of this section.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Within a context of prescribing to patients with a prior history or current status of addiction, clarifies for practitioners that there is an important distinction between addiction and pseudoaddiction.

Cal Health & Saf Code § 11159.2

§ 11159.2. Prescriptions for controlled substances for terminally ill patients

(a) Notwithstanding any other provision of law, a prescription for a controlled substance for use by a patient who has a terminal illness may be written on a prescription form that does not meet the requirements of Section 11162.1 if the prescription meets the following requirements:

(1) Contain the information specified in subdivision (a) of Section 11164.

(2) Indicate that the prescriber has certified that the patient is terminally ill by the words "11159.2 exemption."

(b) A pharmacist may fill a prescription pursuant to this section when there is a technical error in the certification required by paragraph (2) of subdivision (a), provided that he or she has personal knowledge of the patient's terminal illness, and subsequently returns the prescription to the prescriber for correction within 72 hours.

(c) For purposes of this section, "terminally ill" means a patient who meets all of the following conditions:

(1) In the reasonable medical judgment of the prescribing physician, the patient has been determined to be suffering from an illness that is incurable and irreversible.

(2) In the reasonable medical judgment of the prescribing physician, the patient's illness will, if the illness takes its normal course, bring about the death of the patient within a period of one year.

(3) The patient's treatment by the physician prescribing a controlled substance pursuant to this section primarily is for the control of pain, symptom management, or both, rather than for cure of the illness.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY B:
Issues related to patients

COMMENT: Exemption of these patients from special prescription requirements nevertheless continues those requirements for all other patients.

Cal Health & Saf Code § 11210

§ 11210. Permitted prescribing, furnishing, or administering controlled substances by practitioners

A physician, surgeon, dentist, veterinarian, naturopathic doctor acting pursuant to Section 3640.7 of the Business and *Professions Code*, or podiatrist, or pharmacist acting within the scope of a project authorized under Article 1 (commencing with Section 128125) of Chapter 3 of Part 3 of Division 107, or registered nurse acting within the scope of a project authorized under Article 1 (commencing with Section 128125) of Chapter 3 of Part 3 of Division 107, or physician assistant acting within the scope of a project authorized under Article 1 (commencing with Section 128125) of Chapter 3 of Part 3 of Division 107, or naturopathic doctor acting within the scope of *Section 3640.5 of the Business and Professions Code*, or an optometrist acting within the scope of *Section 3041 of the Business and Professions Code* may prescribe for, furnish to, or administer controlled substances to his or her patient when the patient is suffering from a disease, ailment, injury, or infirmities attendant upon old age, other than addiction to a controlled substance.

(+) *CRITERION 3:*
Opioids are part of professional practice

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CALIFORNIA

STATUTES

Medical Practice Act

Cal Bus & Prof Code § 2025

§ 2025. Pain management guidelines

The board through its regular mailing shall notify all licensees of the existence of pain management guidelines published by the Agency for Health Care Policy and Research of the Public Health Service within the United States Department of Health and Human Services, and shall provide the published guidelines to licensees upon request.

Cal Bus & Prof Code § 2089

§ 2089. Proof of completion of medical curriculum; Curriculum requirements

. . .

(b) The curriculum for all applicants shall provide for adequate instruction in the following subjects:

. . .

Pain management and end-of-life care.

. . .

Cal Bus & Prof Code § 2190.5

§ 2190.5. Mandatory continuing education course in pain management and treatment of terminally ill and dying patients; Deadline for completion of course; Exemptions; Application

(a) All physicians and surgeons shall complete a mandatory continuing education course in the subjects of pain management and the treatment of terminally ill and dying patients. For the purposes of this section, this course shall be a one-time requirement of 12 credit hours within the required minimum established by regulation, to be completed by December 31, 2006. All physicians and surgeons licensed on and after January 1, 2002, shall complete this requirement within four years of their initial license or by their second renewal date, whichever occurs first. The board may verify completion of this requirement on the renewal application form.

. . .

Cal Bus & Prof Code § 2196.2

§ 2196.2. Information on pain management

The board shall periodically develop and disseminate information and educational material regarding pain management techniques and procedures to each licensed physician and surgeon and to each general acute care hospital in this state. The board shall consult with the State Department of Health Services in developing the materials to be distributed pursuant to this

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a responsibility to communicate to practitioners about existing pain management standards.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (mandatory medical curriculum) to provide physicians information/education about pain management and end-of-life care.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (mandatory continuing education) to provide practitioners information/education about pain management and palliative care.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a responsibility to communicate to practitioners about acceptable practices governing pain management.

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STATUTES

Medical Practice Act

Cal Bus & Prof Code § 2220.05

§ 2220.05. Prioritization of allegations

(a) In order to ensure that its resources are maximized for the protection of the public, the Medical Board of California shall prioritize its investigative and prosecutorial resources to ensure that physicians and surgeons representing the greatest threat of harm are identified and disciplined expeditiously. Cases involving any of the following allegations shall be handled on a priority basis, as follows, with the highest priority being given to cases in the first paragraph:

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.

(3) Repeated acts of clearly excessive prescribing, furnishing, or administering of controlled substances, or repeated acts of prescribing, dispensing, or furnishing of controlled substances without a good faith prior examination of the patient and medical reason therefore. However, in no event shall a physician and surgeon prescribing, furnishing, or administering controlled substances for intractable pain consistent with lawful prescribing, including, but not limited to, Sections 725, 2241.5, and 2241.6 of this code and *Sections 11159.2 and 124961 of the Health and Safety Code*, be prosecuted for excessive prescribing and prompt review of the applicability of these provisions shall be made in any complaint that may implicate these provisions.

(+) *CRITERION 5:*
Addresses fear of regulatory scrutiny

Cal Bus & Prof Code § 2241

§ 2241. Furnishing drugs to addict

(a) A physician and surgeon may prescribe, dispense, or administer prescription drugs, including prescription controlled substances, to an addict under his or her treatment for a purpose other than maintenance on, or detoxification from, prescription drugs or controlled substances.

(b) A physician and surgeon may prescribe, dispense, or administer prescription drugs or prescription controlled substances to an addict for purposes of maintenance on, or detoxification from, prescription drugs or controlled substances only as set forth in subdivision (c) or in *Sections 11215, 11217, 11217.5, 11218, 11219, and 11220 of the Health and Safety Code*. Nothing in this subdivision shall authorize a physician and surgeon to prescribe, dispense, or administer dangerous drugs or controlled substances to a person he or she knows or reasonably believes is using or will use the drugs or substances for a nonmedical purpose.

(c) Notwithstanding subdivision (a), prescription drugs or controlled substances may also be administered or applied by a physician and surgeon, or by a registered nurse acting under his or her instruction and supervision, under the following circumstances:

(1) Emergency treatment of a patient whose addiction is complicated by the presence of incurable disease, acute accident, illness, or injury, or the infirmities attendant upon age.

(2) Treatment of addicts in state-licensed institutions where the patient is kept under restraint and control, or in city or county jails or state prisons.

(3) Treatment of addicts as provided for by *Section 11217.5 of the Health and Safety Code*.

(d) (1) For purposes of this section and Section 2241.5, "addict" means a person whose actions are characterized by craving in combination with one or more of the following: (A) Impaired control over drug use.
(B) Compulsive use.
(C) Continued use despite harm.

(2) Notwithstanding paragraph (1), a person whose drug-seeking behavior is primarily due to the inadequate control of pain is not an addict within the meaning of this section or Section 2241.5.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY B:
Issues related to patients

COMMENT: Recognizes that a patient's prior history or current status of drug abuse does not contraindicate appropriate pain management.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Within a context of prescribing to patients with a prior history or current status of addiction, clarifies for practitioners that there is an important distinction between addiction and pseudoaddiction.

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CALIFORNIA

STATUTES

Intractable Pain Treatment Act

Cal Bus & Prof Code § 2241.5

§ 2241.5. Administration of controlled substances to person experiencing pain, including "intractable pain"

(a) A physician and surgeon may prescribe for, or dispense or administer to, a person under his or her treatment for a medical condition dangerous drugs or prescription controlled substances for the treatment of pain or a condition causing pain, including, but not limited to, intractable pain.

(b) No physician and surgeon shall be subject to disciplinary action for prescribing, dispensing, or administering dangerous drugs or prescription controlled substances in accordance with this section.

(c) This section shall not affect the power of the board to take any action described in Section 2227 against a physician and surgeon who does any of the following:

(1) Violates subdivision (b), (c), or (d) of Section 2234 regarding gross negligence, repeated negligent acts, or incompetence.

(2) Violates Section 2241 regarding treatment of an addict.

(3) Violates Section 2242 regarding performing an appropriate prior examination and the existence of a medical indication for prescribing, dispensing, or furnishing dangerous drugs.

(4) Violates Section 2242.1 regarding prescribing on the Internet.

(5) Fails to keep complete and accurate records of purchases and disposals of substances listed in the California Uniform Controlled Substances Act (Division 10 (commencing with *Section 11000) of the Health and Safety Code*) or controlled substances scheduled in the federal Comprehensive Drug Abuse Prevention and Control Act of 1970 *(21 U.S.C. Sec. 801* et seq.), or pursuant to the federal Comprehensive Drug Abuse Prevention and Control Act of 1970. A physician and surgeon shall keep records of his or her purchases and disposals of these controlled substances or dangerous drugs, including the date of purchase, the date and records of the sale or disposal of the drugs by the physician and surgeon, the name and address of the person receiving the drugs, and the reason for the disposal or the dispensing of the drugs to the person, and shall otherwise comply with all state recordkeeping requirements for controlled substances.

(6) Writes false or fictitious prescriptions for controlled substances listed in the California Uniform Controlled Substances Act or scheduled in the federal Comprehensive Drug Abuse Prevention and Control Act of 1970.

(7) Prescribes, administers, or dispenses in violation of this chapter, or in violation of Chapter 4 (commencing with Section 11150) or Chapter 5 (commencing with *Section 11210) of Division 10 of the Health and Safety Code.*

(d) A physician and surgeon shall exercise reasonable care in determining whether a particular patient or condition, or the complexity of a patient's treatment, including, but not limited to, a current or recent pattern of drug abuse, requires consultation with, or referral to, a more qualified specialist.

(e) Nothing in this section shall prohibit the governing body of a hospital from taking disciplinary actions against a physician and surgeon pursuant to Sections 809.05, 809.4, and 809.5.

§ 2241.6. Development of standards for review of cases concerning management of a patient's pain

The Division of Medical Quality shall develop standards before June 1, 2002, to assure the competent review in cases concerning the management, including, but not limited to, the undertreatment, undermedication, and overmedication of a patient's pain. The division may consult with entities such as the American Pain Society, the American Academy of Pain Medicine, the California Society of Anesthesiologists, the California Chapter of the American College of Emergency Physicians, and any other medical entity specializing in pain control therapies to develop the standards utilizing, to the extent they are applicable, current authoritative clinical practice guidelines.

(+) *CRITERION 2:*
Pain management is part of healthcare practice

(+) *CRITERION 3:*
Opioids are part of professional practice

(+) *CRITERION 5:*
Addresses fear of regulatory scrutiny

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT*:* Recognizes that inadequate treatment of pain is subject to investigation just as other substandard practices might be.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT*:* Establishes a mechanism (written standards) to ensure competent review of pain management disciplinary cases.

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STATUTES

Pain Patient's Bill of Rights

California Health & Safety Code §124960

§ 124960. Legislative findings and declarations

The Legislature finds and declares all of the following:

(a) The state has a right and duty to control the illegal use of opiate drugs.

(b) Inadequate treatment of acute and chronic pain originating from cancer or noncancerous conditions is a significant health problem.

(c) For some patients, pain management is the single most important treatment a physician can provide.

(d) A patient suffering from severe chronic intractable pain should have access to proper treatment of his or her pain.

(e) Due to the complexity of their problems, many patients suffering from severe chronic intractable pain may require referral to a physician with expertise in the treatment of severe chronic intractable pain. In some cases, severe chronic intractable pain is best treated by a team of clinicians in order to address the associated physical, psychological, social, and vocational issues.

(f) In the hands of knowledgeable, ethical, and experienced pain management practitioners, opiates administered for severe acute pain and severe chronic intractable pain can be safe.

(g) Opiates can be an accepted treatment for patients in severe chronic intractable pain who have not obtained relief from any other means of treatment.

(h) A patient suffering from severe chronic intractable pain has the option to request or reject the use of any or all modalities to relieve his or her pain.

(i) A physician treating a patient who suffers from severe chronic intractable pain may prescribe a dosage deemed medically necessary to relieve pain as long as the prescribing is in conformance with *Section 2241.5 of the Business and Professions Code*.

(j) A patient who suffers from severe chronic intractable pain has the option to choose opiate medication for the treatment of the severe chronic intractable pain as long as the prescribing is in conformance with *Section 2241.5 of the Business and Professions Code*.

(k) The patient's physician may refuse to prescribe opiate medication for a patient who requests the treatment for severe chronic intractable pain. However, that physician shall inform the patient that there are physicians who treat severe chronic intractable pain with methods that include the use of opiates.

(+) *CRITERION 2:*
Pain management is part of healthcare practice

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Recognizes the need for a multidisciplinary approach to pain management.

(+) *CRITERION 4:*
Encourages pain management

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Recognizes that the goal of pain treatment should include improvements in patient functioning and quality of life.

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STATUTES

Effect on Intractable Pain Treatment Act; Bill of Rights

California Health & Safety Code §124961

§ 124961. Effect on Intractable Pain Treatment Act; Bill of Rights

Nothing in this section shall be construed to alter any of the provisions set forth in *Section 2241.5 of the Business and Professions Code*. This section shall be known as the Pain Patient's Bill of Rights.

(a) A patient who suffers from severe chronic intractable pain has the option to request or reject the use of any or all modalities in order to relieve his or her pain.

(b) A patient who suffers from severe chronic intractable pain has the option to choose opiate medications to relieve that pain without first having to submit to an invasive medical procedure, which is defined as surgery, destruction of a nerve or other body tissue by manipulation, or the implantation of a drug delivery system or device, as long as the prescribing physician acts in conformance with the California Intractable Pain Treatment Act, *Section 2241.5 of the Business and Professions Code*.

(c) The patient's physician may refuse to prescribe opiate medication for the patient who requests a treatment for severe chronic intractable pain. However, that physician shall inform the patient that there are physicians who treat pain and whose methods include the use of opiates.

(d) A physician who uses opiate therapy to relieve severe chronic intractable pain may prescribe a dosage deemed medically necessary to relieve the patient's pain, as long as that prescribing is in conformance with *Section 2241.5 of the Business and Professions Code*.

(e) A patient may voluntarily request that his or her physician provide an identifying notice of the prescription for purposes of emergency treatment or law enforcement identification.

(f) Nothing in this section shall do either of the following:

(1) Limit any reporting or disciplinary provisions applicable to licensed physicians and surgeons who violate prescribing practices or other provisions set forth in the Medical Practice Act, Chapter 5 (commencing with *Section 2000) of Division 2 of the Business and Professions Code*, or the regulations adopted thereunder.

(2) Limit the applicability of any federal statute or federal regulation or any of the other statutes or regulations of this state that regulate dangerous drugs or controlled substances.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY B:
Issues related to patients

COMMENT: Recognizes the patient's right to request or reject different types of treatments

(-) *CRITERION 16:*
Provisions that are ambiguous

CATEGORY B:
Unclear intent leading to possible misinterpretation

COMMENT: How does this qualify as a "Pain Patient's Bill of Rights" ? This language falls short of providing any rights to specific treatment and may establish a false expectation for pain management.

(-) *CRITERION 16:*
Provisions that are ambiguous

CATEGORY B:
Unclear intent leading to possible misinterpretation

COMMENT: The phrase "severe chronic intractable pain" is used throughout this policy. The intended result of such elaborate and unconventional medical terminology is unclear, but appears to further limit the patient population which should be given access to "proper treatment" of pain, including the use of opioids, and which is given the option to request or reject any treatments.

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OTHER GOVERNMENTAL POLICY

Medical Board Statement

A STATEMENT BY THE MEDICAL BOARD

INTRODUCTION
The 1993 report of the Medical Board to the Governor signaled a new beginning in the history of medical regulation in California. An important part of this initiative is implementation of the recommendations made by the Board's Task Force on Appropriate Prescribing, chaired by Jacqueline Trestrail, M.D.

The Task Force was established to look into "malprescribing," one of the fastest growing categories of physician discipline. The Board continues to be concerned that controlled substances are subject to abuse by individuals who seek them for their mood altering and other psychological effects, rather than for legitimate medical purposes.

(+) *CRITERION 4:*
Encourages pain management

The Board is also concerned about effective pain management and the appropriate medical use of controlled substances. During the Task Force's public meetings, the members heard testimony that some physicians avoid prescribing controlled substances, including the "triplicate" drugs, for patients with intractable pain for fear of discipline by the Board. The Task Force recommended that the Board take a pro-active approach to emphasize to all California physicians that it supports prescribing of opioid analgesics (narcotics) and other controlled substances when medically indicated for the treatment of pain, including intractable pain. After careful review of this matter, the Board concurs with the following statement.

(+) *CRITERION 3:*
Opioids are part of professional practice

This statement is consistent with good medical practice, protection of public health and consumer interests, with international treaties, federal and California law, including the California Intractable Pain Treatment Act.

THE PAIN PROBLEM
The Board recognizes that pain, whether due to trauma, surgery, cancer and other diseases, is often undertreated. Minorities, women, children, the elderly and people with HIV/AIDS are at particular risk for under treatment of their pain. Unrelieved pain has a harsh and sometimes disastrous impact on the quality of life of people and their families.

While some progress is being made to improve pain and symptom management, the Board is concerned that a number of factors continue to interfere with effective pain management. These include the low priority of pain management in our health care system, incomplete integration of current knowledge into medical education and clinical practice, lack of knowledge among consumers about pain management, exaggerated fears of opioid side effects and addiction, and fear of legal consequences when controlled substances are used.

(+) *CRITERION 2:*
Pain management is part of healthcare practice

PAIN MANAGEMENT SHOULD BE A HIGH PRIORITY IN CALIFORNIA
Principles of quality medical practice dictate that citizens of California who suffer from pain should be able to obtain the relief that is currently available. The Board believes that the appropriate application of current knowledge and treatments would greatly improve the quality of life for many California citizens, and could also reduce the morbidity and the costs that are associated with uncontrolled pain.

In addition to making this statement, the Board will take a number of steps to help make effective pain management a reality in California. The Board has provided information to all state physicians about new clinical practice guidelines for pain management that have been prepared by a panel of experts supported by the Agency for Health Care Policy and Research. The Board also co-sponsored and participated in the March 18, 1994 Pain Management and Appropriate Prescribing Summit in conjunction with the Department of Consumer Affairs on removing impediments to appropriate prescribing of controlled substances for effective pain management. Further, the Board will develop guidelines to help physicians avoid investigation if they appropriately prescribe controlled substances for pain management.

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Medical Board Statement

(CONTINUED)

Prescribing Controlled Substances for Pain

THE APPROPRIATE ROLE OF OPIOID ANALGESICS
There are numerous drug and non-drug treatments that are used for the management of pain and other symptoms. The proper treatment of any patient's pain depends upon a careful diagnosis of the etiology of the pain, selection of appropriate and cost-effective treatments, and ongoing evaluation of the results of treatment. Opioid analgesics and other controlled substances are useful for the treatment of pain, and are considered the cornerstone of treatment of acute pain due to trauma, surgery and chronic pain due to progressive diseases such as cancer. Large doses may be necessary to control pain if it is severe. Extended therapy may be necessary if the pain is chronic.

The Board recognizes that opioid analgesics can also be useful in the treatment of patients with intractable non-malignant pain especially where efforts to remove the cause of pain or to treat it with other modalities have failed. The pain of such patients may have a number of different etiologies and may require several treatment modalities. In addition, the extent to which pain is associated with physical and psychosocial impairment varies greatly. Therefore, the selection of a patient for a trial of opioid therapy should be based upon a careful assessment of the pain as well as the disability experienced by the patient. Continuation of opioid therapy should be based on the physician's evaluation of the results of treatment, including the degree of pain relief, changes in physical and psychological functioning, and appropriate utilization of health care resources. Physicians should not hesitate to obtain consultation from legitimate practitioners who specialize in pain management.

The Board recommends that physicians pay particular attention to those patients who misuse their prescriptions, particularly when the patient or family have a history of substance abuse that could complicate pain management. The management of pain in such patients requires extra care and monitoring, as well as consultation with medical specialists whose area of expertise is substance abuse or pain management.

The Board believes that addiction should be placed into proper perspective. Physical dependence and tolerance are normal physiologic consequences of extended opioid therapy and are not the same as addiction. Addiction is a behavioral syndrome characterized by psychological dependence and aberrant drug-related behaviors. Addicts compulsively use drugs for non-medical purposes despite harmful effects; a person who is addicted may also be physically dependent or tolerant. Patients with chronic pain should not be considered addicts or habitues merely because they are being treated with opioids.

PAIN MANAGEMENT, CONTROLLED SUBSTANCES AND THE LAW
The laws and regulations of the federal government and the State of California impose special requirements for the prescribing of controlled substances, including requirements as to the form of the prescription document, so as to prevent harm to the public health that is caused when prescription drugs are diverted to non-medical uses. For example, it is illegal to prescribe controlled substances solely to maintain narcotic addiction. However, federal and California law clearly recognize that it is a legitimate medical practice for physicians to prescribe controlled substances for the treatment of pain, including intractable pain.

The Medical Board will work with the Drug Enforcement Administration, the Bureau of Narcotic Enforcement, the Office of the Attorney General, the Board of Pharmacy and its own investigators in an attempt to develop policy and guidelines based on the physician's diagnosis and treatment program rather than amounts of drugs prescribed.

(CONTINUED ON NEXT PAGE)

(+) *CRITERION 7:*
Physical dependence or analgesic tolerance are not confused with "addiction"

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Recognizes that the goal of pain treatment should include improvements in patient functioning and quality of life.

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Medical Board Statement

(+) ***CRITERION 5:*** ***Addresses fear of regulatory scrutiny***

(+) ***CRITERION 6:*** ***Prescription amount alone does not determine legitimacy***

(CONTINUED)

Concerns about regulatory scrutiny should not make physicians who follow appropriate guidelines reluctant to prescribe or administer controlled substances, including Schedule II drugs, for patients with a legitimate medical need for them. A physician is not subject to Board action when prescribing in the regular course of his or her profession to one under the physician's treatment for a pathology or condition and where the prescription is issued after a good faith examination and where there is medical indication for the drug. Good faith prescribing requires an equally good faith history, physical examination and documentation.

The Medical Board may identify a pattern of controlled substance use that merits further examination. A private, courteous and professional inquiry can usually determine whether the physician is in good faith appropriately prescribing for patients, or whether an investigation is necessary. The Board will judge the validity of prescribing based on the physician's diagnosis and treatment of the patient and whether the drugs prescribed by the physician are appropriate for that condition, and will not act on the basis of predetermined numerical limits on dosages or length of drug therapy.

The Board hopes to replace practitioners' perception of inappropriate regulatory scrutiny with recognition of the Board's commitment to enhance the quality of life of patients by improving pain management while, at the same time, preventing the diversion and abuse of controlled substances.

(+) ***CRITERION 8:*** ***Other provisions that may enhance pain management***

CATEGORY C: ***Regulatory or policy issues***

COMMENT: Represents the principle of Balance, which states that the regulation of controlled substances should not interfere with legitimate medical use.

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OTHER GOVERNMENTAL POLICY

Medical Board Guideline

Adopted Unanimously by the Board in 1994 and revised in 2007

Preamble
In 1994, the Medical Board of California formally adopted a policy statement titled, "Prescribing Controlled Substances for Pain." The statement outlined the board's proactive approach to improving appropriate prescribing for effective pain management in California, while preventing drug diversion and abuse. The policy statement was the product of a year of research, hearings and discussions. California physicians and surgeons are encouraged to consult this policy statement and the guidelines below.

In May 2002, as a result of AB 487, a task force was established to review the 1994 Guidelines and to assist the Division of Medical Quality to "develop standards to assure the competent review in cases concerning the management, including, but not limited to, the under treatment, under medication, and over medication of a patient's pain." The task force expanded the scope of the Guidelines from intractable pain patients to all patients with pain.

Under past law, both Business and Professions Code section 2241 and Health and Safety Code section 11156 made it unprofessional conduct for a practitioner to prescribe to an addict. However, the standard of care has evolved over the past several years such that a practitioner may, under certain circumstances, appropriately prescribe to an addict. AB 2198, which became law on January 1, 2007, sought to align existing law with the current standard of care. Accordingly, a physician is permitted to prescribe, dispense, or administer prescription drugs, including prescription controlled substances, to an addict under his or her treatment for a purpose other than maintenance on, or detoxification from, prescription drugs or controlled substances. The law, Business and Professions Code section 2241, also set forth the conditions under which such prescribing may occur. Further, Business and Professions Code 2241.5 now permits a physician to prescribe for or dispense or administer to a person under his or her treatment of pain or a condition causing pain, including, but not limited to, intractable pain.

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Medical Board Guideline

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT*:* Recognizes that inadequate treatment of pain is subject to disciplinary action just as other substandard practices might be.

(+) *CRITERION 2:*
Pain management is part of medical practice

(+) *CRITERION 5:*
Addresses fear of regulatory scrutiny

(CONTINUED)

Inappropriate prescribing of controlled substances, including opioids, can lead to drug abuse or diversion and can also lead to ineffective management of pain, unnecessary suffering of patients, and increased health costs. The Medical Board recognized that some physicians do not treat pain appropriately due to a lack of knowledge or concern about pain, and others may fail to treat pain properly due to fear of discipline by the board. These Guidelines are intended to improve effective pain management in California, by avoiding under treatment, over treatment, or other inappropriate treatment of a patient's pain and by clarifying the principles of professional practice that are endorsed by the Medical Board so that physicians have a higher level of comfort in using controlled substances, including opioids, in the treatment of pain. These Guidelines are intended to promote improved pain management for all forms of pain and for all patients in pain.

A HIGH PRIORITY

The board strongly urges physicians and surgeons to view effective pain management as a high priority in all patients, including children, the elderly, and patients who are terminally ill. Pain should be assessed and treated promptly, effectively and for as long as pain persists. The medical management of pain should be based on up-to-date knowledge about pain, pain assessment and pain treatment. Pain treatment may involve the use of several medications and non-pharmacological treatment modalities, often in combination. For some types of pain, the use of medications is emphasized and should be pursued vigorously; for other types, the use of medications is better de-emphasized in favor of other therapeutic modalities. Physicians and surgeons should have sufficient knowledge or utilize consultations to make such judgments for their patients.

Medications, in particular opioid analgesics, are considered the cornerstone of treatment for pain associated with trauma, surgery, medical procedures, or cancer. A number of medical organizations have developed guidelines for acute and chronic pain management.

The prescribing of opioid analgesics for patients with pain, may also be beneficial, especially when efforts to alleviate the pain with other modalities have been unsuccessful.

Business and Professions Code section 2241.5 provides in part: "(a) A physician and surgeon may prescribe for, or dispense or administer to, a person under his or her treatment for a medical condition dangerous drugs or prescription controlled substances for the treatment of pain or a condition causing pain, including, but not limited to, intractable pain. (b) No physician and surgeon shall be subject to disciplinary action for prescribing, dispensing, or administering dangerous drugs or prescription controlled substances in accordance with this section."

However, this section does not affect the power of the board to discipline a physician and surgeon for any act that violates the law, including gross negligence, repeated negligent acts, or incompetence; violation of section 2241 regarding treatment of an addict; violation of section 2242 regarding performing an appropriate prior examination and the existence of a medical indication for prescribing, dispensing, or furnishing dangerous drugs; violation of section 2242.1 regarding prescribing on the Internet; failure to keep complete and accurate records of purchases and disposals of controlled substances; writing false or fictitious prescriptions for controlled substances; or prescribing, administering, or dispensing in violation of the pertinent sections of the Health and Safety Code.

The Medical Board expects physicians and surgeons to follow the standard of care in managing pain patients.

(+) *CRITERION 4:*
Encourages pain management

(+) *CRITERION 3:*
Opioids are part of professional practice

2013

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OTHER GOVERNMENTAL POLICY

Medical Board Guideline

(CONTINUED)

Guidelines

• History/Physical Examination
A medical history and physical examination must be accomplished. This includes an assessment of the pain, physical and psychological function; a substance abuse history; history of prior pain treatment; an assessment of underlying or coexisting diseases or conditions; and documentation of the presence of a recognized medical indication for the use of a controlled substance.

Annotation One: The prescribing of controlled substances for pain may require referral to one or more consulting physicians.

Annotation Two: The complexity of the history and physical examination may vary based on the practice location. In the emergency department, the operating room, at night or on the weekends, the physician and surgeon may not always be able to verify the patient's history and past medical treatment. In continuing care situations for chronic pain management, the physician and surgeon should have a more extensive evaluation of the history, past treatment, diagnostic tests and physical exam.

• Treatment Plan, Objectives
The treatment plan should state objectives by which the treatment plan can be evaluated, such as pain relief and/or improved physical and psychosocial function, and indicate if any further diagnostic evaluations or other treatments are planned. The physician and surgeon should tailor pharmacological therapy to the individual medical needs of each patient. Multiple treatment modalities and/or a rehabilitation program may be necessary if the pain is complex or is associated with physical and psychosocial impairment.

Annotation One: Physicians and surgeons may use control of pain, increase in function, and improved quality of life as criteria to evaluate the treatment plan.

Annotation Two: When the patient is requesting opioid medications for their pain and inconsistencies are identified in the history, presentation, behaviors to physical findings, physicians and surgeons who make a clinical decision to withhold opioid medications should document the basis for their decision.

• Informed Consent
The physician and surgeon should discuss the risks and benefits of the use of controlled substances and other treatment modalities with the patient, caregiver or guardian.

Annotation: A written consent or pain agreement for chronic use is not required but may make it easier for the physician and surgeon to document patient education, the treatment plan, and the informed consent. Patient, guardian, and caregiver attitudes about medicines may influence the patient's use of medications for relief from pain.

(CONTINUED ON NEXT PAGE)

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Recognizes that the goal of pain treatment should include improvements in patient functioning and quality of life.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Encourages healthcare professionals to incorporate in their practice the evaluations of, and discussions with patients about, the potential benefits and risks of treatment with opioids, which can better ensure a clinical indication of such treatment so that opioids will be used for medical purposes.

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OTHER GOVERNMENTAL POLICY

Medical Board Guideline

(CONTINUED)

• **Periodic**
Review The physician and surgeon should periodically review the course of pain treatment of the patient and any new information about the etiology of the pain or the patient's state of health. Continuation or modification of controlled substances for pain management therapy depends on the physician's evaluation of progress toward treatment objectives. If the patient's progress is unsatisfactory, the physician and surgeon should assess the appropriateness of continued use of the current treatment plan and consider the use of other therapeutic modalities.

Annotation One: Patients with pain who are managed with controlled substances should be seen monthly, quarterly, or semiannually as required by the standard of care.

Annotation Two: Satisfactory response to treatment may be indicated by the patient's decreased pain, increased level of function, or improved quality of life. Information from family members or other caregivers should be considered in determining the patient's response to treatment.

• **Consultation**
The physician and surgeon should consider referring the patient as necessary for additional evaluation and treatment in order to achieve treatment objectives. Complex pain problems may require consultation with a pain medicine specialist.

In addition, physicians should give special attention to those pain patients who are at risk for misusing their medications including those whose living arrangements pose a risk for medication misuse or diversion.
Annotation One: Coordination of care in prescribing chronic analgesics is of paramount importance.

Annotation Two: In situations where there is dual diagnosis of opioid dependence and intractable pain, both of which are being treated with controlled substances, protections apply to physicians and surgeons who prescribe controlled substances for intractable pain provided the physician complies with the requirements of the general standard of care and California Business and Professions Code sections 2241 and 2241.5.

• **Records**
The physician and surgeon should keep accurate and complete records according to items above, including the medical history and physical examination, other evaluations and consultations, treatment plan objectives, informed consent, treatments, medications, rationale for changes in the treatment plan or medications, agreements with the patient, and periodic reviews of the treatment plan.

Annotation One: Documentation of the periodic reviews should be done at least annually or more frequently as warranted.

Annotation Two: Pain levels, levels of function, and quality of life should be documented. Medical documentation should include both subjective complaints of patient and caregiver, and objective findings by the physician.

(CONTINUED ON NEXT PAGE)

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CALIFORNIA

OTHER GOVERNMENTAL POLICY

Medical Board Guideline

(CONTINUED)

• Compliance with Controlled Substances Laws and Regulations

To prescribe controlled substances, the physician and surgeon must be appropriately licensed in California, have a valid controlled substances registration and comply with federal and state regulations for issuing controlled substances prescriptions. Physicians and surgeons are referred to the Physicians Manual of the U.S. Drug Enforcement Administration and the Medical Board's Guidebook to Laws Governing the Practice of Medicine by Physicians and Surgeons for specific rules governing issuance of controlled substances prescriptions.

Annotation One: There is not a minimum or maximum number of medications which can be prescribed to the patient under either federal or California law. *Annotation Two*: Physicians and surgeons who supervise Physician Assistants (PA's) or Nurse Practitioners (NP's) should carefully review the respective supervision requirements.

Additional information on PA supervision requirements is available at www.pac.ca.gov.

PA's are able to obtain their own DEA number to use when writing prescriptions for drug orders for controlled substances. Current law permits physician assistants to write and sign prescription drug orders when authorized to do so by their supervising physician for Schedule II-IV. Further, a PA may only administer, provide or transmit a drug order for Schedule II through V controlled substances with the advanced approval by a supervising physician for a specific patient unless a physician assistant completes an approved education course in controlled substances and if delegated by the supervising physician. To ensure that a PA's actions involving the prescribing, administration, or dispensing of drugs is in strict accordance with the directions of the physician, every time a PA administers or dispenses a drug or transmits a drug order, the physician supervisor must sign and date the patient's medical record or drug chart within seven days. (Section 1399.545(f) of Title 16, California Code of Regulations)

NP's are allowed to furnish Schedule III-V controlled substances under written protocols.

POSTSCRIPT

While it is lawful under both federal and California law to prescribe controlled substances for the treatment of pain – including intractable pain - there are limitations on the prescribing of controlled substances to or for patients for the treatment of chemical dependency (see Sections 11215-11222 of the California Health and Safety Code). In summary, a physician and surgeon must follow the same standard of care when prescribing and/or administering a narcotic controlled substance to a "known addict" patient as he or she would for any other patient.

The physician and surgeon must:

- Perform an appropriate prior medical examination;
- Identify a medical indication;
- Keep accurate and complete medical records, including treatments, periodic reviews of treatment plans, etc.;
- Provide ongoing and follow-up medical care as appropriate and necessary.

The Medical Board emphasizes the above issues, both to ensure physicians and surgeons know that a patient in pain who is also chemically dependent should not be deprived of appropriate pain relief, and to recognize the special issues and difficulties associated with patients who suffer both from drug addiction and pain. The Medical Board expects that the acute pain from trauma or surgery will be addressed regardless of the patient's current or prior history of substance abuse. This postscript should not be interpreted as a deterrent for appropriate treatment of pain.

(+) *CRITERION 6:*
Prescription amount alone does not determine legitimacy

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Encourages healthcare professionals to understand and follow federal and state laws governing their practice, which can better ensure that practitioners follow the *balanced* approach represented by federal law and the laws in many states.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY B:
Issues related to patients

COMMENT:
Acknowledges that a patient's prior history or current status of drug abuse does not necessarily contraindicate appropriate pain management.

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STATUTES

Reports of Injuries

Cal Pen Code § 11161.5

§ 11161.5. Legislative intent regarding development of protocols for interagency investigations of a physician's prescription of medication to patients

(a) It is the intent of the Legislature that on or before January 1, 2006, the California District Attorneys Association, in conjunction with interested parties, including, but not limited to, the Department of Justice, the California Narcotic Officers' Association, the California Police Chiefs' Association, the California State Sheriffs' Association, the California Medical Association, the American Pain Society, the American Academy of Pain Medicine, the California Society of Anesthesiologists, the California Chapter of the American College of Emergency Physicians, the California Medical Board, the California Orthopedic Association, and other medical and patient advocacy entities specializing in pain control therapies, shall develop protocols for the development and implementation of interagency investigations in connection with a physician's prescription of medication to patients. The protocols are intended to assure the competent review of, and that relevant investigation procedures are followed for, the suspected undertreatment, undermedication, overtreatment, and overmedication of pain cases. Consideration shall be made for the special circumstances of urban and rural communities. The investigation protocol shall be designed to facilitate communication between the medical and law enforcement communities and the timely return of medical records pertaining to the identity, diagnosis, prognosis, or treatment of any patient that are seized by law enforcement from a physician who is suspected of engaging in or having engaged in criminal activity related to the documents.

(b) The costs incurred by the California District Attorneys Association in implementing this section shall be solicited and funded from nongovernmental entities.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (protocols for interagency investigations) to ensure competent review of pain management cases.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Recognizes that inadequate treatment of pain is subject to investigation just as other substandard practices might be.

STATUTES

Legal End-of-Life Care Options

Cal Health & Saf Code § 442.5

§ 442.5. Comprehensive information and counseling regarding legal end-of-life care options

When a health care provider makes a diagnosis that a patient has a terminal illness, the health care provider shall, upon the patient's request, provide the patient with comprehensive information and counseling regarding legal end-of-life care options pursuant to this section. When a terminally ill patient is in a health facility, as defined in Section 1250, the health care provider, or medical director of the health facility if the patient's health care provider is not available, may refer the patient to a hospice provider or private or public agencies and community-based organizations that specialize in end-of-life care case management and consultation to receive comprehensive information and counseling regarding legal end-of-life care options.

(a) If the patient indicates a desire to receive the information and counseling, the comprehensive information shall include, but not be limited to, the following:

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(5) The patient's right to comprehensive pain and symptom management at the end of life, including, but not limited to, adequate pain medication, treatment of nausea, palliative chemotherapy, relief of shortness of breath and fatigue, and other clinical treatments useful when a patient is actively dying.

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(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (counseling) for practitioners to ensure that pain management is an essential part of patient end-of-life care.

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STATUTES

Health Facility Licensing

Cal Health & Saf Code § 1254.7

§ 1254.7. Pain assessment

(a) It is the intent of the Legislature that pain be assessed and treated promptly, effectively, and for as long as pain persists.

(b) Every health facility licensed pursuant to this chapter shall, as a condition of licensure, include pain as an item to be assessed at the same time as vital signs are taken. The health facility shall ensure that pain assessment is performed in a consistent manner that is appropriate to the patient. The pain assessment shall be noted in the patient's chart in a manner consistent with other vital signs.

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Cal Health & Saf Code § 1262.6

§ 1262.6. Patient's rights information requirements provided by hospital

(a) Each hospital shall provide each patient, upon admission or as soon thereafter as reasonably practical, written information regarding the patient's right to the following:

(1) To be informed of continuing health care requirements following discharge from the hospital.

(2) To be informed that, if the patient so authorizes, that a friend or family member may be provided information about the patient's continuing health care requirements following discharge from the hospital.

(3) Participate actively in decisions regarding medical care. To the extent permitted by law, participation shall include the right to refuse treatment.

(4) Appropriate pain assessment and treatment consistent with Sections 124960 and 124961.

(b) A hospital may include the information required by this section with other notices to the patient regarding patient rights. If a hospital chooses to include this information along with existing notices to the patient regarding patient rights, this information shall be provided when the hospital exhausts its existing inventory of written materials and prints new written materials.

(+) *CRITERION 4:*
Encourages pain management

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a responsibility for health facilities to ensure that pain management is an essential part of patient care.

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REGULATIONS

Hospice Services

28 CCR 1300.68.2

§ 1300.68.2. Hospice Services

(a) For purposes of this section, the following definitions shall apply:

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(2) "Hospice service" or "hospice program" means a specialized form of interdisciplinary health care that is designed to provide palliative care, alleviate the physical, emotional, social and spiritual discomforts of an enrollee who is experiencing the last phases of life due to the existence of a terminal disease, to provide supportive care to the primary care giver and the family of the hospice patient, and which meets all of the following criteria;

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(C) Requires the interdisciplinary team to develop an overall plan of care and to provide coordinated care which emphasizes supportive services, including, but not limited to, home care, pain control, and short-term inpatient services. Short-term inpatient services are intended to ensure both continuity of care and appropriateness of services for those enrollees who cannot be managed at home because of acute complications or the temporary absence of a capable primary caregiver.

(D) Provides for the palliative medical treatment of pain and other symptoms associated with a terminal disease, but does not provide for efforts to cure the disease.

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(7) "Medical direction" means those services provided by a licensed physician and surgeon who is charged with the responsibility of acting as a consultant to the interdisciplinary team, a consultant to the enrollee's attending physician and surgeon, as requested, with regard to pain and symptom management, and liaison with physicians and surgeons in the community. For purposes of this section, the person providing these services shall be referred to as the "medical director."

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(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes mechanisms for hospices to ensure that pain management is an essential part of patient care.

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STATUTES

- CONTROLLED SUBSTANCES ACT
  Title 18. Criminal Code; Article 18. Uniform Controlled Substances Act of 1992

- MEDICAL PRACTICE ACT
  Title 12. Professions and Occupations; Health Care; Article 36. Medical Practice

- PHARMACY PRACTICE ACT
  Title 12. Professions and Occupations; Health Care;
  Article 42.5. Pharmacists, Pharmacy Businesses, and Pharmaceuticals

REGULATIONS

- CONTROLLED SUBSTANCES REGULATIONS
  No policy found

- MEDICAL BOARD REGULATIONS
  Department of Regulatory Agencies; Colorado Medical Board

- PHARMACY BOARD REGULATIONS (*No provisions found*)
  Department of Regulatory Agencies; State Board of Pharmacy

OTHER GOVERNMENTAL POLICIES

- MEDICAL BOARD GUIDELINE
  Colorado Medical Board. *Guidelines Regarding the Treatment of Terminally Ill Patients.*
  Adopted: November 12, 1998; Updated: July 1, 2010.

RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY KEY WORD SEARCHES

- OFFENSES AGAINST THE PERSON
  Title 18. Criminal Code; Article 3. Offenses Against the Person

- STANDARDS FOR HOSPITALS AND HEALTH FACILITIES
  Department of Public Health and Environment; Health Facilities and Emergency Medical Services Division

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STATUTES

Controlled Substances Act

C.R.S. 18-18-102

18-18-102. Definitions

As used in this article:

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(29) "Practitioner" means a physician, podiatrist, dentist, optometrist, veterinarian, researcher, pharmacist, pharmacy, hospital, or other person licensed, registered, or otherwise permitted, by this state, to distribute, dispense, conduct research with respect to, administer, or to use in teaching or chemical analysis, a controlled substance in the course of professional practice or research.

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(+) *CRITERION 3:*
Opioids are part of professional practice

C.R.S. 18-18-308

18-18-308. Prescriptions

(1) As used in this section, "medical treatment" includes dispensing or administering a narcotic drug for pain, including intractable pain.

(2) Except as provided in section 18-18-414, a person may dispense a controlled substance only as provided in this section.

(3) Except when dispensed directly by a practitioner, other than a pharmacy, to an ultimate user, a substance included in schedule II may not be dispensed without the written prescription of a practitioner.

(4) Except when dispensed directly by a practitioner, other than a pharmacy, to an ultimate user, a substance included in schedule III, IV, or V may not be dispensed without a written or oral prescription order of a practitioner. The prescription order must not be filled or refilled more than six months after the date thereof or be refilled more than five times.

(5) A practitioner may dispense or deliver a controlled substance to or for an individual or animal only for medical treatment or authorized research in the ordinary course of that practitioner's profession.

(6) No civil or criminal liability or administrative sanction may be imposed on a pharmacist for action taken in reliance on a reasonable belief that an order purporting to be a prescription was issued by a practitioner in the usual course of professional treatment or in authorized research.

(+) *CRITERION 2:*
Pain management is part of healthcare practice

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STATUTES

Medical Practice Act

C.R.S. 12-36-106

12-36-106. Practice of medicine defined - exemptions from licensing requirements - repeal

(1) For the purpose of this article, "practice of medicine" means:

(a) Holding out one's self to the public within this state as being able to diagnose, treat, prescribe for, palliate, or prevent any human disease, ailment, pain, injury, deformity, or physical or mental condition, whether by the use of drugs, surgery, manipulation, electricity, telemedicine, the interpretation of tests, including primary diagnosis of pathology specimens, images, or photographs, or any physical, mechanical, or other means whatsoever;

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C.R.S. 12-36-117

12-36-117. Unprofessional conduct

(1) "Unprofessional conduct" as used in this article means:

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(mm) Failure to comply with the requirements of *section 14 of article XVIII of the state constitution, section 25-1.5-106, C.R.S.*, or the rules promulgated by the state health agency pursuant to *section 25-1.5-106 (3), C.R.S.*

(ii) Entering into or continuing a collaborative agreement pursuant to sections 12-38-111.6 (4) (d) (IV) and 12-36-106.3 that fails to meet generally acceptable standards of medical practice.

(1.5) (a) A licensee shall not be subject to disciplinary action by the board solely for prescribing controlled substances for the relief of intractable pain.

(b) For the purposes of this subsection (1.5), "intractable pain" means a pain state in which the cause of the pain cannot be removed and which in the generally accepted course of medical practice no relief or cure of the cause of the pain is possible or none has been found after reasonable efforts including, but not limited to, evaluation by the attending physician and one or more physicians specializing in the treatment of the area, system, or organ of the body perceived as the source of the pain.

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(+) *CRITERION 2:*
Pain management is part of healthcare practice

(-) *CRITERION 16:*
Provisions that are ambiguous

CATEGORY B:
Unclear intent leading to possible misinterpretation

COMMENT: Although similar language is used in Federal regulation, in the context of this statute this definition suggests that physicians would qualify for the immunity and, thus, relief from concerns about regulatory scrutiny provided by this statute only if they prescribe opioids after other treatments have been tried and failed, regardless of other clinical considerations.

(+) *CRITERION 5:*
Addresses fear of regulatory scrutiny

(-) *CRITERION 10:*
Implies opioids are not part of professional practice

(-) *CRITERION 12:*
Medical decisions are restricted

CATEGORY B:
Mandated consultation

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STATUTES

Pharmacy Practice Act

C.R.S. 12-22-702

12-22-702. Definitions

As used in this part 7, unless the context otherwise requires:

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(6) "Practitioner" shall have the same meaning as in *section 18-18-102 (29), C.R.S.* By reference: "Practitioner" means a physician, podiatrist, dentist, optometrist, veterinarian, researcher, pharmacist, pharmacy, hospital, or other person licensed, registered, or otherwise permitted, by this state, to distribute, dispense, conduct research with respect to, administer, or to use in teaching or chemical analysis, a controlled substance in the course of professional practice or research.

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(+) *CRITERION 3:*
Opioids are part of professional practice

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REGULATIONS

Medical Board Regulations

3 CCR 713-30

3 CCR 713-30. RULE 800 - DELEGATION AND SUPERVISION OF MEDICAL SERVICES TO UNLICENSED HEALTH CARE PROVIDERS PURSUANT TO § 12-36-106(3)(l), C.R.S.

RULES

I. Scope of Rules. These Rules apply to the delegation of medical services constituting the practice of medicine to a person who is not licensed to practice medicine, is not qualified for licensure as a physician or physician assistant, and is not otherwise exempt pursuant to *section 12-36-106, C.R.S.* from holding a license to practice medicine.

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B. Exemption from these Rules: Acts that do not constitute "medical services" as defined by the Medical Practice Act.

1. These Rules do not apply to a person performing acts that do not constitute the practice of medicine as defined by *section 12-36-106(1), C.R.S.* of the Medical Practice Act.

2. In part, "medical services" are defined by the Medical Practice Act to include suggesting, recommending, prescribing, or administering any form of treatment, operation, or healing for the intended palliation, relief, or cure of any physical or mental disease, ailment, injury, condition or defect of any person. "Medical services" also include holding oneself out to the public as being able to diagnose, treat, prescribe for, palliate or prevent any human disease, ailment, pain, injury, deformity, or physical or mental condition. "Medical services" are further defined by *section 12-36-106(1), C.R.S.*

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(+) *CRITERION 2:*
Pain management is part of healthcare practice

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COLORADO

OTHER GOVERNMENTAL POLICY

Medical Board Guideline

COLORADO MEDICAL BOARD GUIDELINES REGARDING THE TREATMENT OF TERMINALLY ILL PATIENTS

INTRODUCTION

The Colorado Medical Board ("Board") recognizes that people have pain and suffering associated with terminal illness which may not be effectively managed by currently available therapies. The Board also recognizes that many of these people are of sound mind and wish to direct their end of life care, including choices involving medical interventions as well as whether to begin, continue or withdraw life-sustaining artificial nutrition and hydration. Indeed, there may be patients, relatives, or an authentic proxy who request of physicians, in response to the pain or suffering associated with terminal illness, a more active approach to end the person's life. Other patients, family members and/or an authentic proxy will more readily access available palliative, social, and spiritual support to make the person's last days meaningful and as comfortable as possible.

Physicians treating patients with terminal illness may therefore be faced with the difficulty of respecting the wishes of their patients and obeying state laws which prohibit euthanasia or physician assisted suicide. The issue is further complicated as a result of the ongoing debate concerning what constitutes appropriate societal policy on euthanasia and physician assisted suicide, which continues to be a significant and emotional issue throughout the nation.

The United States Supreme Court has recently ruled that certain state legislation prohibiting assisted suicide does not violate the Due Process or Equal Protection Clauses of the United States Constitution. State laws regarding physician assisted suicide vary, ranging from legislation prohibiting physician assisted suicide (the current position in the state of Colorado) to the Oregon law (reaffirmed by voters on November 4, 1997) to allow physician assisted suicide. Many other states have rejected proposed legislation to allow physician assisted suicide and many others have yet to adopt legislation on this matter.

The Board has decided to issue guidelines to Colorado physicians to help them address the needs of their patients in a manner which is consistent with Colorado law. Guidelines do not have the legal status of laws and regulations, but guidelines can explain what activities the Board considers to be within the boundaries of professional practice. Guidelines alert licensees to unprofessional practices of concern to the Board and give physicians practical information about how to avoid these problems.

DEFINITIONS

1. EUTHANASIA, means the direct, intentional intervention of a physician or another party to end the life of a patient whether it is taken at the patient's request, without the knowledge of the patient, or taken against the patient's wishes.

   Competent patients have a moral and a legal right to refuse treatment if that is their wish. The withholding or withdrawal of medical interventions, allowing the disease process to continue its natural course leading to death, is not considered euthanasia. Physicians have an obligation to honor the wishes of their competent patients, or the authentic proxy of their incompetent patients, with respect to withholding and withdrawing undesired medical interventions.

(CONTINUED ON NEXT PAGE)

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OTHER GOVERNMENTAL POLICY

Medical Board Guideline

(CONTINUED)

2. SUICIDE, means the intentional termination of one's own life.

Refusing a treatment which may delay the moment of death is not suicide. However, taking a dose of medication with the intent that it be lethal, even when fatally ill, would be suicide.

3. PHYSICIAN ASSISTED SUICIDE, means a physician intentionally aiding a patient to commit suicide through any method including, but not limited to, intentionally providing a lethal dose of medication for the purpose of aiding a patient to commit suicide.

This differs from providing an adequate dose of medication for the purpose of regulating pain relief (when no lesser dose is effective) even though the dose may foreseeably, but unintentionally, hasten the moment of death.

GUIDELINES

1. Physicians shall obey Colorado law which currently prohibits both euthanasia and physician assisted suicide as defined in these guidelines. Because controversy surrounds these issues, physicians ought to respond to patient and family concerns about the pain and suffering associated with terminal illness with respect and compassion. Physicians should continue to participate in society's ongoing examination, clarification and responses to these matters.

2. Physicians must resist the natural tendency to withdraw physically and emotionally from their terminally ill patients. When the treatment goals for a patient in the end stages of a terminal illness shift from curative efforts to comfort care, the level of physician involvement in the patient's care should in no way decrease.

3. It is critical that the medical profession redouble its efforts to ensure that dying patients are provided optimal treatment for their pain and other discomfort. The use of more aggressive comfort care measures, including effective pain management and greater reliance on hospice care, can alleviate the physical and emotional suffering that many dying patients experience. The foregoing, along with evaluation and treatment by a health care professional with expertise in psychological aspects of terminal illness, can often alleviate the suffering that leads a patient to desire euthanasia or physician assisted suicide.

4. Requests for euthanasia or physician assisted suicide should be a signal to the physician that the patient's needs are unmet and further evaluation to identify the elements contributing to the patient's suffering is necessary. Interdisciplinary interventions, including specialty consultations, spiritual care, family counseling, and other modalities should be sought as clinically indicated.

5. Physicians should recognize that courts and regulatory bodies readily distinguish between the use of medications including opioids to relieve pain in dying patients and use in other situations. (Reference Board Guidelines for Prescribing Controlled Substances for Chronic Non-Malignant Pain)

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(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Recognizes the need for a multidisciplinary approach to pain management.

(+) *CRITERION 4:*
Encourages pain management

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Recognizes need to conform to existing state practice standards.

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OTHER GOVERNMENTAL POLICY

Medical Board Guideline

(CONTINUED)

6. The principle of patient autonomy requires that physicians must respect the decision to forego life-sustaining treatment of a patient who possesses decision making capacity or that of an authentic proxy acting on an incompetent patient's behalf. Life-sustaining treatment is any medical treatment that serves to prolong life without reversing the underlying medical condition. Life-sustaining treatment includes, but is not limited to, mechanical ventilation, renal dialysis, chemotherapy, antibiotics, and artificial nutrition and hydration.

7. There is no ethical distinction between withdrawing and withholding life-sustaining treatment.

8. Physicians must be vigilant in assuring that frail and debilitated persons who may appear to be terminally ill are thoroughly assessed to determine whether treatments could reverse their current condition.

9. Physicians have an obligation to relieve pain and suffering and to promote the dignity and autonomy of dying patients in their care. This includes providing effective palliative treatment even though it may foreseeably, but unintentionally, hasten the moment of death.

10. Physician assisted suicide and euthanasia are fundamentally inconsistent with the physician's professional role.

CONCLUSION

Physicians must not perform euthanasia or participate in assisted suicide. Support, comfort, respect for patient autonomy, good communication, and effective pain control may decrease dramatically both the public and private requests for euthanasia and assisted suicide. In carefully defined circumstances, it would be humane to recognize that death is certain and suffering great. However, the societal risks of involving physicians in medical interventions to cause patients' deaths is too great to condone euthanasia or physician assisted suicide.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT*:* Clarifies for physicians the important distinction between physician-assisted suicide and prescribing controlled substances for pain relief; this language identifies a clinical misperception that is pervasive in end-of-life care and attempts to lessen its impact on patient treatment, and the practitioners who provide it.

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Madison, Wisconsin

COLORADO

STATUTES

Offenses Against the Person

C.R.S. 18-3-104

18-3-104. Manslaughter

(1) A person commits the crime of manslaughter if:

(a) Such person recklessly causes the death of another person; or

(b) Such person intentionally causes or aids another person to commit suicide.

(c) (Deleted by amendment, L. 96, p. 1844, § 13, effective July 1, 1996.)

(2) Manslaughter is a class 4 felony.

(3) This section shall not apply to a person, including a proxy decision-maker as such person is described in *section 15-18.5-103, C.R.S.*, who complies with any advance medical directive in accordance with the provisions of title 15, C.R.S., including a medical durable power of attorney, a living will, or a cardiopulmonary resuscitation (CPR) directive.

(4) (a) This section shall not apply to a medical caregiver with prescriptive authority or authority to administer medication who prescribes or administers medication for palliative care to a terminally ill patient with the consent of the terminally ill patient or his or her agent.

(b) For purposes of this subsection (4):

(I) "Agent" means a person appointed to represent the interests of the terminally ill patient by a medical power of attorney, power of attorney, health care proxy, or any other similar statutory or regular procedure used for designation of such person.

(II) "Medical caregiver" means a physician, registered nurse, nurse practitioner, or physician assistant licensed by this state.

(III) "Palliative care" means medical care and treatment provided by a licensed medical caregiver to a patient with an advanced chronic or terminal illness whose condition may not be responsive to curative treatment and who is, therefore, receiving treatment that relieves pain and suffering and supports the best possible quality of his or her life.

(c) Paragraph (a) of this subsection (4) shall not be interpreted to permit a medical caregiver to assist in the suicide of the patient.

(+) *CRITERION 2:*
Pain management is part of healthcare practice

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT*:* Clarifies for practitioners that there is an important distinction between manslaughter and prescribing controlled substances for palliative care; this language identifies a clinical misperception that is pervasive in end-of-life care and attempts to lessen its impact on patient treatment and the professionals who provide it.

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REGULATIONS

Standards for Hospitals and Health Facilities

6 CCR 1011-1 et seq

6 CCR 1011-1. STANDARDS FOR HOSPITALS AND HEALTH FACILITIES

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CHAPTER XXI - HOSPICES

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SECTION 2 DEFINITIONS

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2.9 "Palliative Care" means specialized medical care for people with serious illnesses. This type of care is focused on providing patients with relief from the symptoms, pain and stress of serious illness, whatever the diagnosis. The goal is to improve quality of life for both the patient and the family. Palliative care is provided by a team of physicians, nurses and other specialists who work with a patient's other health care providers to provide an extra layer of support. Palliative care is appropriate at any age and at any stage in a serious illness and can be provided together with curative treatment. Hospice providers may perform palliative care services that are separate and distinct from hospice care services.

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SECTION 4 ADMINISTRATION

4.5 The hospice shall develop, implement, and maintain an effective, ongoing, hospice-wide data-driven quality assessment and performance improvement program that complies with *6 CCR 1011-1*, Chapter II, Part 3. In addition, the hospice's governing body shall ensure that the program:

(A) Reflects the complexity of its organization and services;

(B) Involves all hospice services (including those services furnished under contract or arrangement);

(C) Focuses on indicators related to improved palliative outcomes, and

(D) Takes actions to demonstrate improvement in hospice performance.

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(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (quality assessment and performance improvement plan) for hospices to ensure that pain management (by reference) is an essential part of patient care.

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Madison, Wisconsin

COLORADO

REGULATIONS

Standards for Hospitals and Health Facilities

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (written plan of care) for hospices to ensure that pain management is an essential part of patient care.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (medical director) for hospices to ensure that pain management is an essential part of patient care.

6 CCR 1011-1 et seq

SECTION 6 PATIENT CARE SERVICES

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6.4 An individualized written plan of care shall be developed to reflect patient and family goals and interventions based on the problems identified in the initial, comprehensive and updated comprehensive assessments. The plan of care shall include all services necessary for the palliation and management of the terminal illness and include but not be limited to:

(A) Interventions to manage pain and symptoms;

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6.6 The interdisciplinary group (in collaboration with the individual's attending physician or nurse practitioner) shall review, revise and document the individualized plan as frequently as the patient's condition requires, but no less frequently than every 15 calendar days. A revised plan of care shall include information from the patient's updated comprehensive assessment and shall note the patient's progress toward outcomes and goals specified in the plan of care.

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6.8 Medical Director: The hospice shall designate a physician who shall act as medical director. The physician shall be a doctor of medicine or osteopathy who is an employee, or is under contract with the hospice, and has a current license in good standing to practice in the State of Colorado.

6.9 The medical director or physician designee shall be a member of the interdisciplinary group and be responsible for the medical component of the hospice's patient care program including, but not limited to, the following:

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(J) Approving written protocols for symptom control such as pain or nausea.

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(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (interdisciplinary group) for hospices to ensure that pain management (by reference) is an essential part of patient care.

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CONNECTICUT

STATUTES

- UNIFORM CONTROLLED SUBSTANCES ACT
  Title 21a. Consumer Protection; Chapter 420b. Dependency-Producing Drugs

- MEDICAL PRACTICE ACT
  Title 20. Professional and Occupational Licensing, Certification, Title Protection and Registration; Examining Boards; Chapter 370. Medicine and Surgery

- PHARMACY PRACTICE ACT (*No provisions found*)
  Title 20. Professional and Occupational Licensing, Certification, Title Protection and Registration; Examining Boards; Chapter 400j. Pharmacy

- INTRACTABLE PAIN TREATMENT ACT
  No policy found

REGULATIONS

- CONTROLLED SUBSTANCES REGULATIONS
  Title 21a. Consumer Protection; Department of Consumer Protection; Designation of Controlled Drugs

- MEDICAL BOARD REGULATIONS (*No provisions found*)
  Title 20. Professional Licenses; Connecticut Medical Examining Board

- Pharmacy Board Regulations (*No provisions found*)
  Title 20. Professional Licenses; Department of Consumer Protection; Practice of Pharmacy

OTHER GOVERNMENTAL POLICIES

- MEDICAL BOARD GUIDELINE
  Connecticut Medical Examining Board. *Statement of the Connecticut Medical Examining Board on the Use of Controlled Substances for the Treatment of Pain*. Adopted: June 21, 2005.

RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY KEY WORD SEARCHES

- HEALTH CARE INSTITUTIONS
  Title 19a. Health and Well-Being; Chapter 368v. Health Care Institutions.

- LICENSURE OF HOME HEALTH CARE AGENCIES
  Title 19. Health and Safety; Department of Public Health and Addiction Services; The Public Health Code of the State of Connecticut; Chapter IV. Hospitals, Child Day Care Centers, Other Institutions and Children's General Hospitals; Licensure of Home Health Care Agencies.

- SHORT-TERM HOSPITALS, SPECIAL, HOSPICE AND HOSPICE INPATIENT FACILITIES
  Title 19A. Public Health and Well-Being; Department of Public Health; Short-Term Hospitals, Special, Hospice and Hospice Inpatient Facilities.

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CONNECTICUT

STATUTES

Controlled Substances Act

Conn. Gen. Stat. § 21a-240

§ 21a-240. Definitions.

The following words and phrases, as used in this chapter, shall have the following meanings, unless the context otherwise requires:

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(43) "Practitioner" means: (A) A physician, dentist, veterinarian, podiatrist, scientific investigator or other person licensed, registered or otherwise permitted to distribute, dispense, conduct research with respect to or to administer a controlled substance in the course of professional practice or research in this state; (B) a pharmacy, hospital or other institution licensed, registered or otherwise permitted to distribute, dispense, conduct research with respect to or to administer a controlled substance in the course of professional practice or research in this state;

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(+) *CRITERION 3:*
Opioids are part of professional practice

Conn. Gen. Stat. § 21a-254

§ 21a-254. Designation of restricted drugs or substances by regulations. Records required by chapter. Establishment of electronic prescription drug monitoring program. Pharmacy and outpatient pharmacy controlled substance prescription reporting. Vendor collection of information. Confidentiality. Disclosure of information. Regulations.

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(j) (1) The commissioner shall, within available appropriations, establish an electronic prescription drug monitoring program to collect, by electronic means, prescription information for schedules II, III, IV and V controlled substances, as defined in subdivision (9) of *section 21a-240*, that are dispensed by pharmacies and outpatient pharmacies in hospitals or institutions. The program shall be designed to provide information regarding the prescription of controlled substances in order to prevent the improper or illegal use of the controlled substances and shall not infringe on the legitimate prescribing of a controlled substance by a prescribing practitioner acting in good faith and in the course of professional practice.

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(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT*:* Represents the principle of Balance, which states that the regulation of controlled substances should not interfere with legitimate medical use.

Conn. Gen. Stat. § 21a-254a

§ 21a-254a. Appointment of prescription drug monitoring working group. Membership.

The Commissioner of Consumer Protection shall appoint a prescription drug monitoring working group for the purpose of advising the commissioner on the implementation of the electronic prescription drug monitoring program established pursuant to *section 21a-254*, including the adoption of regulations by the commissioner. Such advice shall include, but not be limited to, recommendations on how to effectively use the data collected pursuant to such program to detect fraud while protecting the legitimate use of controlled substances. The working group shall include, but not be limited to: (1) A physician, licensed pursuant to chapter 370, specializing in internal medicine; (2) a board certified oncologist; (3) a person licensed to perform advanced level nursing practice activities pursuant to subsection (b) of *section 20-87a*; (4) a representative from an acute care hospital licensed pursuant to chapter 368v; (5) a state police officer appointed in accordance with *section 29-4*; (6) a municipal police chief; (7) a representative from the Division of Criminal Justice; (8) a representative from a hospice licensed by the Department of Public Health or certified pursuant to *42 USC 1395x*; (9) a pain management specialist, as defined in *section 38a-492i*; (10) a pharmacist licensed pursuant to *section 20-590*, *20-591* or *20-592*; and (11) a representative from the Department of Mental Health and Addiction Services.

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(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT*:* Establishes a mechanism (review by working group member who is a pain management specialist) to appropriately interpret prescription monitoring program information.

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CONNECTICUT

STATUTES

Medical Practice Act

Conn. Gen. Stat. § 20-14c

§ 20-14c. Dispensing and labeling of drugs. Definitions.

As used in this section and *sections 20-14d* to *20-14g*, inclusive, and *section 20-12d*:

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(3) "Prescribing practitioner" means a physician, dentist, podiatrist, optometrist, physician assistant, advanced practice registered nurse, nurse-midwife or veterinarian licensed by the state of Connecticut and authorized to prescribe medication within the scope of such person's practice.

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(+) *CRITERION 3:*
Opioids are part of professional practice

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REGULATIONS

Controlled Substances Regulations

Regs., Conn. State Agencies § 21a-326-1

Sec. 21a-326-1. Definitions

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(c) "Course of Professional Practice" means the limitation of prescribing, dispensing, or administering of controlled substances for professional treatment authorized pursuant to regulations and/or statutes of the appropriate state licensing authority under which situations there must be a bona fide practitioner-patient relationship. The prescribing or dispensing of controlled substances for patients, friends, relatives, associates, and/or employees wherein a bona fide practitioner-patient relationship does not exist or wherein the practitioner has not medically evaluated the need for controlled substances shall not be considered to be in the "course of professional practice."

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(e) "Therapeutic or Other Proper Medical or Scientific Purposes" means the following:

(1) The prescribing, dispensing, or administering of a controlled substance for treatment of a specific disease or medical condition, recognized by medical consensus and/or stated in the literature of the manufacturers of the controlled substances as being the purposes for which the controlled substance is intended.

(2) Investigational use of a controlled substance by a researcher or scientist wherein documentation of necessity of use of such controlled substances is maintained.

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(+) *CRITERION 3:*
Opioids are part of professional practice

(-) *CRITERION 12:*
Healthcare decisions are restricted

CATEGORY D:
Undue prescription limitations

COMMENT: Although physicians are not restricted under Federal law to FDA approved indications listed in the manufacturer's literature, it appears that "off label" prescribing of controlled substances would be outside "therapeutic or other proper medical or scientific purposes." Also, what constitutes a "medical consensus" and who determines this?

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CONNECTICUT

OTHER GOVERNMENTAL POLICY

Medical Board Guideline

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT*:* Recognizes that inadequate treatment of pain is subject to disciplinary action just as other substandard practices might be.

(+) *CRITERION 3:*
Opioids are part of professional practice

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Recognizes that the goal of pain treatment should include improvements in patient functioning and quality of life.

Statement of the Connecticut Medical Examining Board on the Use of Controlled Substances for the Treatment of Pain

Section I: Preamble
The Connecticut Medical Examining Board (Board) recognizes that principles of quality medical practice dictate that the people of the State of Connecticut have access to appropriate and effective pain relief. The purpose of this statement is to express the Board's support for the development and implementation of practices to assure the appropriate application of up-to-date knowledge and treatment modalities which can serve to improve the quality of life for those patients who suffer from pain as well as reduce the morbidity and costs associated with untreated or inappropriately treated pain. For the purposes of this Statement, the inappropriate treatment of pain includes nontreatment, undertreatment, overtreatment, and the continued use of ineffective treatments.

The diagnosis and treatment of pain is integral to the practice of medicine. Therefore, the Board encourages physicians to view pain management as a part of quality medical practice for all patients with pain, acute or chronic, and it is especially urgent for patients who experience pain in conjunction with terminal illness. All physicians and health care professionals should become knowledgeable about assessing patients' pain and effective methods of pain treatment, as well as statutory and regulatory requirements for prescribing controlled substances. Accordingly this Statement has been developed to encourage physicians to consider the importance of pain control, particularly as related to the use of controlled substances and to encourage comprehensive pain management.

The Board recognizes that applicable standards of care permit the use of controlled substances including opioid analgesics in the treatment of acute pain due to trauma or surgery and chronic pain, whether due to cancer or non-cancer origins. The Board also believes that physicians should be able to prescribe, dispense or administer controlled substances, including opioid analgesics, when done for a legitimate medical purpose and in accord with applicable standards of care and applicable law. The Board recognizes that the aim of current practice guidelines is to control the patient's pain while effectively addressing other aspects of the patient's functioning, including physical, psychological, social and work-related factors. Current practice guidelines accept that tolerance and physical dependence are normal consequences of sustained use of opioid analgesics and are not pathognomonic of addiction.

The Board acknowledges the medical community's view that the goals of effective pain management include (i) pain is to be assessed and treated promptly; (ii) the amount of medication and frequency of dosing adjusted according to the intensity, duration of the pain, and treatment outcomes; (iii) consideration of current clinical knowledge and scientific research; and (iv) the use of pharmacologic and non-pharmacologic modalities.

(CONTINUED ON NEXT PAGE)

(+) *CRITERION 2:*
Pain management is part of healthcare practice

(+) *CRITERION 4:*
Encourages pain management

(+) *CRITERION 7:*
Physical dependence or analgesic tolerance are not confused with "addiction"

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OTHER GOVERNMENTAL POLICY

Medical Board Guideline

(CONTINUED)

The Board is obligated under the laws of the State of Connecticut to protect the public health and safety. Connecticut law reflects the public policy that the use of opioid analgesics for other than legitimate medical purposes poses a threat to the individual and society and that the inappropriate prescribing of controlled substances, including opioid analgesics, may lead to drug diversion and abuse by individuals who seek them for other than legitimate medical use. Accordingly, current practice guidelines also note that effective pain management incorporates safeguards into the practice to minimize the potential for the abuse and diversion of controlled substances such as periodic reviews and written agreements outlining patient responsibility. However, physicians may face serious questions as to the legitimate medical purpose of a prescription where no physician-patient relationship exists or the prescription is not based on a diagnosis and clear documentation of pain.

As in all proceedings, matters involving issues of pain management will be reviewed and decided on a case-by-case basis. The Board may consider clinical practice guidelines, expert opinions, witness testimony, medical records and other relevant evidence. In accord with its case-by-case approach to such cases, the Board may not judge the validity of treatment solely on the quantity and duration of medication administration; may take into account whether the drug used is appropriate for the diagnosis as well as the outcome of pain treatment including improvement in patient functioning and/or quality of life; and will not assume that all types of pain can be completely relieved.

(+) *CRITERION 6:*
Prescription amount alone does not determine legitimacy

Section II: Treatment of Pain Practices
The Board recognizes that the medical community has encouraged the following practices as appropriate for the treatment of pain, including the use of controlled substances:

1. Evaluation of the Patient
A medical history and physical examination must be obtained, evaluated, and documented in the medical record. The medical record should document the nature and intensity of the pain, current and past treatments for pain, underlying or coexisting diseases or conditions, the effect of the pain on physical and psychological function, and history of substance abuse. The medical record also should document the presence of one or more recognized medical indications for the use of a controlled substance.

2. Treatment Plan
The written treatment plan should state objectives that will be used to determine treatment success, such as pain relief and improved physical and psychosocial function, and should indicate if any further diagnostic evaluations or other treatments are planned. After treatment begins, the physician should adjust drug therapy to the individual medical needs of each patient. Other treatment modalities or a rehabilitation program may be necessary depending on the etiology of the pain and the extent to which the pain is associated with physical and psychosocial impairment.

3. Informed Consent and Agreement for Treatment
The physician should discuss the risks and benefits of the use of controlled substances with the patient, persons designated by the patient or with the patient's surrogate or guardian if the patient is without medical decision-making capacity. The patient should receive prescriptions from one physician and one pharmacy whenever possible. If the patient is at high risk for medication abuse or has a history of substance abuse, the physician should consider the use of a written agreement between physician and patient outlining patient responsibilities, including

- urine/serum medication levels screening when requested;
- number and frequency of all prescription refills; and
- reasons for which drug therapy may be discontinued (e.g., violation of agreement).

(CONTINUED ON NEXT PAGE)

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Encourages healthcare professionals to incorporate in their practice the evaluations of, and discussions with patients about, the potential benefits and risks of treatment with opioids, which can better ensure a clinical indication of such treatment so that opioids will be used for medical purposes.

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Madison, Wisconsin

CONNECTICUT

OTHER GOVERNMENTAL POLICY

Medical Board Guideline

(CONTINUED)

4. Periodic Review
The physician should periodically review the course of pain treatment and any new information about the etiology of the pain or the patient's state of health. Continuation or modification of controlled substances for pain management therapy depends on the physician's evaluation of progress toward treatment objectives. Satisfactory response to treatment may be indicated by the patient's decreased pain, increased level of function, or improved quality of life. Objective evidence of improved or diminished function should be monitored and information from family members or other caregivers may be considered in determining the patient's response to treatment. If the patient's progress is unsatisfactory, the physician should assess the appropriateness of continued use of the current treatment plan and consider the use of other therapeutic modalities.

5. Consultation
The physician should be willing to refer the patient as necessary for additional evaluation and treatment in order to achieve treatment objectives. Special attention should be given to those patients with pain who are at risk for medication misuse or diversion. The management of pain in patients with a history of substance abuse or with a comorbid psychiatric disorder may require extra care, monitoring, documentation and consultation with or referral to an expert in the management of such patients.

6. Medical Records
The physician should keep accurate and complete records to include

- the medical history and physical examination;
- diagnostic, therapeutic and laboratory results;
- evaluations and consultations;
- treatment objectives;
- discussion of risks and benefits;
- informed consent;
- treatments;
- patient response to treatments;
- medications (including date, type, dosage and quantity prescribed);
- instructions and agreements; and
- periodic reviews.

Records should remain current and be maintained in an accessible manner and readily available for review.

7. Compliance With Controlled Substances Laws and Regulations
To prescribe, dispense or administer controlled substances, the physician must be licensed in Connecticut and comply with applicable federal and state regulations. Physicians are referred to the Physicians Manual of the U.S. Drug Enforcement Administration for specific rules governing controlled substances as well as applicable state statutes and regulations.

(CONTINUED ON NEXT PAGE)

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT*:* Encourages healthcare professionals to understand and follow federal and state laws governing their practice, which can better ensure that practitioners follow the *balanced* approach represented by federal law and the laws in many states.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY B:
Issues related to patients

COMMENT*:*
Acknowledges that a patient's prior history or current status of drug abuse does not necessarily contraindicate appropriate pain management.

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Madison, Wisconsin

CONNECTICUT

OTHER GOVERNMENTAL POLICY

Medical Board Guideline

(CONTINUED)

Section III: Definitions
For the purposes of this statement, the following terms are defined as follows:

Acute Pain
Acute pain is the normal, predicted physiological response to a noxious chemical, thermal or mechanical stimulus and typically is associated with invasive procedures, trauma and disease. It is generally time-limited.

Addiction
Addiction is a primary, chronic, neurobiologic disease, with genetic, psychosocial, and environmental factors influencing its development and manifestations. It is characterized by behaviors that include the following: impaired control over drug use, craving, compulsive use, and continued use despite harm. Physical dependence and tolerance are normal physiological consequences of extended opioid therapy for pain and are not the same as addiction.

Chronic Pain
Chronic pain is a state in which pain persists beyond the usual course of an acute disease or healing of an injury, or that may or may not be associated with an acute or chronic pathologic process that causes continuous or intermittent pain over months or years.

Pain
An unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage.

Physical Dependence
Physical dependence is a state of adaptation that is manifested by drug class specific signs and symptoms that can be produced by abrupt cessation, rapid dose reduction, decreasing blood level of the drug, and/or administration of an antagonist. Physical dependence, by itself, does not equate with addiction.

Substance Abuse
Substance abuse is the use of any substance(s) for non-therapeutic purposes or use of medication for purposes other than those for which it is prescribed.

Tolerance
Tolerance is a physiologic state resulting from regular use of a drug in which an increased dosage is needed to produce a specific effect, or a reduced effect is observed with a constant dose over time. Tolerance may or may not be evident during opioid treatment and does not equate with addiction.

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Madison, Wisconsin

CONNECTICUT

STATUTES

Health Care Institutions

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (training requirements) for health care institutions to ensure that pain management is an essential part of care of patients with Alzheimer's disease.

Conn. Gen. Stat. § 19a-562a

Sec. 19a-562a. Pain recognition and management training requirements for nursing home facility staff. Staff training requirements for Alzheimer's special care units or programs.

(a) Each nursing home facility that is not a residential care home or an Alzheimer's special care unit or program shall annually provide a minimum of two hours of training in pain recognition and administration of pain management techniques to all licensed and registered direct care staff and nurse's aides who provide direct patient care to residents.

(b) Each Alzheimer's special care unit or program shall annually provide Alzheimer's and dementia specific training to all licensed and registered direct care staff and nurse's aides who provide direct patient care to residents enrolled in the Alzheimer's special care unit or program. Such requirements shall include, but not be limited to, (1) not less than eight hours of dementia-specific training, which shall be completed not later than six months after the date of employment and not less than eight hours of such training annually thereafter, and (2) annual training of not less than two hours in pain recognition and administration of pain management techniques for direct care staff.

(c) Each Alzheimer's special care unit or program shall annually provide a minimum of one hour of Alzheimer's and dementia specific training to all unlicensed and unregistered staff, except nurse's aides, who provide services and care to residents enrolled in the Alzheimer's special care unit or program. For such staff hired on or after October 1, 2007, such training shall be completed not later than six months after the date of employment.

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CONNECTICUT

REGULATIONS

Licensure of Home Health Care Agencies

Regs., Conn. State Agencies § 19-13-D72

Sec. 19-13-D72. Patient care policies

(a) General Program Policies. An agency shall have written policies governing referrals received, admission of patients to agency services, delivery of such services and discharge of patients. Such policies shall cover all services provided by the agency, directly or under contract. A copy shall be readily available to patients and staff and shall include but not be limited to:

(B) An agency shall develop and implement written policies and procedures for all hospice services provided which include:

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(iii) Procedures for the provision of care and services to the patient family including advising the patient or legal representative of the nature of the palliative care offered. Palliative care includes pain control, symptom management, quality of life enhancement and spiritual and emotional comfort for patients and their caregivers; the patient's needs are continuously assessed and all treatment options are explored and evaluated in the context of the patient's values and symptoms;

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(vii) For hospice employees, six hours of the annual in-service education requirements in accordance with Section 19-13-D71(a)(2) of these regulations shall address topics related to hospice care. The agency shall ensure, as part of its coordination of inpatient care agreement with an inpatient setting, that all direct service staff receive in-service education including two hours specific to hospice care. The inservice education shall include current information regarding drugs and treatments, specific service procedures and techniques, pain and symptom management, psychosocial and spiritual aspects of care, interdisciplinary team approach to care, bereavement care, acceptable professional standards, and criteria and classification of clients served;

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(iii) The medical director's responsibilities shall include, but not be limited to:

II. Consultation with attending physicians regarding pain and symptom control and medical management as appropriate.

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(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (written policies and procedures) for hospices to ensure that pain management is an essential part of patient care.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (education requirement) for hospices to ensure that pain management is an essential part of patient care.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a responsibility for hospices to ensure that pain management is an essential part of patient care.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (consultation responsibilities) for hospices to ensure that pain management is an essential part of patient care.

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CONNECTICUT

REGULATIONS

Short-Term Hospitals, Special, Hospice and Hospice Inpatient Facilities

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT*:* Establishes a mechanism (written policies and procedures) for healthcare facilities to ensure that pain management is an essential part of patient care.

Regs., Conn. State Agencies § 19a-495-6e

Sec. 19a-495-6e. General requirements

(a) Core services provided directly by the licensee shall, except as provided in subsection (b) of this section, include the following:
(1) Services of a physician or advanced practice registered nurse;
(2) Nursing services provided by a registered nurse, or licensed practical nurse;
(3) Social services;
(4) Counseling services if required;
(5) Pain assessment and management; and

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(f) The licensee shall ensure the continuity of patient and family care through adoption and implementation of written policies, procedures and criteria providing for the following:
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(9) Management of pain and symptom control through palliative care and utilization of therapeutic services; and
(10) Constraints imposed by limitations of services or family conditions and such other criteria as may be deemed appropriate for each patient and family.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT*:* Establishes a responsibility for healthcare facilities to ensure that pain management is an essential part of patient care.

Regs., Conn. State Agencies § 19a-495-6h

Sec. 19a-495-6h. Patient rights and hospice inpatient facility responsibilities

(a) The licensee shall have a written bill of rights and responsibilities governing services, which shall be provided and explained to each patient, family or representative at the time of admission. The medical record of each patient shall contain documentation of compliance with this provision.
(1) The patient's rights and responsibilities shall include, but are not limited to:
(A) Be afforded considerate and respectful care;
(B) Receive effective pain management and symptom control on a twenty-four hour basis for the palliation and management of the terminal illness and related conditions;

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(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT*:* Establishes a mechanism (statement of resident rights) for healthcare facilities to ensure that pain management is an essential part of patient care.

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CONNECTICUT

REGULATIONS

Short-Term Hospitals, Special, Hospice and Hospice Inpatient Facilities

Regs., Conn. State Agencies § 19a-495-6i

Sec. 19a-495-6i. Quality assessment and performance improvement

(a) The licensee shall implement the quality assessment and performance improvement program established by the governing authority that includes all patient care disciplines and services provided, including those services provided by a contractor, throughout the hospice inpatient facility. The governing authority shall ensure that the program reflects the complexity of its organization and services, involves leadership working with input from facility staff, patients and families, involves all hospice inpatient facility services including those furnished under contract or arrangement, focuses on performance indicators to monitor a wide range of care processes and outcomes related to palliative care, and initiates actions to demonstrate improvement in hospice inpatient facility performance and promote sustained improvement.

(b) Such plan and program shall be ongoing and shall include:
(1) Oversight responsibility and program objectives;
(2) The use of quality indicator data to assess and monitor patient care and services;
(3) Evidenced based practices and policies for:
(A) Pain and symptom management;

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Regs., Conn. State Agencies § 19a-495-6j

Sec. 19a-495-6j. Assessment and patient centered plan of care

(a) At the time of admission, an initial assessment shall be completed by a licensed registered nurse to identify and meet the immediate needs of the patient. Within forty-eight hours of a patient's admission, a licensed registered nurse shall complete the assessment to evaluate the patient's immediate physical, psychosocial, emotional, and spiritual status.

(b) Not later than five days after a patient's admission to the hospice inpatient facility, the interdisciplinary team shall complete a comprehensive assessment for the patient that shall include but not be limited to the following:
(1) History of pain, symptoms, and treatment;
(2) Characteristics of pain and symptoms;

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(h) The patient centered plan of care shall include, but not be limited to:
(1) Pertinent diagnosis and prognosis;
(2) Interventions to facilitate the management of pain and other symptoms;
(3) Measurable targeted outcomes anticipated from implementing and coordinating the patient centered plan of care;
(4) A detailed statement of the patient and family needs addressing the:
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(G) Management of pain and control of other symptoms; and

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(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (quality assessment and performance improvement program) for healthcare facilities to ensure that pain management is an essential part of patient care.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (assessment by interdisciplinary team) for healthcare facilities to ensure that pain management is an essential part of patient care.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (plan of care) for healthcare facilities to ensure that pain management is an essential part of patient care.

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Madison, Wisconsin

DELAWARE

STATUTES

- CONTROLLED SUBSTANCES ACT
  Title 16. Health and Safety; Part IV. Food and Drugs; Chapter 47. Uniform Controlled Substances Act

- MEDICAL PRACTICE ACT
  Title 24. Professions and Occupations; Chapter 17. Medical Practice Act

- PHARMACY PRACTICE ACT
  Title 24. Professions and Occupations; Chapter 25. Pharmacy

- INTRACTABLE PAIN TREATMENT ACT
  No policy found

REGULATIONS

- CONTROLLED SUBSTANCES REGULATIONS
  Agency 24. Regulated Professions and Occupations; Sub-Agency. Department of State; Division of Professional Regulation; Chapter 0001. Controlled Substance Advisory Committee; Uniform Controlled Substances Act Regulations

- MEDICAL BOARD REGULATIONS
  Agency 24. Regulated Professions and Occupations; Sub-Agency. Department of State; Division of Professional Regulation; Chapter 1700. Board of Medical Licensure and Discipline; Rules and Regulations

- PHARMACY BOARD REGULATIONS (*No provisions found*)
  Agency 24. Regulated Professions and Occupations; Sub-Agency. Department of State; Division of Professional Regulation; Chapter 2500. Board of Pharmacy; Rules and Regulations

OTHER GOVERNMENTAL POLICIES

No policies found

RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES

- DELIVERY OF HOSPICE SERVICES
  Agency 16. Department of Health and Social Services; Sub-Agency 4000. Division of Public Health; Health Systems Protection (4400); Chapter 4468. Delivery of Hospice Services

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Madison, Wisconsin

DELAWARE

STATUTES

Controlled Substances Act

16 Del. C. § 4701

§ 4701. Definitions

As used in this chapter:

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(35) "Practitioner" means:

a. A physician, dentist, veterinarian, scientific investigator or other person licensed, registered or otherwise permitted to distribute, dispense, conduct research with respect to or to administer a controlled substance in the course of professional practice or research in this State.

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16 Del. C. § 4798

§ 4798. The Delaware Prescription Monitoring Program

(a) It is the intent of the General Assembly that the Delaware Prescription Monitoring Act established pursuant to this section serves as a means to promote public health and welfare and to detect the illegal use of controlled substances. The Delaware Prescription Monitoring Act shall have the dual purpose of reducing misuse and diversion of controlled substances in the State while promoting improved professional practice and patient care.

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(c) The Office of Controlled Substances shall establish and maintain a PMP program to monitor the prescribing and dispensing of all Schedule II, III, IV and V controlled substances by prescribers in this State, and to research the prescribing and dispensing of drugs of concern. The PMP shall not interfere with the legal use of a controlled substance or drug of concern. The PMP shall be:

(1) Used to provide information to prescribers, dispensers, and patients to help avoid the illegal use of controlled substances;

(2) Used to assist law enforcement to investigate illegal activity related to the prescribing, dispensing and consumption of controlled substances or drugs of concern; and

(3) Designed to minimize inconvenience to patients and prescribing medical practitioners while effectuating the collection and storage of prescription monitoring information.

(+) *CRITERION 3:*
Opioids are part of professional practice

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Represents the principle of Balance, which states that the regulation of controlled substances should not interfere with legitimate medical use.

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Madison, Wisconsin

DELAWARE

STATUTES

Medical Practice Act

24 Del. C. § 1702

§ 1702. Definitions

The following definitions apply to this chapter unless otherwise expressly stated or implied by the context.

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(9) "Practice of medicine" or "practice medicine" includes:

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c. Offering or undertaking to prevent or to diagnose, correct, and/or treat in any manner or by any means, methods, or devices a disease, illness, pain, wound, fracture, infirmity, defect, or abnormal physical or mental condition of another person, including the management of pregnancy and parturition;

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(+) CRITERION 2:
Pain management is part of healthcare practice

STATUTES

Pharmacy Practice Act

24 Del. C. § 2502

§ 2502. Definitions as used in this chapter

The following words, terms, and phrases when used in this chapter have the meanings ascribed to them in this section, except where the context clearly indicates a different meaning.

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(20) "Practitioner" or "prescriber" means any person who is authorized by law to prescribe drugs in the course of professional practice or research in any State.

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(+) CRITERION 3:
Opioids are part of professional practice

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DELAWARE

REGULATIONS

Controlled Substances Regulations

CDR 16-4000-4426

4.0 Prescriptions

4.1 Definitions. As used in this section:

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4.1.2 The term "practitioner" means physician, dentist, veterinarian, podiatrist, nurse practitioner, physician assistant or other individual, licensed, registered, or otherwise permitted, by the United States or the State of Delaware to prescribe, dispense or store a controlled substance in the course of professional practice but does not include a pharmacist, a pharmacy, or an institutional practitioner.

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CDR 16-4000-4426

4.8 Expiration of Prescription.

4.8.1 Prescriptions for controlled substances in Schedules II and III will become void unless dispensed within seven (7) days of the original date of the prescription or if the original prescriber authorizes the prescription past the seven (7) days period. Such prescriptions cannot be written nor dispensed for more than 100 dosage units or a 31 day supply whatever is the greater at one time. As an exception to dosage limitations set forth in this subparagraph, and in accordance with 21 C.F.R. Section 1306.1(b), prescriptions for controlled substances in Schedule II for patients either having a medically documented terminal illness or patients in Long Term Facilities (LTCF), may be filled in partial quantities, to include individual dosage units. For each partial filling, the dispensing pharmacist shall record on the back of the prescription (or another appropriate record, uniformly maintained, and readily retrievable) the date of the partial filling, quantity dispensed, remaining quantity authorized to be dispensed and the identification of the dispensing pharmacist. The total quantity of Schedule II controlled substances dispensed in all partial fillings must not exceed the total quantity prescribed.

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(+) *CRITERION 3:*
Opioids are part of professional practice

(-) *CRITERION 13:*
Length of prescription validity is restricted

2013

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Madison, Wisconsin

DELAWARE

REGULATIONS

Medical Board Regulations

CDR 24-1700

CHAPTER 1700. BOARD OF MEDICAL LICENSURE AND DISCIPLINE; RULES AND REGULATIONS

Section 18.0 Use of Controlled Substances for the Treatment of Pain: Purpose.

The Board has adopted the Federation of State Medical Board's "Model Policy for the Use of Controlled Substances for the Treatment of Pain" ("Model Policy). These regulations have been developed to define specific requirements applicable to pain control, particularly related to the use of controlled substances, to alleviate licensed practitioners' uncertainty, to encourage better pain management, and to minimize practices that deviate from the appropriate standard of care and lead to abuse and diversion. Licensed practitioners should familiarize themselves with the Model Policy available online at www.dpr.delaware.gov. To the extent there are any inconsistencies between these regulations and the Model Policy, these regulations shall control.

The principles of quality medical practice dictate that citizens of Delaware have access to appropriate and effective pain relief. The appropriate application of up-to-date knowledge and treatment modalities can serve to improve the quality of life for those patients who suffer from pain as well as reduce the morbidity and costs associated with untreated or inappropriately treated pain. The inappropriate treatment of pain includes a wide spectrum of issues that do not provide treatment appropriate to the patients' specific needs.

The diagnosis and treatment of pain is integral to the practice of medicine. Licensed practitioners view pain management as a part of quality medical practice for all patients with pain, acute or chronic, and it is especially urgent for patients who experience pain as a result of terminal illness. Licensed practitioners should become knowledgeable about assessing patients' pain and effective methods of pain treatment, as well as statutory requirements for prescribing controlled substances. These regulations are primarily directed to the treatment of chronic pain but may be applicable to prescribing controlled substances for the treatment of acute pain when clinically appropriate.

Inappropriate pain treatment may result from the practitioner's lack of knowledge about pain management. Fears of investigation or sanction by federal, state and local agencies may also result in inappropriate treatment of pain. Appropriate pain management is the treating practitioner's responsibility. As such, the Board will consider the inappropriate treatment of pain to be a departure from standards of practice and will investigate such allegations, recognizing that some types of pain cannot be completely relieved, and taking into account whether the treatment is appropriate for the diagnosis.

The Board recognizes that controlled substances including opioid analgesics may be essential in the treatment of acute pain due to trauma or surgery and chronic pain, whether due to cancer or non-cancer origins. The Board may refer to current clinical practice guidelines and/or expert review in approaching cases involving the management of pain. The medical management of pain should consider current clinical knowledge and scientific research and the use of pharmacologic and non-pharmacologic modalities according to the judgment of the licensed practitioner. Pain should be assessed and treated promptly, and the quantity and frequency of doses should be adjusted according to the intensity, duration of the pain, and treatment outcomes. Licensed practitioners should recognize that tolerance and physical dependence are normal consequences of sustained use of opioid analgesics and alone are not the same as addiction.

The Board recognizes that the use of opioid analgesics for other than legitimate medical purposes can pose a threat to the individual and society and that the inappropriate prescribing of controlled substances, including opioid analgesics, may lead to drug diversion and abuse by individuals who seek them for other than legitimate medical use. Accordingly, these regulations mandate that licensed practitioners incorporate safeguards into their practices to minimize the potential for the abuse and diversion of controlled substances.

(CONTINUED ON NEXT PAGE)

(+) *CRITERION 4:*
Encourages pain management

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Identifies the potential impact of important barriers on the provision of effective pain care.

(+) *CRITERION 2:*
Pain management is part of healthcare practice

(+) *CRITERION 7:*
Physical dependence or analgesic tolerance are not confused with "addiction"

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DELAWARE

REGULATIONS

Medical Board Regulations

[CONTINUED]

Licensed practitioners should not fear disciplinary action from the Board for ordering, prescribing, dispensing or administering controlled substances, including opioid analgesics, for a legitimate medical purpose and in the course of professional practice. The Board will consider prescribing, ordering, dispensing or administering controlled substances for pain to be for a legitimate medical purpose if based on sound clinical judgment. All such prescribing must be based on clear documentation of unrelieved pain. To be within the usual course of professional practice, a licensed practitioner-patient relationship must exist and the prescribing should be based on a diagnosis and documentation of unrelieved pain. Compliance with applicable state or federal law is required.

The Board will judge the validity of the licensed practitioner's treatment of the patient based on available documentation, rather than solely on the quantity and duration of medication administration. The goal is to control the patient's pain while effectively addressing other aspects of the patient's functioning, including physical, psychological, social and work-related factors.

Allegations of inappropriate pain management will be evaluated on an individual basis. The Board will take disciplinary action against a licensed practitioner for deviating from these regulations unless contemporaneous medical records document reasonable cause for deviation. The practitioner's conduct will be evaluated to a great extent by the outcome of pain treatment, recognizing that some types of pain cannot be completely relieved, and by taking into account whether the drug used is appropriate for the diagnosis, as well as improvement in patient functioning and/or quality of life.

18.1 The following criteria must be used when evaluating the treatment of chronic pain but may be applicable to prescribing controlled substances for the treatment of acute pain when clinically appropriate:

18.1.1 Evaluation of the Patient- A medical history and physical examination must be obtained, evaluated, and documented in the medical record. The evaluation must document:

18.1.1.1 etiology, the nature and intensity of the pain, current and past treatments for pain,

18.1.1.2 underlying or coexisting diseases or conditions,

18.1.1.3 the effect of the pain on physical and psychological function, and history of substance abuse,

18.1.1.4 the presence of one or more recognized medical indications for the use of a controlled substance.

18.2 Treatment Plan- A written treatment plan is required and must state goals and objectives that will be used to determine treatment success, such as pain relief and improved physical and psychosocial function, and should indicate if any further diagnostic evaluations or other treatments are planned. The treatment plan must address whether treatment modalities or a rehabilitation program are necessary depending on the etiology of the pain and the extent to which the pain is associated with physical and psychosocial impairment. After treatment begins, the practitioner must adjust drug therapy to the individual medical needs of each patient.

18.3 Informed Consent - The practitioner must discuss the risks and benefits of the use of controlled substances with the patient, persons designated by the patient or with the patient's surrogate or guardian if the patient is without medical decision-making capacity.

(CONTINUED ON NEXT PAGE)

(+) *CRITERION 5:*
Addresses fear of regulatory scrutiny

(+) *CRITERION 6:*
Prescription amount alone does not determine legitimacy

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Acknowledges the need for treatment flexibility for physicians to respond to individual clinical circumstances, as long as their prescribing maintains the standards of good medical practice.

(+) *CRITERION 3:*
Opioids are part of professional practice

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Recognizes that the goal of pain treatment should include improvements in patient functioning and quality of life.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Encourages healthcare professionals to incorporate in their practice the evaluations of, and discussions with patients about, the potential benefits and risks of treatment with opioids, which can better ensure a clinical indication of such treatment so that opioids will be used for medical purposes.

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Madison, Wisconsin

DELAWARE

REGULATIONS

Medical Board Regulations

[CONTINUED]

18.4 Agreement for Treatment- If the patient is at high risk for medication abuse or has a history of substance abuse, the practitioner must use a written agreement between the practitioner and patient outlining patient responsibilities, including;

18.4.1 urine/serum medication levels screening when requested;

18.4.2 number and frequency of all prescription refills; and

18.4.3 reasons for which drug therapy may be discontinued (e.g., violation of agreement).

18.4.4 a requirement that the patient receive prescriptions from one licensed practitioner and one pharmacy where possible.

18.5 Periodic Review- The licensed practitioner shall periodically review the course of pain treatment and any new information about the etiology of the pain or the patient's state of health. Periodic review shall include, at a minimum, evaluation of the following:

18.5.1 continuation or modification of controlled substances for pain management therapy depending on the practitioner's evaluation of the patient's progress toward treatment goals and objectives.

18.5.2 satisfactory response to treatment as indicated by the patient's decreased pain, increased level of function, or improved quality of life. Objective evidence of improved or diminished function must be monitored and information from family members or other caregivers should be considered in determining the patient's response to treatment.

18.5.3 if the patient's progress is unsatisfactory, the practitioner shall assess the appropriateness of continued use of the current treatment plan and consider the use of other therapeutic modalities.

18.6 Consultation- The practitioner shall refer the patient as necessary for additional evaluation and treatment in order to achieve treatment objectives. Special attention must be given to those patients with pain who are at risk for medication misuse, abuse or diversion. The management of pain in patients with a history of substance abuse or with a co-morbid psychiatric disorder requires extra care, monitoring, documentation and may require consultation with or referral to an expert in the management of such patients. At a minimum, practitioners who regularly treat patients for chronic pain must educate themselves about the current standards of care applicable to those patients.

18.7 Medical Records- The practitioner shall keep accurate and complete records. The entire record must, include the:

18.7.1 medical history and physical examination,

18.7.2 diagnostic, therapeutic and laboratory results,

18.7.3 evaluations and consultations,

18.7.4 documentation of etiology;

18.7.5 treatment objectives,

18.7.6 discussion of risks and benefits,

18.7.7 informed consent,

18.7.8 treatments,

18.7.9 medications (including date, type, dosage and quantity prescribed),

18.7.10 instructions and agreements, and

18.7.11 periodic review.

(CONTINUED ON NEXT PAGE)

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY B:
Issues related to patients

COMMENT:
Acknowledges that a patient's prior history or current status of drug abuse does not necessarily contraindicate appropriate pain management.

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DELAWARE

REGULATIONS

Medical Board Regulations

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Encourages healthcare professionals to understand and follow federal and state laws governing their practice, which can better ensure that practitioners follow the *balanced* approach represented by federal law and the laws in many states.

[CONTINUED]

18.8 Records should remain current and be maintained in an accessible manner and readily available for review. Each practitioner should include documentation appropriate for each visit's level of care and will include the:

18.8.1 interim history and physical examination,

18.8.2 vital signs as clinically relevant,

18.8.3 assessment of progress, and

18.8.4 medication plan.

18.9 Compliance with Controlled Substances Laws and Regulations- To prescribe, dispense or administer controlled substances, the practitioner must be licensed in the state and comply with all applicable federal and state regulations. Licensed practitioners are referred to the Practitioner's Manual of the U.S. Drug Enforcement Administration and specific rules governing controlled substances as well as applicable state regulations.

18.10 The following terms are defined as follows:

18.10.1 Acute Pain- Acute pain is the normal, predicted physiological response to a noxious chemical, thermal or mechanical stimulus and typically is associated with invasive procedures, trauma and disease. It is generally time-limited.

18.10.2 Addiction- Addiction is a primary, chronic, neurobiologic disease, with genetic, psychosocial, and environmental factors influencing its development and manifestations. It is characterized by behaviors that include the following: impaired control over drug use, craving, compulsive use, and continued use despite harm. Physical dependence and tolerance are normal physiological consequences of extended opioid therapy for pain and are not the same as addiction.

18.10.3 Chronic Pain- Chronic pain is a state in which pain persists beyond the usual course of an acute disease or healing of an injury, or that may or may not be associated with an acute or chronic pathologic process that causes continuous or intermittent pain over months or years.

18.10.4 Licensed Practitioner - Licensed practitioner means those licensed individuals with prescriptive authority regulated under the Medical Practice Act including, but not limited to, physicians, physician assistants and nurse practitioners, except as exempted by *16 Del.C. §4798(b)(9)*.

18.10.5 Pain- An unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage.

18.10.6 Physical Dependence- Physical dependence is a state of adaptation that is manifested by drug class-specific signs and symptoms that can be produced by abrupt cessation, rapid dose reduction, decreasing blood level of the drug, and/or administration of an antagonist. Physical dependence, by itself, does not equate with addiction.

18.10.7 Pseudo addiction- The iatrogenic syndrome resulting from the misinterpretation of relief seeking behaviors as though they are drug-seeking behaviors that are commonly seen with addiction. The relief seeking behaviors resolve upon institution of effective analgesic therapy.

18.10.8 Substance Abuse- Substance abuse is the use of any substance(s) for non-therapeutic purposes or use of medication for purposes other than those for which it is prescribed.

18.10.9 Tolerance- Tolerance is a physiologic state resulting from regular use of a drug in which an increased dosage is needed to produce a specific effect, or a reduced effect is observed with a constant dose over time. Tolerance may or may not be evident during opioid treatment and does not equate with addiction.

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DELAWARE

REGULATIONS

Delivery of Hospice Services

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (interdisciplinary team) for hospices to ensure that pain management is an essential part of patient care.

CDR 16-4000-4468

16 4000 4468. DELIVERY OF HOSPICE SERVICES

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3.0 Hospice Care

3.1 Hospice is an option for care which utilizes an interdisciplinary team of the patient's choice. The team shall consist of at least a physician, nurse, social worker, clergy, trained volunteer, and the patient/family.

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3.3 The interdisciplinary team shall have the following responsibilities:

3.3.1 Perform an admission history which includes medical, social, spiritual, emotional aspects of the patient/family.

3.3.2 Develop the care plan for each patient/family. The patient care coordinator will be responsible for assuring the implementation and ongoing review of the care plan.

3.3.3 Hold an interdisciplinary care team meeting at least semimonthly or more often if needed to review and update the care plan.

3.3.4 Emphasize prevention and control of pain and other distressing symptoms.

3.3.5 Make provision for 24 hours per day, seven days a week coverage.

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DISTRICT OF COLUMBIA

STATUTES

- CONTROLLED SUBSTANCES ACT
  Division VIII. General Laws; Title 48. Food and Drugs;
  Subtitle II. Prescription Drugs
  Subtitle III. Illegal Drugs; Chapter 9. Controlled Substances

- PROFESSIONAL PRACTICE ACT (*Relevant to both Medicine and Pharmacy*)
  Division I: Government of District; Title 3. District of Columbia Boards and Commissions;
  Subtitle 1. General; Chapter 12. Health Occupations Boards

- INTRACTABLE PAIN TREATMENT ACT
  No policy found

REGULATIONS

- CONTROLLED SUBSTANCES REGULATIONS
  Title 22. Public Health and Medicine; Subtitle B. Health
  Chapter 12. Controlled Substances Act Rules
  Chapter 13. Prescriptions and Distribution

- MEDICAL BOARD REGULATIONS
  Title 17. Business, Occupations, and Professions; Chapter 46. Medicine

- PHARMACY BOARD REGULATIONS (*No provisions found*)
  Title 17. Business, Occupations, and Professions; Chapter 65. Pharmacists

OTHER GOVERNMENTAL POLICIES

No policies found

RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY KEY WORD SEARCHES

- PROTECTION AND CARE SYSTEMS
  Division I. Government of District; Title 7. Human Health Care and Safety;
  Subtitle I. Protection and Care Systems

- Nursing Home Administration
  Title 17. Business, Occupations and Professions; Chapter 62. Nursing Home Administration

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Madison, Wisconsin

DISTRICT OF COLUMBIA

STATUTES

Controlled Substances Act

D.C. Code § 48-901.02

§ 48-901.02. Definitions

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(20) "Practitioner" means:

(A) A physician, dentist, advanced practice registered nurse, veterinarian, scientific investigator, or other person licensed, registered, or otherwise permitted to distribute, dispense, conduct research with respect to, or to administer a controlled substance in the course of professional practice or research in the District of Columbia; or.

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(+) *CRITERION 3:*
Opioids are part of professional practice

STATUTES

Health Occupations Boards Act

D.C. Code § 3-1205.10

§ 3-1205.10. Term and renewal of licenses, registrations, or certifications

(a) A license, registration, or certification expires 1 year from the date of its first issuance or renewal unless renewed by the board that issued it as provided in this section, except that the Mayor, by rule, may provide for a period of licensure, registration, or certification of not more than 3 years.

(b) The Mayor may establish by rule continuing education requirements as a condition for renewal of licenses, registrations, or certifications under this section; provided, that the Mayor shall:

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(3) Establish continuing education requirements for nursing home administrators that include instruction on one or more of the following topics:

(A) Staff management;

(B) Continuity in assigning the same nursing staff to the same residents as often as practicable;

(C) Creating a resident-centered environment;

(D) Activities of daily living and instrumental activities of daily living;

(E) Wound care;

(F) Pain management;

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(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (continuing education) for nursing home administrators to ensure that pain management is an essential part of patient care.

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DISTRICT OF COLUMBIA

REGULATIONS

Controlled Substances Regulations

(+) *CRITERION 3:*
Opioids are part of professional practice

CDCR 22-B1399

22-B1399. DEFINITIONS.

1399.1 As used in this chapter, the following words and phrases shall have the meanings ascribed:

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Individual Practitioner an individual who is licensed or registered in the District of Columbia to prescribe a prescription drug or medical device in the course of his or her professional practice, including a physician, dentist, veterinarian, podiatrist, optometrist, or advanced practice nurse. It does not include a pharmacist, pharmacy, or an institutional practitioner.

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DISTRICT OF COLUMBIA

REGULATIONS

Medical Board Regulations

CDCR 17-4614

Section 17-4616. Standards for the Use of Controlled Substances for the Treatment of Pain

4616.1 A licensed physician shall prescribe, order, administer, or dispense controlled substances for pain only for a legitimate medical purpose based on accepted scientific knowledge of the treatment of pain or based on sound clinical grounds. All such prescribing shall be based on clear documentation of unrelieved pain and in compliance with applicable District or federal law.

4616.2 A licensed physician shall employ up-to-date treatment modalities in order to improve the quality of life for patients who suffer from pain as well as to reduce the morbidity and costs incurred by patients associated with untreated or inappropriately treated pain. For purposes of this section, "inappropriately treated pain" includes the following:

(a) Non-treatment;

(b) Under-treatment;

(c) Over-treatment; and

(d) The continued use of ineffective treatments.

4616.3 A licensed physician shall perform an evaluation of the patient by taking a complete medical history and performing a physical examination. The medical history and physical examination shall be documented in the medical record. The medical record shall contain a description of the following:

(a) The nature and intensity of the patient's pain;

(b) The patient's current and past treatments for pain;

(c) The patient's underlying or coexisting diseases or conditions;

(d) The effect of the pain on the patient's physical and psychological function;

(e) A history of the patient's substance abuse if applicable; and

(f) The presence of one or more recognized medical indications in the patient for the use of a controlled substance.

4616.4 A licensed physician shall maintain a written treatment plan which states the objectives used to determine treatment success, such as pain relief and improved physical and psychosocial function

4616.5 The treatment plan shall indicate if any further diagnostic evaluations or other treatments are planned.

4616.6 The physician shall adjust drug therapy to the individual medical needs of each patient after treatment begins.

4616.7 The physician shall consider other treatment modalities or a rehabilitation program if necessary depending on the etiology of the pain and the extent to which the pain is associated with physical and psychosocial impairment.

4616.8 The physician shall discuss the risks and benefits of the use of controlled substances with the patient, person(s) designated by the patient, or with the patient's surrogate or guardian if the patient is incompetent.

(CONTINUED ON NEXT PAGE)

(+) *CRITERION 2:*
Pain management is part of healthcare practice

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Recognizes that inadequate treatment of pain is subject to disciplinary action just as other substandard practices might be.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Encourages healthcare professionals to incorporate in their practice the evaluations of, and discussions with patients about, the potential benefits and risks of treatment with opioids, which can better ensure a clinical indication of such treatment so that opioids will be used for medical purposes.

(+) *CRITERION 3:*
Opioids are part of professional practice

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Recognizes that the goal of pain treatment should include improvements in patient functioning and quality of life.

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DISTRICT OF COLUMBIA

REGULATIONS

Medical Board Regulations

(CONTINUED)

4616.9 If the patient is determined to be at high risk for medication abuse or have a history of substance abuse, the physician shall employ the use of a written agreement between the physician and patient outlining the patient's responsibilities, including, but not limited to:

(a) Urine/serum medication levels screening when requested;

(b) Number and frequency of all prescription refills; and

(c) Reasons for which drug therapy may be discontinued, such as violation of an agreement.

4616.10 The physician shall do the following:

(a) Review the course of treatment and any new information about the etiology of the pain at reasonable intervals based on the individual circumstances of the patient;

(b) Continue or modify the pain therapy depending on the physician's evaluation of the patient's progress;

(c) Reevaluate the appropriateness of continued treatment if treatment goals are not being achieved despite medication adjustments; and

(d) Monitor the patient's compliance in medication usage and and related treatment plans.

4616.11 The physician shall refer the patient, as necessary, to another physician for additional evaluation and treatment in order to achieve treatment objectives. Special attention shall be given to those pain patients who are at risk for misusing their medications and those whose living arrangements pose a risk for medication misuse or diversion.

4616.12 The physician shall consult with or refer to an expert for management the following types of patients:

(a) Patients with a history of substance abuse; or

(b) Patients with comorbid psychiatric disorders that require extra care, monitoring, and documentation.

4616.13 The physician shall recognize that tolerance and physical dependence are normal consequences of sustained use of opioid analgesics and are not the same as addiction.

4616.14 The physician shall keep accurate and complete records that include, but are not limited to:

(a) The medical history and physical examination, including history of drug abuse or dependence, as appropriate;

(b) Diagnostic, therapeutic, and laboratory results;

(c) Evaluations and consultations;

(c) Treatment objectives;

(d) Discussion of risks and benefits;

(e) Treatments;

(f) Medications including date, type, dosage, and quantity prescribed;

(g) Instructions and agreements; and

(h) Periodic reviews.

(-) *CRITERION 12:*
Healthcare decisions are restricted

CATEGORY B:
Mandated consultation

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY B:
Issues related to patients

COMMENT:
Acknowledges that a patient's prior history or current status of drug abuse does not necessarily contraindicate appropriate pain management.

(+) *CRITERION 7:*
Physical dependence or analgesic tolerance are not confused with "addiction"

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Madison, Wisconsin

DISTRICT OF COLUMBIA

STATUTES

Protection and Care Systems

D.C. Code § 7-2071.01

§ 7-2071.01. Definitions

For the purposes of this chapter, the term:

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(8) "Health care services" means items or services provided under the supervision of a physician or other person trained or licensed to render health care necessary for the prevention, care, diagnosis, or treatment of human disease, pain, injury, deformity, or other physical or mental condition, including the following: pre-admission, outpatient, inpatient, and post-discharge care; home care; physician's care; nursing care; medical care provided by interns or residents in training; other paramedical care; ambulance service and care; bed and board; drugs; supplies; appliances; equipment; laboratory services; any form of diagnostic imaging or therapeutic radiological services; and services mandated under Chapter 31 of Title 31.

(+) *CRITERION 2:*
Pain management is part of healthcare practice

Pain & Policy Studies Group
University of Wisconsin Carbone Cancer Center
Madison, Wisconsin

DISTRICT OF COLUMBIA

REGULATIONS

Nursing Home Administration

CDCR 17-6206

17-6206. Continuing Education Requirements.

6206.1 Subject to § 6206.2, this section shall apply to applicants for the renewal, reactivation, or reinstatement of a license for a term expiring June 30, 2004.

6206.2 This section shall not apply to applicants for an initial license by examination, reciprocity, or endorsement, nor shall it apply to applicants for the first renewal of a license granted by examination.

6206.3 A continuing education credit shall be valid only if it is part of a program or activity approved by the Board in accordance with § 6207.

6206.4 An applicant for renewal of a license shall submit proof of having completed forty (40) hours of approved continuing education credit during the two (2)-year period preceding the date the license expires. At least ten (10) hours of the required forty (40) hours shall have been in one (1) or more of the following areas:

(a) Staff management;

(b) Continuity in assigning the same nursing staff to the same residents as often as practicable;

(c) Creating a resident-centered environment;

(d) Activities of daily living and instrumental activities of daily living;

(e) Wound care;

(f) Pain management;

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(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (continuing education) for nursing homes to ensure that pain management is an essential part of patient care.

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Madison, Wisconsin

FLORIDA

STATUTES

- CONTROLLED SUBSTANCES ACT
  Title 46. Crimes; Chapter 893. Drug Abuse Prevention and Control

- MEDICAL PRACTICE ACT
  Title 32. Regulation of Professions and Occupations; Chapter 458. Medical Practice

- OSTEOPATHIC PRACTICE ACT
  Title 32. Regulation of Professions and Occupations; Chapter 459. Osteopathic Medicine

- PHARMACY PRACTICE ACT
  Title 32. Regulation of Professions and Occupations; Chapter 465. Pharmacy

- INTRACTABLE PAIN TREATMENT ACT
  No policy found

REGULATIONS

- CONTROLLED SUBSTANCES REGULATIONS *(No provisions found)*
  Title 61. Department of Business and Professional Regulation; 61N. Drugs, Devices and Cosmetics; Chapter 61N-1. Regulations for Drugs, Devices and Cosmetics

- MEDICAL BOARD REGULATIONS
  Title 64. Department of Health; 64B8. Board of Medicine

- OSTEOPATHIC BOARD REGULATIONS
  Title 64. Department of Health; 64B15. Board of Osteopathic Medicine

- PHARMACY BOARD REGULATIONS (*No provisions found*)
  Title 64. Department of Health; 64B16. Board of Pharmacy

OTHER GOVERNMENTAL POLICIES

No policies found

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RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY KEY WORD SEARCHES

- CHILDREN'S MEDICAL SERVICES
  Title 29. Public Health; Chapter 391. Children's Medical Services; Part I. General Provisions

- HOSPICES
  Title 29. Public Health; Chapter 400. Nursing Homes and Related Health Care Facilities; Part VI. Hospices

- PROFESSIONAL PRACTICE
  Title 32. Regulation of Professions and Occupations; Chapter 456. Health Professions and Occupations: General Provisions

- CIVIL RIGHTS
  Title 44. Civil Rights; Chapter 765. Health Care Advanced Directives; Part 1. General Provisions

- HOSPICE SERVICES
  Title 58. Department of Elder Affairs; Division 58A. Federal Aging Programs; Chapter 58A-2. Hospice

FLORIDA

STATUTES

Controlled Substances Act

Fla. Stat. § 893.13

§ 893.13. Prohibited acts; penalties

(1) (a) Except as authorized by this chapter and chapter 499, it is unlawful for any person to sell, manufacture, or deliver, or possess with intent to sell, manufacture, or deliver, a controlled substance…

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(9) The provisions of subsections (1)-(8) are not applicable to the delivery to, or actual or constructive possession for medical or scientific use or purpose only of controlled substances by, persons included in any of the following classes, or the agents or employees of such persons, for use in the usual course of their business or profession or in the performance of their official duties:

(a) Pharmacists.

(b) Practitioners.

(c) Persons who procure controlled substances in good faith and in the course of professional practice only, by or under the supervision of pharmacists or practitioners employed by them, or for the purpose of lawful research, teaching, or testing, and not for resale.

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Fla. Stat. § 893.055

§ 893.055. Prescription drug monitoring program

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(2) (a) The department shall design and establish a comprehensive electronic database system that has controlled substance prescriptions provided to it and that provides prescription information to a patient's health care practitioner and pharmacist who inform the department that they wish the patient advisory report provided to them. Otherwise, the patient advisory report will not be sent to the practitioner, pharmacy, or pharmacist. The system shall be designed to provide information regarding dispensed prescriptions of controlled substances and shall not infringe upon the legitimate prescribing or dispensing of a controlled substance by a prescriber or dispenser acting in good faith and in the course of professional practice.

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(+) *CRITERION 3:*
Opioids are part of professional practice

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT*:* Represents the principle of Balance, which states that the regulation of controlled substances should not interfere with legitimate medical use.

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Madison, Wisconsin

FLORIDA

STATUTES

Medical Practice Act

Fla. Stat. § 458.305

458.305 Definitions.

As used in this chapter:

(1) "Board" means the Board of Medicine.

(2) "Department" means the Department of Health.

(3) "Practice of medicine" means the diagnosis, treatment, operation, or prescription for any human disease, pain, injury, deformity, or other physical or mental condition.

(+) *CRITERION 2:*
Pain management is part of healthcare practice

(4) "Physician" means a person who is licensed to practice medicine in this state.

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Fla. Stat. § 458.326

§ 458.326. Intractable pain; authorized treatment

(1) For the purposes of this section, the term "intractable pain" means pain for which, in the generally accepted course of medical practice, the cause cannot be removed and otherwise treated.

(2) Intractable pain must be diagnosed by a physician licensed under this chapter and qualified by experience to render such diagnosis.

(3) Notwithstanding any other provision of law, a physician may prescribe or administer any controlled substance under Schedules II-V, as provided for in s. 893.03, to a person for the treatment of intractable pain, provided the physician does so in accordance with that level of care, skill, and treatment recognized by a reasonably prudent physician under similar conditions and circumstances.

(+) *CRITERION 3:*
Opioids are part of professional practice

(4) Nothing in this section shall be construed to condone, authorize, or approve mercy killing or euthanasia, and no treatment authorized by this section may be used for such purpose.

Fla. Stat. § 458.331

458.331 Grounds for disciplinary action; action by the board and department.

(1) The following acts shall constitute grounds for which the disciplinary actions specified in subsection (2) may be taken:

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(q) Prescribing, dispensing, administering, mixing, or otherwise preparing a legend drug, including any controlled substance, other than in the course of the physician's professional practice. For the purposes of this paragraph, it shall be legally presumed that prescribing, dispensing, administering, mixing, or otherwise preparing legend drugs, including all controlled substances, inappropriately or in excessive or inappropriate quantities is not in the best interest of the patient and is not in the course of the physician's professional practice, without regard to his or her intent.

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(-) *CRITERION 16:*
Provisions that are ambiguous

CATEGORY A:
Arbitrary standards for legitimate prescribing

COMMENT: Although it is reasonable to expect physicians to avoid contributing to diversion, "excessive or inappropriate" implies there is a known standard, but the standard is not specified. Also, elimination of the critically important intent of the physician in deciding cases appears to add to the uncertainty of how this provision might be interpreted.

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Madison, Wisconsin

FLORIDA

STATUTES

Osteopathic Practice Act

Fla. Stat. § 459

§ 459.003. Definitions

As used in this chapter:

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(3) "Practice of osteopathic medicine" means the diagnosis, treatment, operation, or prescription for any human disease, pain, injury, deformity, or other physical or mental condition, which practice is based in part upon educational standards and requirements which emphasize the importance of the musculoskeletal structure and manipulative therapy in the maintenance and restoration of health.

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§ 459.015. Grounds for disciplinary action; action by the board and department

(1) The following acts constitute grounds for denial of a license or disciplinary action, as specified in s. *456.072(2)*:

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(t) Prescribing, dispensing, administering, supplying, selling, giving, mixing, or otherwise preparing a legend drug, including all controlled substances, other than in the course of the osteopathic physician's professional practice. For the purposes of this paragraph, it shall be legally presumed that prescribing, dispensing, administering, supplying, selling, giving, mixing, or otherwise preparing legend drugs, including all controlled substances, inappropriately or in excessive or inappropriate quantities is not in the best interest of the patient and is not in the course of the osteopathic physician's professional practice, without regard to his or her intent.

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(+) *CRITERION 2:*
Pain management is part of healthcare practice

(-) *CRITERION 16:*
Provisions that are ambiguous

CATEGORY A:
Arbitrary standards for legitimate prescribing

COMMENT: Although it is reasonable to expect osteopathic physicians to avoid contributing to diversion, "excessive or inappropriate" implies there is a known standard, but the standard is not specified. Also, elimination of the critically important intent of the physician in deciding cases appears to add to the uncertainty of how this provision might be interpreted.

STATUTES

Pharmacy Practice Act

Fla. Stat. § 465.016

465.016 Disciplinary actions.

(1) The following acts shall be grounds for disciplinary action set forth in this section:

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(i) Compounding, dispensing, or distributing a legend drug, including any controlled substance, other than in the course of the professional practice of pharmacy. For purposes of this paragraph, it shall be legally presumed that the compounding, dispensing, or distributing of legend drugs in excessive or inappropriate quantities is not in the best interests of the patient and is not in the course of the professional practice of pharmacy.

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(-) *CRITERION 16:*
Provisions that are ambiguous

CATEGORY A:
Arbitrary standards for legitimate prescribing

COMMENT: Although it is reasonable to expect pharmacists to avoid contributing to diversion, "excessive or inappropriate" implies there is a known standard, but the standard is not specified.

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FLORIDA

REGULATIONS

Medical Board Regulations

64B8-9.013, F.A.C.

64B8-9.013 Standards for the Use of Controlled Substances for Treatment of Pain.

(1) Pain management principles.

(a) The Board of Medicine recognizes that principles of quality medical practice dictate that the people of the State of Florida have access to appropriate and effective pain relief. The appropriate application of up-to-date knowledge and treatment modalities can serve to improve the quality of life for those patients who suffer from pain as well as reduce the morbidity and costs associated with untreated or inappropriately treated pain. The Board encourages physicians to view effective pain management as a part of quality medical practice for all patients with pain, acute or chronic, and it is especially important for patients who experience pain as a result of terminal illness. All physicians should become knowledgeable about effective methods of pain treatment as well as statutory requirements for prescribing controlled substances.

(b) Inadequate pain control may result from physicians' lack of knowledge about pain management or an inadequate understanding of addiction. Fears of investigation or sanction by federal, state, and local regulatory agencies may also result in inappropriate or inadequate treatment of chronic pain patients. Physicians should not fear disciplinary action from the Board or other state regulatory or enforcement agencies for prescribing, dispensing, or administering controlled substances including opioid analgesics, for a legitimate medical purpose and that is supported by appropriate documentation establishing a valid medical need and treatment plan. Accordingly, these standards have been developed to clarify the Board's position on pain control, specifically as related to the use of controlled substances, to alleviate physician uncertainty and to encourage better pain management.

(c) The Board recognizes that controlled substances, including opioid analgesics, may be essential in the treatment of acute pain due to trauma or surgery and chronic pain, whether due to cancer or non-cancer origins. The medical management of pain including intractable pain should be based on current knowledge and research and includes the use of both pharmacologic and non-pharmacologic modalities. Pain should be assessed and treated promptly, and the quantity and frequency of doses should be adjusted according to the intensity and duration of the pain. Physicians should recognize that tolerance and physical dependence are normal consequences of sustained use of opioid analgesics and are not synonymous with addiction.

(d) The Board of Medicine is obligated under the laws of the State of Florida to protect the public health and safety. The Board recognizes that inappropriate prescribing of controlled substances, including opioid analgesics, may lead to drug diversion and abuse by individuals who seek them for other than legitimate medical use. Physicians should be diligent in preventing the diversion of drugs for illegitimate purposes.

(e) The Board will consider prescribing, ordering, administering, or dispensing controlled substances for pain to be for a legitimate medical purpose if based on accepted scientific knowledge of the treatment of pain or if based on sound clinical grounds. All such prescribing must be based on clear documentation of unrelieved pain and in compliance with applicable state or federal law.

(f) Each case of prescribing for pain will be evaluated on an individual basis. The Board will not take disciplinary action against a physician for failing to adhere strictly to the provisions of these standards, if good cause is shown for such deviation. The physician's conduct will be evaluated to a great extent by the treatment outcome, taking into account whether the drug used is medically and/or pharmacologically recognized to be appropriate for the diagnosis, the patient's individual needs including any improvement in functioning, and recognizing that some types of pain cannot be completely relieved.

[CONTINUED ON NEXT PAGE]

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Identifies the potential impact of important barriers on the provision of effective pain care.

(+) *CRITERION 4:*
Encourages pain management

(+) *CRITERION 7:*
Physical dependence or analgesic tolerance are not confused with "addiction"

(+) *CRITERION 3:*
Opioids are part of professional practice

(+) *CRITERION 2:*
Pain management is part of healthcare practice

(+) *CRITERION 5:*
Addresses fear of regulatory scrutiny

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Recognizes the need for treatment flexibility for physicians to respond to individual clinical circumstances, as long as their prescribing maintains the standards of good medical practice.

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Pain & Policy Studies Group
University of Wisconsin Carbone Cancer Center
Madison, Wisconsin

FLORIDA

REGULATIONS

Medical Board Regulations

[CONTINUED]

(+) *CRITERION 6:*
Prescription amount alone does not determine legitimacy

(g) The Board will judge the validity of prescribing based on the physician's treatment of the patient and on available documentation, rather than on the quantity and chronicity of prescribing. The goal is to control the patient's pain for its duration while effectively addressing other aspects of the patient's functioning, including physical, psychological, social, and work-related factors. The following standards are not intended to define complete or best practice, but rather to communicate what the Board considers to be within the boundaries of professional practice.

(2) Definitions.

(a) Acute Pain. For the purpose of this rule, "acute pain" is defined as the normal, predicted physiological response to an adverse chemical, thermal, or mechanical stimulus and is associated with surgery, trauma, and acute illness. It is generally time-limited and is responsive to opioid therapy, among other therapies.

(b) Addiction. For the purpose of this rule, "addiction" is defined as a neurobehavioral syndrome with genetic and environmental influences that results in psychological dependence on the use of substances for their psychic effects and is characterized by compulsive use despite harm. Addiction may also be referred to by terms such as "drug dependence" and "psychological dependence." Physical dependence and tolerance are normal physiological consequences of extended opioid therapy for pain and should not be considered addiction.

(c) Analgesic Tolerance. For the purpose of this rule, "analgesic tolerance" is defined as the need to increase the dose of opioid to achieve the same level of analgesia. Analgesic tolerance may or may not be evident during opioid treatment and does not equate with addiction.

(d) Chronic Pain. For the purpose of this rule, "chronic pain" is defined as a pain state which is persistent.

(e) Pain. For the purpose of this rule, "pain" is defined as an unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage.

(f) Physical Dependence. For the purpose of this rule, "physical dependence" on a controlled substance is defined as a physiologic state of neuro-adaptation which is characterized by the emergence of a withdrawal syndrome if drug use is stopped or decreased abruptly, or if an antagonist is administered. Physical dependence is an expected result of opioid use. Physical dependence, by itself, does not equate with addiction.

(g) Pseudoaddiction. For the purpose of this rule, "pseudoaddiction" is defined as a pattern of drug-seeking behavior of pain patients who are receiving inadequate pain management that can be mistaken for addiction.

(h) Substance Abuse. For the purpose of this rule, "substance abuse" is defined as the use of any substances for non-therapeutic purposes or use of medication for purposes other than those for which it is prescribed.

(i) Tolerance. For the purpose of this rule, "tolerance" is defined as a physiologic state resulting from regular use of a drug in which an increased dosage is needed to produce the same effect, or a reduced effect is observed with a constant dose.

[CONTINUED ON NEXT PAGE]

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Recognizes that the goal of pain treatment should include improvements in patient functioning and quality of life.

Pain & Policy Studies Group
University of Wisconsin Carbone Cancer Center
Madison, Wisconsin

FLORIDA

REGULATIONS

Medical Board Regulations

[CONTINUED]

(3) Standards. The Board has adopted the following standards for the use of controlled substances for pain control:

(a) Evaluation of the Patient. A complete medical history and physical examination must be conducted and documented in the medical record. The medical record shall document the nature and intensity of the pain, current and past treatments for pain, underlying or coexisting diseases or conditions, the effect of the pain on physical and psychological function, and history of substance abuse. The medical record also shall document the presence of one or more recognized medical indications for the use of a controlled substance.

(b) Treatment Plan. The written treatment plan shall state objectives that will be used to determine treatment success, such as pain relief and improved physical and psychosocial function, and shall indicate if any further diagnostic evaluations or other treatments are planned. After treatment begins, the physician shall adjust drug therapy, if necessary, to the individual medical needs of each patient. Other treatment modalities or a rehabilitation program may be necessary depending on the etiology of the pain and the extent to which the pain is associated with physical and psychosocial impairment.

(c) Informed Consent and Agreement for Treatment. The physician shall discuss the risks and benefits of the use of controlled substances with the patient, persons designated by the patient, or with the patient's surrogate or guardian if the patient is incompetent. The patient shall receive prescriptions from one physician and one pharmacy where possible. If the patient is determined to be at high risk for medication abuse or have a history of substance abuse, the physician shall employ the use of a written agreement between physician and patient outlining patient responsibilities, including, but not limited to:

1. Urine/serum medication levels screening when requested;
2. Number and frequency of all prescription refills; and
3. Reasons for which drug therapy may be discontinued (i.e., violation of agreement).

(d) Periodic Review. Based on the individual circumstances of the patient, the physician shall review the course of treatment and any new information about the etiology of the pain. Continuation or modification of therapy shall depend on the physician's evaluation of the patient's progress. If treatment goals are not being achieved, despite medication adjustments, the physician shall reevaluate the appropriateness of continued treatment. The physician shall monitor patient compliance in medication usage and related treatment plans.

(e) Consultation. The physician shall be willing to refer the patient as necessary for additional evaluation and treatment in order to achieve treatment objectives. Special attention must be given to those pain patients who are at risk for misusing their medications and those whose living arrangements pose a risk for medication misuse or diversion. The management of pain in patients with a history of substance abuse or with a comorbid psychiatric disorder requires extra care, monitoring, and documentation, and may require consultation with or referral to an expert in the management of such patients.

[CONTINUED ON NEXT PAGE]

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Encourages healthcare professionals to incorporate in their practice the evaluations of, and discussions with patients about, the potential benefits and risks of treatment with opioids, which can better ensure a clinical indication of such treatment so that opioids will be used for medical purposes.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY B:
Issues related to patients

COMMENT:
Acknowledges that a patient's prior history or current status of drug abuse does not necessarily contraindicate appropriate pain management.

Pain & Policy Studies Group
University of Wisconsin Carbone Cancer Center
Madison, Wisconsin

FLORIDA

REGULATIONS

Medical Board Regulations

[CONTINUED]

(f) Medical Records. The physician is required to keep accurate and complete records to include, but not be limited to:

1. The complete medical history and a physical examination, including history of drug abuse or dependence, as appropriate;

2. Diagnostic, therapeutic, and laboratory results;

3. Evaluations and consultations;

4. Treatment objectives;

5. Tiscussion of risks and benefits;

6. Treatments;

7. Medications (including date, type, dosage, and quantity prescribed);

8. Instructions and agreements;

9. Drug testing results; and

10. Periodic reviews. Records must remain current, maintained in an accessible manner, readily available for review, and must be in full compliance with *Rule 64B8-9.003*, F.A.C, and *Section 458.331(1)(m), F.S.*

Records must remain current and be maintained in an accessible manner and readily available for review.

(g) Compliance with Controlled Substances Laws and Regulations. To prescribe, dispense, or administer controlled substances, the physician must be licensed in the state and comply with applicable federal and state regulations. Physicians are referred to the Physicians Manual: An Informational Outline of the Controlled Substances Act of 1970, published by the U.S. Drug Enforcement Agency, for specific rules governing controlled substances as well as applicable state regulations.

64B8-9.0131, F.A.C.

64B8-9.0131 Training Requirements for Physicians Practicing in Pain Management Clinics.

Effective July 1, 2012, physicians who have not met the qualifications set forth in subsections (1) through (6), below, shall have successfully completed a pain medicine fellowship that is accredited by the Accreditation Council for Graduate Medical Education (ACGME) or a pain medicine residency that is accredited by ACGME. Prior to July 1, 2012, physicians prescribing or dispensing controlled substance medications in pain-management clinics registered pursuant to *Section 458.3265, F.S.*, must meet one of the following qualifications:

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(6) Three years of documented full-time practice, which is defined as an average of 20 hours per week each year, in pain-management and attendance and successful completion of 40 hours of in-person, live-participatory AMA Category I CME courses in pain management that address all the following subject areas:

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(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Encourages healthcare professionals to understand and follow federal and state laws governing their practice, which can better ensure that practitioners follow the *balanced* approach represented by federal law and the laws in many states.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (continuing education) for pain management clinics to ensure that appropriate pain treatment is an essential part of patient care.

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FLORIDA

REGULATIONS

Osteopathic Board Regulations

64B15-14.005, F.A.C.

64B15-14.005 Standards for the Use of Controlled Substances for Treatment of Pain.

(1) Pain management principles.

(a) The Board of Osteopathic Medicine recognizes that principles of quality medical practice dictate that the people of the State of Florida have access to appropriate and effective pain relief. The appropriate application of up-to-date knowledge and treatment modalities can serve to improve the quality of life for those patients who suffer from pain as well as reduce the morbidity and costs associated with untreated or inappropriately treated pain. The Board encourages osteopathic physicians to view effective pain management as a part of quality medical practice for all patients with pain, acute or chronic, and it is especially important for patients who experience pain as a result of terminal illness. All osteopathic physicians should become knowledgeable about effective methods of pain treatment as well as statutory requirements for prescribing controlled substances.

(b) Inadequate pain control may result from an osteopathic physician's lack of knowledge about pain management or an inadequate understanding of addiction. Fears of investigation or sanction by federal, state, and local regulatory agencies may also result in inappropriate or inadequate treatment of chronic pain patients. Osteopathic physicians should not fear disciplinary action from the Board or other state regulatory or enforcement agencies for prescribing, dispensing, or administering controlled substances including opioid analgesics, for a legitimate medical purpose and that is supported by appropriate documentation establishing a valid medical need and treatment plan. Accordingly, these guidelines have been developed to clarify the Board's position on pain control, specifically as related to the use of controlled substances, to alleviate physician uncertainty and to encourage better pain management.

(c) The Board recognizes that controlled substances, including opioid analgesics, may be essential in the treatment of acute pain due to trauma or surgery and chronic pain, whether due to cancer or non-cancer origins. Osteopathic physicians are referred to the U.S. Agency for Health Care Policy and Research Clinical Practice Guidelines for a sound approach to the management of acute and cancer-related pain. The medical management of pain including intractable pain should be based on current knowledge and research and includes the use of both pharmacologic and non-pharmacologic modalities. Pain should be assessed and treated promptly, and the quantity and frequency of doses should be adjusted according to the intensity and duration of the pain. Osteopathic physicians should recognize that tolerance and physical dependence are normal consequences of sustained use of opioid analgesics and are not synonymous with addiction.

(d) The Board of Osteopathic Medicine is obligated under the laws of the State of Florida to protect the public health and safety. The Board recognizes that inappropriate prescribing of controlled substances, including opioid analgesics, may lead to drug diversion and abuse by individuals who seek them for other than legitimate medical use. Osteopathic physicians should be diligent in preventing the diversion of drugs for illegitimate purposes.

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(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Identifies the potential impact of important barriers on the provision of effective pain care.

(+) *CRITERION 4:*
Encourages pain management

(+) *CRITERION 7:*
Physical dependence or analgesic tolerance are not confused with "addiction"

(+) *CRITERION 2:*
Pain management is part of healthcare practice

(+) *CRITERION 5:*
Addresses fear of regulatory scrutiny

2013

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Madison, Wisconsin

FLORIDA

REGULATIONS

Osteopathic Board Regulations

[CONTINUED]

(e) The Board will consider prescribing, ordering, administering, or dispensing controlled substances for pain to be for a legitimate medical purpose if based on accepted scientific knowledge of the treatment of pain or if based on sound clinical grounds. All such prescribing must be based on clear documentation of unrelieved pain and in compliance with applicable state or federal law.

(f) Each case of prescribing for pain will be evaluated on an individual basis. The Board will not take disciplinary action against an osteopathic physician for failing to adhere strictly to the provisions of these guidelines, if good cause is shown for such deviation. The osteopathic physician's conduct will be evaluated to a great extent by the treatment outcome, taking into account whether the drug used is medically and/or pharmacologically recognized to be appropriate for the diagnosis, the patient's individual needs including any improvement in functioning, and recognizing that some types of pain cannot be completely relieved.

(g) The Board will judge the validity of prescribing based on the osteopathic physician's treatment of the patient and on available documentation, rather than on the quantity and chronicity of prescribing. The goal is to control the patient's pain for its duration while effectively addressing other aspects of the patient's functioning, including physical, psychological, social, and work-related factors. The following guidelines are not intended to define complete or best practice, but rather to communicate what the Board considers to be within the boundaries of professional practice.

(2) Definitions.

(a) Acute Pain. For the purpose of this rule, "acute pain" is defined as the normal, predicted physiological response to an adverse chemical, thermal, or mechanical stimulus and is associated with surgery, trauma, and acute illness. It is generally time-limited and is responsive to opioid therapy, among other therapies.

(b) Addiction. For the purpose of this rule, "addiction" is defined as a neurobehavioral syndrome with genetic and environmental influences that results in psychological dependence on the use of substances for their psychic effects and is characterized by compulsive use despite harm. Addiction may also be referred to by terms such as "drug dependence" and "psychological dependence." Physical dependence and tolerance are normal physiological consequences of extended opioid therapy for pain and should not be considered addiction.

(c) Analgesic Tolerance. For the purpose of this rule, "analgesic tolerance" is defined as the need to increase the dose of opioid to achieve the same level of analgesia. Analgesic tolerance may or may not be evident during opioid treatment and does not equate with addiction.

(d) Chronic Pain. For the purpose of this rule, "chronic pain" is defined as a pain state which is persistent.

(e) Pain. For the purpose of this rule, "pain" is defined as an unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage.

(f) Physical Dependence. For the purpose of this rule, "physical dependence" on a controlled substance is defined as a physiologic state of neuro-adaptation which is characterized by the emergence of a withdrawal syndrome if drug use is stopped or decreased abruptly, or if an antagonist is administered. Physical dependence is an expected result of opioid use. Physical dependence, by itself, does not equate with addiction.

(g) Pseudoaddiction. For the purpose of this rule, "pseudoaddiction" is defined as a pattern of drug-seeking behavior of pain patients who are receiving inadequate pain management that can be mistaken for addiction.

[CONTINUED ON NEXT PAGE]

(+) *CRITERION 3:*
Opioids are part of professional practice

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT:
Acknowledges need for treatment flexibility for physicians to respond to individual clinical circumstances, as long as their prescribing maintains the standards of good medical practice.

(+) *CRITERION 6:*
Prescription amount alone does not determine legitimacy

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Recognizes that the goal of pain treatment should include improvements in patient functioning and quality of life.

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FLORIDA

REGULATIONS

Osteopathic Board Regulations

[CONTINUED]

(h) Substance Abuse. For the purpose of this rule, "substance abuse" is defined as the use of any substances for non-therapeutic purposes or use of medication for purposes other than those for which it is prescribed.

(i) Tolerance. For the purpose of this rule, "tolerance" is defined as a physiologic state resulting from regular use of a drug in which an increased dosage is needed to produce the same effect, or a reduced effect is observed with a constant dose.

(3) Guidelines. The Board has adopted the following guidelines when evaluating the use of controlled substances for pain control:

(a) Evaluation of the Patient. A complete medical history and physical examination must be conducted and documented in the medical record. The medical record should document the nature and intensity of the pain, current and past treatments for pain, underlying or coexisting diseases or conditions, the effect of the pain on physical and psychological function, and history of substance abuse. The medical record also should document the presence of one or more recognized medical indications for the use of a controlled substance.

(b) Treatment Plan. The written treatment plan should state objectives that will be used to determine treatment success, such as pain relief and improved physical and psychosocial function, and should indicate if any further diagnostic evaluations or other treatments are planned. After treatment begins, the osteopathic physician should adjust drug therapy to the individual medical needs of each patient. Other treatment modalities or a rehabilitation program may be necessary depending on the etiology of the pain and the extent to which the pain is associated with physical and psychosocial impairment.

(c) Informed Consent and Agreement for Treatment. The osteopathic physician should discuss the risks and benefits of the use of controlled substances with the patient, persons designated by the patient, or with the patient's surrogate or guardian if the patient is incompetent. The patient should receive prescriptions from one osteopathic physician and one pharmacy where possible. If the patient is determined to be at high risk for medication abuse or have a history of substance abuse, the osteopathic physician may employ the use of a written agreement between physician and patient outlining patient responsibilities, including, but not limited to:

1. Urine/serum medication levels screening when requested;

2. Number and frequency of all prescription refills; and

3. Reasons for which drug therapy may be discontinued (i.e., violation of agreement).

(d) Periodic Review. At reasonable intervals based on the individual circumstances of the patient, the osteopathic physician should review the course of treatment and any new information about the etiology of the pain. Continuation or modification of therapy should depend on the osteopathic physician's evaluation of progress toward stated treatment objectives such as improvement in patient's pain intensity and improved physical and/or psychosocial function, i.e., ability to work, need of health care resources, activities of daily living, and quality of social life. If treatment goals are not being achieved, despite medication adjustments, the osteopathic physician should reevaluate the appropriateness of continued treatment. The osteopathic physician should monitor patient compliance in medication usage and related treatment plans.

(e) Consultation. The osteopathic physician should be willing to refer the patient as necessary for additional evaluation and treatment in order to achieve treatment objectives. Special attention should be given to those pain patients who are at risk for misusing their medications and those whose living arrangements pose a risk for medication misuse or diversion. The management of pain in patients with a history of substance abuse or with a comorbid psychiatric disorder may require extra care, monitoring, documentation, and consultation with or referral to an expert in the management of such patients.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Encourages healthcare professionals to incorporate in their practice the evaluations of, and discussions with patients about, the potential benefits and risks of treatment with opioids, which can better ensure a clinical indication of such treatment so that opioids will be used for medical purposes.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY B:
Issues related to patients

COMMENT:
Acknowledges that a patient's prior history or current status of drug abuse does not necessarily contraindicate appropriate pain management.

2013

Pain & Policy Studies Group
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Madison, Wisconsin

FLORIDA

REGULATIONS

Osteopathic Board Regulations

[CONTINUED]

(f) Medical Records. The osteopathic physician is required to keep accurate and complete records to include, but not be limited to:

1. The medical history and physical examination;
2. Diagnostic, therapeutic, and laboratory results;
3. Evaluations and consultations;
4. Treatment objectives;
5. Discussion of risks and benefits;
6. Treatments;
7. Medications (including date, type, dosage, and quantity prescribed);
8. Instructions and agreements; and
9. Periodic reviews.

Records must remain current and be maintained in an accessible manner and readily available for review.

(g) Compliance with Controlled Substances Laws and Regulations. To prescribe, dispense, or administer controlled substances, the osteopathic physician must be licensed in the state and comply with applicable federal and state regulations. Osteopathic physicians are referred to the Physicians Manual: An Informational Outline of the Controlled Substances Act of 1970, published by the U.S. Drug Enforcement Agency, for specific rules governing controlled substances as well as applicable state regulations.

64B15-14.0051, F.A.C.

64B15-14.0051 Training Requirements for Physicians Practicing in Pain Management Clinics.

Effective July 1, 2012, physicians who have not met the qualifications set forth in subsections (1) through (6), below, shall have successfully completed a pain medicine fellowship that is accredited by the Accreditation Council for Graduate Medical Education (ACGME) or the American Osteopathic Association (AOA) or a pain medicine residency that is accredited by ACGME or the AOA. Prior to July 1, 2012, physicians prescribing or dispensing controlled substance medications in pain management clinics registered pursuant to *Section 459.0137(1), F.S.*, must meet one of the following qualifications:

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(6) Three years of documented full-time practice, which is defined as an average of 20 hours per week each year, in pain-management and attendance and successful completion of 40 hours of in-person, live-participatory AMA Category I CME courses in pain management that address all the following subject areas:

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(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT*:* Establishes a mechanism (continuing education) for pain management clinics to ensure that appropriate pain treatment is an essential part of patient care.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT*:* Encourages healthcare professionals to understand and follow federal and state laws governing their practice, which can better ensure that practitioners follow the *balanced* approach represented by federal law and the laws in many states.

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Madison, Wisconsin

FLORIDA

STATUTES

Children's Medical Services

Fla. Stat. § 391.021

§ 391.021. Definitions

When used in this act, unless the context clearly indicates otherwise:

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(6) "Health services" includes the prevention, diagnosis, and treatment of human disease, pain, injury, deformity, or disabling conditions.

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(+) *CRITERION 2:*
Pain management is part of healthcare practice

STATUTES

Hospices

Fla. Stat. § 400.60501

§ 400.60501. Outcome measures; adoption of national initiatives; annual report

(1) No later than December 31, 2007, the Department of Elderly Affairs, in conjunction with the Agency for Health Care Administration, shall develop outcome measures to determine the quality and effectiveness of hospice care for hospices licensed in the state. At a minimum, these outcome measures shall include a requirement that 50 percent of patients who report severe pain on a 0-to-10 scale must report a reduction to 5 or less by the end of the 4th day of care on the hospice program.

(2) For hospices licensed in the state, the Department of Elderly Affairs, in conjunction with the Agency for Health Care Administration, shall:

(a) Consider and adopt national initiatives, such as those developed by the National Hospice and Palliative Care Organization, to set benchmarks for measuring the quality of hospice care provided in the state.

(b) Develop an annual report that analyzes and evaluates the information collected under this act and any other data collection or reporting provisions of law.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (outcome measures) for hospices to ensure that pain management is an essential part of patient care.

2013

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University of Wisconsin Carbone Cancer Center
Madison, Wisconsin

FLORIDA

STATUTES

Professional Practice

Fla. Stat. § 456.057

§ 456.057. Ownership and control of patient records; report or copies of records to be furnished

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(8) (a) 1. The department may obtain patient records pursuant to a subpoena without written authorization from the patient if the department and the probable cause panel of the appropriate board, if any, find reasonable cause to believe that a health care practitioner has excessively or inappropriately prescribed any controlled substance specified in chapter 893 in violation of this chapter or any professional practice act or that a health care practitioner has practiced his or her profession below that level of care, skill, and treatment required as defined by this chapter or any professional practice act and also find that appropriate, reasonable attempts were made to obtain a patient release.

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Fla. Stat. § 456.44

§ 456.44. Controlled substance prescribing

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(3) *Standards of practice.* --The standards of practice in this section do not supersede the level of care, skill, and treatment recognized in general law related to health care licensure.

(a) A complete medical history and a physical examination must be conducted before beginning any treatment and must be documented in the medical record. The exact components of the physical examination shall be left to the judgment of the clinician who is expected to perform a physical examination proportionate to the diagnosis that justifies a treatment. The medical record must, at a minimum, document the nature and intensity of the pain, current and past treatments for pain, underlying or coexisting diseases or conditions, the effect of the pain on physical and psychological function, a review of previous medical records, previous diagnostic studies, and history of alcohol and substance abuse. The medical record shall also document the presence of one or more recognized medical indications for the use of a controlled substance. Each registrant must develop a written plan for assessing each patient's risk of aberrant drug-related behavior, which may include patient drug testing. Registrants must assess each patient's risk for aberrant drug-related behavior and monitor that risk on an ongoing basis in accordance with the plan.

(b) Each registrant must develop a written individualized treatment plan for each patient. The treatment plan shall state objectives that will be used to determine treatment success, such as pain relief and improved physical and psychosocial function, and shall indicate if any further diagnostic evaluations or other treatments are planned. After treatment begins, the physician shall adjust drug therapy to the individual medical needs of each patient. Other treatment modalities, including a rehabilitation program, shall be considered depending on the etiology of the pain and the extent to which the pain is associated with physical and psychosocial impairment. The interdisciplinary nature of the treatment plan shall be documented.

[CONTINUED ON NEXT PAGE]

(-) *CRITERION 16:*
Provisions that are ambiguous

CATEGORY A:
Arbitrary standards for legitimate prescribing

COMMENT: Although it is reasonable to expect practitioners to avoid contributing to diversion, "excessive or inappropriate" implies there is a known standard, but the standard is not specified.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Recognizes that the goals of pain treatment should include improvements in patient functioning and quality of life.

Pain & Policy Studies Group
University of Wisconsin Carbone Cancer Center
Madison, Wisconsin

FLORIDA

STATUTES

Professional Practice

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Encourages healthcare professionals to incorporate in their practice the evaluations of, and discussions with patients about, the potential benefits and risks of treatment with opioids, which can better ensure a clinical indication of such treatment so that opioids will be used for medical purposes.

[CONTINUED]

(c) The physician shall discuss the risks and benefits of the use of controlled substances, including the risks of abuse and addiction, as well as physical dependence and its consequences, with the patient, persons designated by the patient, or the patient's surrogate or guardian if the patient is incompetent. The physician shall use a written controlled substance agreement between the physician and the patient outlining the patient's responsibilities, including, but not limited to:

1. Number and frequency of controlled substance prescriptions and refills.

2. Patient compliance and reasons for which drug therapy may be discontinued, such as a violation of the agreement.

3. An agreement that controlled substances for the treatment of chronic nonmalignant pain shall be prescribed by a single treating physician unless otherwise authorized by the treating physician and documented in the medical record.

(d) The patient shall be seen by the physician at regular intervals, not to exceed 3 months, to assess the efficacy of treatment, ensure that controlled substance therapy remains indicated, evaluate the patient's progress toward treatment objectives, consider adverse drug effects, and review the etiology of the pain. Continuation or modification of therapy shall depend on the physician's evaluation of the patient's progress. If treatment goals are not being achieved, despite medication adjustments, the physician shall reevaluate the appropriateness of continued treatment. The physician shall monitor patient compliance in medication usage, related treatment plans, controlled substance agreements, and indications of substance abuse or diversion at a minimum of 3- month intervals.

(e) The physician shall refer the patient as necessary for additional evaluation and treatment in order to achieve treatment objectives. Special attention shall be given to those patients who are at risk for misusing their medications and those whose living arrangements pose a risk for medication misuse or diversion. The management of pain in patients with a history of substance abuse or with a comorbid psychiatric disorder requires extra care, monitoring, and documentation and requires consultation with or referral to an addiction medicine specialist or psychiatrist.

[CONTINUED ON NEXT PAGE]

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY B:
Issues related to patients

COMMENT:
Acknowledges that a patient's prior history or current status of drug abuse does not necessarily contraindicate appropriate pain management.

Pain & Policy Studies Group
University of Wisconsin Carbone Cancer Center
Madison, Wisconsin

FLORIDA

STATUTES

Professional Practice

[CONTINUED]

(f) A physician registered under this section must maintain accurate, current, and complete records that are accessible and readily available for review and comply with the requirements of this section, the applicable practice act, and applicable board rules. The medical records must include, but are not limited to:

1. The complete medical history and a physical examination, including history of drug abuse or dependence.

2. Diagnostic, therapeutic, and laboratory results.

3. Evaluations and consultations.

4. Treatment objectives.

5. Discussion of risks and benefits.

6. Treatments.

7. Medications, including date, type, dosage, and quantity prescribed.

8. Instructions and agreements.

9. Periodic reviews.

10. Results of any drug testing.

11. A photocopy of the patient's government-issued photo identification.

12. If a written prescription for a controlled substance is given to the patient, a duplicate of the prescription.

13. The physician's full name presented in a legible manner.

(g) Patients with signs or symptoms of substance abuse shall be immediately referred to a board-certified pain management physician, an addiction medicine specialist, or a mental health addiction facility as it pertains to drug abuse or addiction unless the physician is board-certified or board-eligible in pain management. Throughout the period of time before receiving the consultant's report, a prescribing physician shall clearly and completely document medical justification for continued treatment with controlled substances and those steps taken to ensure medically appropriate use of controlled substances by the patient. Upon receipt of the consultant's written report, the prescribing physician shall incorporate the consultant's recommendations for continuing, modifying, or discontinuing controlled substance therapy. The resulting changes in treatment shall be specifically documented in the patient's medical record. Evidence or behavioral indications of diversion shall be followed by discontinuation of controlled substance therapy, and the patient shall be discharged, and all results of testing and actions taken by the physician shall be documented in the patient's medical record.

This subsection does not apply to a board-eligible or board-certified anesthesiologist, physiatrist, rheumatologist, or neurologist, or to a board-certified physician who has surgical privileges at a hospital or ambulatory surgery center and primarily provides surgical services. This subsection does not apply to a board-eligible or board-certified medical specialist who has also completed a fellowship in pain medicine approved by the Accreditation Council for Graduate Medical Education or the American Osteopathic Association, or who is board eligible or board certified in pain medicine by the American Board of Pain Medicine or a board approved by the American Board of Medical Specialties or the American Osteopathic Association and performs interventional pain procedures of the type routinely billed using surgical codes. This subsection does not apply to a physician who prescribes medically necessary controlled substances for a patient during an inpatient stay in a hospital licensed under chapter 395.

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Madison, Wisconsin

FLORIDA

STATUTES

Civil Rights

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (standards and guidelines and continuing education) to provide practitioners information/education about pain management and palliative care.

Fla. Stat. § 765.102

§ 765.102. Legislative findings and intent

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(4) The Legislature recognizes the need for all health care professionals to rapidly increase their understanding of end-of-life and palliative care. Therefore, the Legislature encourages the professional regulatory boards to adopt appropriate standards and guidelines regarding end-of-life care and pain management and encourages educational institutions established to train health care professionals and allied health professionals to implement curricula to train such professionals to provide end-of-life care, including pain management and palliative care.

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Fla. Stat. § 765.1103

§ 765.1103. Pain management and palliative care

(1) A patient shall be given information concerning pain management and palliative care when he or she discusses with the attending or treating physician, or such physician's designee, the diagnosis, planned course of treatment, alternatives, risks, or prognosis for his or her illness. If the patient is incapacitated, the information shall be given to the patient's health care surrogate or proxy, court-appointed guardian as provided in chapter 744, or attorney in fact under a durable power of attorney as provided in chapter 709. The court-appointed guardian or attorney in fact must have been delegated authority to make health care decisions on behalf of the patient.

(2) Health care providers and practitioners regulated under chapter 458, chapter 459, or chapter 464 must, as appropriate, comply with a request for pain management or palliative care from a patient under their care or, for an incapacitated patient under their care, from a surrogate, proxy, guardian, or other representative permitted to make health care decisions for the incapacitated patient. Facilities regulated under chapter 395, chapter 400, or chapter 429 must comply with the pain management or palliative care measures ordered by the patient's physician.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Establishes a responsibility for practitioners to try to comply with patients' requests for pain management or palliative care.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Recognizes a practitioner's responsibility to provide patients information about pain management and palliative care when considering treatment options.

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Madison, Wisconsin

FLORIDA

REGULATIONS

Hospice Services

58A-2.014, F.A.C.

58A-2.014 Medical Direction.

(1) The hospice shall employ a medical director who shall be a hospice physician licensed in the State of Florida pursuant to Chapter 458 or 459, F.S., who has admission privileges at one or more hospitals commonly serving patients in that hospice's service area as defined in Rule *59C-1.0355, F.A.C.* Duties shall be enumerated in a job description, including job qualifications, which shall be kept in an administrative file.

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(b) Duties of the medical director shall include:

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9. Establishing written protocols for symptom control, i.e., pain, nausea, vomiting, or other symptoms.

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(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (written protocols) for hospices to ensure that pain management is an essential part of patient care.

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Madison, Wisconsin

GEORGIA

STATUTES

- CONTROLLED SUBSTANCES ACT
  Title 16. Crimes and Offenses; Chapter 13. Controlled Substances

- MEDICAL PRACTICE ACT
  Title 43. Professions and Businesses; Chapter 34. Physicians, Acupuncture, Physician's Assistants, Cancer and Glaucoma Treatment, Respiratory Care, Clinical Perfusionists, and Orthotics and Prosthetics Practice; Article 2. Physicians

- PHARMACY PRACTICE ACT (*No provisions found*)
  Title 26. Food, Drugs, and Cosmetics; Chapter 4. Pharmacists and Pharmacies

- INTRACTABLE PAIN TREATMENT ACT
  No policy found

REGULATIONS

- CONTROLLED SUBSTANCES REGULATIONS (*Part of Pharmacy Board Regulations*) (*No provisions found*)
  Title 480. Georgia State Board of Pharmacy; Chapter 480-34. Controlled Substances

- MEDICAL BOARD REGULATIONS
  Title 360. Composite State Board of Medical Examiners

- PHARMACY BOARD REGULATIONS
  Title 480. Georgia State Board of Pharmacy

OTHER GOVERNMENTAL POLICIES

- MEDICAL BOARD GUIDELINE
  Georgia Composite State Board of Medical Examiners. *Guidelines for the Use of Controlled Substances for the Treatment of Pain: Ten Steps*. Adopted: January 11, 2008.

RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY KEY WORD SEARCHES

- HOMICIDE
  Title 16. Crimes and Offenses; Chapter 5. Crimes Against the Person; Article 1. Homicide

- HOSPICE SERVICES
  Title 290. Department of Human Resources Office of Regulatory Services; Chapter 290-9-43. Rules and Regulations for Hospices

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Madison, Wisconsin

GEORGIA

STATUTES

Controlled Substances Act

O.C.G.A. § 16-13-21

§ 16-13-21. Definitions

As used in this article, the term:

(0.5) "Addiction" means a primary, chronic, neurobiologic disease with genetic, psychosocial, and environmental factors influencing its development and manifestations. It is characterized by behaviors that include the following: impaired control drug use, craving, compulsive use, and continued use despite harm. Physical dependence and tolerance are normal physiological consequences of extended opioid therapy for pain and are not the same as addiction.

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(8) "Dependent," "dependency," "physical dependency," "psychological dependency," or "psychic dependency" means and includes the state of adaptation that is manifested by drug class specific signs and symptoms that can be produced by abrupt cessation, rapid dose reduction, decreasing blood level of the drug, and administration of an antagonist. Physical dependence, by itself, does not equate with addiction.

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(23) "Practitioner" means:

(A) A physician, dentist, pharmacist, podiatrist, veterinarian, scientific investigator, or other person licensed, registered, or otherwise authorized under the laws of this state to distribute, dispense, conduct research with respect to, or to administer a controlled substance in the course of professional practice or research in this state;

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O.C.G.A. § 16-13-57

§ 16-13-57. Program to record prescription information into electronic database; administration and oversight

(a) Subject to funds as may be appropriated by the General Assembly or otherwise available for such purpose, the agency shall, in consultation with members of the Georgia Composite Medical Board, establish and maintain a program to electronically record into an electronic data base prescription information resulting from the dispensing of Schedule II, III, IV, or V controlled substances and to electronically review such prescription information that has been entered into such data base. The purpose of such program shall be to assist in the reduction of the abuse of controlled substances, to improve, enhance, and encourage a better quality of health care by promoting the proper use of medications to treat pain and terminal illness, and to reduce duplicative prescribing and overprescribing of controlled substance practices.

(b) Such program shall be administered by the agency at the direction and oversight of the board.

(+) *CRITERION 7:*
Physical dependence or analgesic tolerance are not confused with "addiction"

(+) *CRITERION 3:*
Opioids are part of professional practice

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Represents the principle of Balance, which states that the regulation of controlled substances should not interfere with legitimate medical use.

2013

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GEORGIA

STATUTES

Controlled Substances Act

O.C.G.A. § 16-13-61

§ 16-13-61. Electronic Database Review Advisory Committee; members; terms; officers; procedure; compensation

(a) There is established an Electronic Database Review Advisory Committee for the purposes of consulting with and advising the agency on matters related to the establishment, maintenance, and operation of how prescriptions are electronically reviewed pursuant to this part. This shall include, but shall not be limited to, data collection, regulation of access to data, evaluation of data to identify benefits and outcomes of the reviews, communication to prescribers and dispensers as to the intent of the reviews and how to use the data base, and security of data collected.

(b) The advisory committee shall consist of ten members as follows:

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(6) A pain management specialist, appointed by the Georgia Composite Medical Board;

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O.C.G.A. § 16-13-62

§ 16-13-62. Rules and regulations

The agency shall establish rules and regulations to implement the requirements of this part. Nothing in this part shall be construed to authorize the agency to establish policies, rules, or regulations which limit, revise, or expand or purport to limit, revise, or expand any prescription or dispensing authority of any prescriber or dispenser subject to this part. Nothing in this part shall be construed to impede, impair, or limit a prescriber from prescribing pain medication in accordance with the pain management guidelines developed and adopted by the Georgia Composite Medical Board.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Recognizes that a PMP Advisory Committee's objective to review practitioner prescribing profiles could benefit from the involvement of a pain management expert.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Recognizes need for avoid conflict between requirements from PMP laws and existing state practice standards.

Pain & Policy Studies Group
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Madison, Wisconsin

GEORGIA

STATUTES

Medical Practice Act

O.C.G.A. § 43-34-281

§ 43-34-281. Legislative intent

(a) This article is enacted for the purpose of safeguarding the public health, safety, and welfare by providing for state administrative control, supervision, and regulation of pain management clinics. It is the intention of the General Assembly that people be able to obtain appropriate and safe medical care to treat conditions in which the control of pain is an element. However, the illegal and improper distribution of controlled substances is a growing problem in this state. Licensure and regulation of pain management clinics will better protect the public from criminal activities associated with the illegal distribution of controlled substances as well as provide for a safer place for people to obtain appropriate medical treatment by requiring certain minimum training of practitioners and by the regulation of pain management clinics.

(b) Nothing in this article shall be construed to limit the authority and regulations of the board relating to pain management as such authority and regulations existed on June 30, 2013.

O.C.G.A. § 43-34-282

§ 43-34-282. Definitions

As used in this article, the term:

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(9) "Physician" means a person who possesses a current, unrestricted license to practice medicine in the State of Georgia pursuant to Article 2 of this chapter; who, during the course of his or her practice, has not been denied the privilege of prescribing, dispensing, administering, supplying, or selling any controlled substance; and who has not, during the course of his or her practice, had board action taken against his or her medical license as a result of dependency on drugs or alcohol.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Represents the principle of Balance, which states that the regulation of controlled substances should not interfere with legitimate medical use.

(+) *CRITERION 3:*
Opioids are part of professional practice

2013

Pain & Policy Studies Group
University of Wisconsin Carbone Cancer Center
Madison, Wisconsin

GEORGIA

REGULATIONS

Medical Board Regulations

Ga. Comp. R. & Regs. r. 360-3-.06.

Rule 360-3-.06. Pain Management.

(1) Definitions. As used in this rule, the following terms shall mean:

(a) "Annual patient population" shall mean those patients seen by a clinic or practice in a twelve month calendar year, but shall not include patients that are in-patient in hospital, nursing home or hospice facilities licensed pursuant to O.C.G.A. T. 31, Ch. 7.

(b) "Board" shall mean the Georgia Composite Medical Board.

(c) "Chronic pain" shall mean pain requiring treatment which has persisted for a period of ninety days or greater in a year, but shall not include perioperative pain, i.e., pain immediately preceding and immediately following a surgical procedure, when such perioperative pain is being treated by a physician in connection with a surgical procedure.

(d) "Monitoring" means any method to assure treatment compliance including but not limited to the use of pill counts, pharmacy or prescription program verification. Monitoring must include a urine, saliva, sweat, or serum test performed on a random basis.

(e) "Terminal condition" means an incurable or irreversible condition, which would result in death in a relatively short period of time.

(2) O.C.G.A. § 43-34-8 authorizes the Board to take disciplinary action against licensees for unprofessional conduct, which includes conduct below the minimum standards of practice. With respect to the prescribing of controlled substances for the treatment of pain and chronic pain, the Board has determined that the minimum standards of practice include, but are not limited to the following:

(a) Physicians cannot delegate the dispensing of controlled substances to an unlicensed person.

(b) When prescribing controlled substances, a physician shall use a prescription pad that complies with state law.

(c) When initially prescribing a controlled substance for the treatment of pain or chronic pain, a physician shall have a medical history of the patient, a physical examination of the patient shall have been conducted, and informed consent shall have been obtained. In the event of a documented emergency, a physician may prescribe an amount of medication to cover a period of not more than 72 hours without a physical examination.

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Pain & Policy Studies Group
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GEORGIA

REGULATIONS

Medical Board Regulations

[CONTINUED]

(d) When a physician is treating a patient with controlled substances for pain or chronic pain for a condition that is not terminal, the physician shall obtain or make a diligent effort to obtain any prior diagnostic records relative to the condition for which the controlled substances are being prescribed and shall obtain or make a diligent effort to obtain any prior pain treatment records. The records obtained from prior treating physicians shall be maintained by the prescribing physician with the physician's medical records for a period of at least ten (10) years. If the physician has made a diligent effort and is unable to obtain prior diagnostic records, then the physician must order appropriate tests to document the condition requiring treatment for pain or chronic pain. If the physician has made a diligent effort and the prior pain treatment records are not available, then the physician must document the efforts made to obtain the records and shall maintain the documentation of the efforts in his/her patient record.

(e) When a physician determines that a patient for whom he is prescribing controlled scheduled substances is abusing the medication, then the physician shall make an appropriate referral for treatment for substance abuse.

(f) When prescribing a Schedule II or III controlled substance for 90 (ninety) days or greater for the treatment of chronic pain arising from conditions that are not terminal, a physician must have a written treatment agreement with the patient and shall require the patient to have a clinical visit at least once every three (3) months to evaluate the patient's response to treatment, compliance with the therapeutic regimen through monitoring appropriate for that patient, and any new condition that may have developed and be masked by the use of Schedule II or III controlled substances. The physician shall respond to any abnormal result of any monitoring and such response shall be recorded in the patient's record. Exceptions to the requirement of a clinical visit once every three (3) months may be made for hardship in certain cases and such hardship must be well documented in the patient record. When a physician determines that a new medical condition exists that is beyond their scope of training, he/she shall make a referral to the appropriate practitioner.

(g) Any physician who prescribes Schedule II or III substances for chronic pain for greater than 50% of that physician's annual patient population must document competence to the Board through certification or eligibility for certification in pain management or palliative medicine as approved by the Georgia Composite Medical Board ("Board"). The Board recognizes certifications in pain medicine or palliative medicine by the American Board of Medical Specialties or the American Osteopathic Association, the American Board of Pain Medicine and the American Board of Interventional Pain Physicians. If the physician does not hold this certification or eligibility he/she must demonstrate competence by biennially obtaining 20 (twenty) hours of continuing medical education ("CME") pertaining to pain management or palliative medicine. Such CME must be an AMA/AOA PRA Category I CME, a board approved CME program, or any federally approved CME. The CME obtained pursuant to this rule may count towards the CME required for license renewal.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (continuing education) to ensure that pain management is an essential part of patient care.

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REGULATIONS

Pharmacy Board Regulations

Ga. Comp. R. & Regs. r. 480-22-.14

480-22-.14 Ordering and Receipt of Samples.

(1) For purposes of this rule, a practitioner means:

(a) A physician, dentist, podiatrist, veterinarian, or other person licensed, registered, or otherwise authorized under the laws of this state to distribute, dispense, with respect to, or to administer a controlled substance or dangerous drug in the course of professional practice in this state;

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(+) *CRITERION 3:*
Opioids are part of professional practice

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GEORGIA

OTHER GOVERNMENTAL POLICY

Medical Board Guideline

GEORGIA COMPOSITE STATE BOARD OF MEDICAL EXAMINERS

Guidelines for the Use of Controlled Substances for the Treatment of Pain: Ten Steps

Disclaimer
These guidelines are primarily intended to provide orientation for physicians intending to prescribe schedule II and III analgesics for the purpose of treating chronic pain conditions and do not necessarily apply to clinical conditions where rapid adjustments in medical management are required such as acute pain management following surgery, emergency care pain management and end-of-life care.

The Georgia Composite State Board of Medical Examiners (the Medical Board) recognizes that principles of quality medical practice dictate that the people of the state of Georgia have access to appropriate and effective pain relief by licensed physicians. The appropriate application of up-to-date knowledge and treatment modalities can serve to improve the quality of life for those patients who suffer pain as well as reduce the morbidity and costs associated with untreated or inappropriately treated pain. For the purposes of these guidelines, the inappropriate treatment of pain includes no treatment, under treatment, over treatment, and the continued use of ineffective treatments.

(+) *CRITERION 8:*
Other provisions that may enhance pain treatment

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Recognizes that inadequate treatment of pain is subject to disciplinary action just as other substandard practices might be.

(+) *CRITERION 2:*
Pain management is part of healthcare practice

The diagnosis and treatment of pain is integral to the practice of medicine. The Board encourages physicians to view pain management as an essential part of quality medical practice for all patients with pain, including both acute and chronic disease. All physicians should be or seek to become knowledgeable about assessing patients' pain and effective methods of pain treatment, as well as becoming familiar with statutory requirements for prescribing controlled substances. These guidelines have been developed to clarify the Board's position on pain management, particularly as it relates to the use of controlled substances, to alleviate physician uncertainty and to encourage better pain management practices. The guidelines are also intended to curtail drug diversion, a serious public safety concern for the Board and law enforcement agencies.

(+) *CRITERION 4:*
Encourages pain management

Adherence to the guidelines outlined here will not only improve quality medical practice but will also improve the board's efficiency in its investigations by distinguishing legitimate practice from foul play.

(+) *CRITERION 5:*
Addresses fear of regulatory scrutiny

Physicians should not fear disciplinary action from the Board for ordering, prescribing, dispensing or administering controlled substances, including opioid analgesics, for a legitimate medical purpose and in the course of professional practice.

To prevent any misunderstanding, it is necessary to state what the Board does not have.
The Board does not have a list of "bad" or "disallowed" drugs. All formulary drugs are generally effective if prescribed and administered when properly indicated. Conversely, drugs are potentially ineffective, dangerous, or even lethal when used inappropriately.

(+) *CRITERION 6:*
Prescription amount alone does not determine legitimacy

The Board does not have a "magic formula" for determining the dosage and duration of administration for any drug. These are aspects of prescribing that must be determined within the confines of the individual clinical case and continued under proper monitoring. What is good for one patient may be insufficient or fatal for another.

The Board does have the expectation that physicians will create a record that shows evaluation of every patient receiving a controlled substance prescription as follows:

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OTHER GOVERNMENTAL POLICY

Medical Board Guideline

[CONTINUED]

- Proper indication for the use of drug or other therapy
- Monitoring of the patient where necessary
- The patient's response to therapy on follow-up visits
- All rationale for continuing or modifying the therapy
- Discussion of risks/benefits
- Periodic medical record review
- Prescription records

STEP ONE

A medical history and physical examination must be obtained, evaluated, and documented in the medical record. The medical record should document the nature and intensity of the pain, current and past treatments for pain, underlying or coexisting diseases or conditions, the effect of the pain on physical and psychological function, and history of substance abuse. The medical record also should document the presence of one or more recognized medical indications for the use of a controlled substance. Perform a workup sufficient to support a diagnosis including all necessary tests, history and physical examination. If medical testing is negative, carefully document the rationale of therapy and its effectiveness. When a diagnosis is undetermined, despite the complaint of severe pain, consider consultation for further analysis. The medical record will need to document sufficient and appropriate H&P and diagnostic testing to support the diagnosis necessitating the use of controlled substances.

STEP TWO

Create a treatment plan, which includes the use of appropriate non-controlled drugs, and consider referrals to appropriate specialists, such as neurologists, orthopedists, pain management specialists, addictionologists, psychiatrists, etc. The result of the referral should be included in the patient's chart. The written treatment plan should state objectives that will be used to determine treatment success, such as pain relief and improved physical and psychosocial function, and should indicate if any further diagnostic evaluations or other treatments are planned.

STEP THREE

Before beginning a regimen of controlled drugs, make a determination through trial or through a documented history and physical that non-controlled drugs are not appropriate or effective for the patient's condition. The above does NOT apply to acutely painful conditions such as an acute injury or surgery, nor does it apply to the management of pain in cancer or hospice patients. It may also not apply for patients who have a contraindication to, or are at high risk of experiencing side effects from non-steroidal anti-inflammatory drugs such as the elderly.

Although non-controlled drugs (e.g., aspirin, acetaminophen, NSAIDS) often are adequate to treat painful conditions of mild severity, the Board recognizes that controlled substances including opioid analgesics may be essential in the treatment of acute pain due to trauma or surgery and chronic pain, whether due to cancer or non-cancer origins. This does not mean that opioids and other controlled substances cannot be used as a first-line therapy, but it is important to document the rationale when used as such.

STEP FOUR

Review the patient's prescription records and discuss the patient's chemical history before prescribing a controlled drug. If the patient is new or otherwise unknown to you, at a minimum obtain an oral drug history and medication allergies, and discuss chemical use and family chemical history with the patient and obtain old records which may include pharmacy records.

[CONTINUED ON NEXT PAGE]

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY B:
Issues related to patients

COMMENT*:* Recognizes that controlled substances can be used as a first-line therapy when there is medical justification (e.g., severe chronic pain).

(+) *CRITERION 8:*
Other provisions that may enhance pain treatment

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Recognizes that the goal of pain treatment should include improvements in patient functioning and quality of life.

(+) *CRITERION 3:*
Opioids are part of professional practice

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OTHER GOVERNMENTAL POLICY

Medical Board Guideline

[CONTINUED]

STEP FIVE

The physician should discuss the risks and benefits of the use of controlled substances with the patient, persons designated by the patient, or with the patient's surrogate or guardian if the patient does not have decision making capacity. The physician must remain in compliance with HIPAA regulations. Take the time to explain the relative risks and benefits of the drug and record in the chart the fact that this was done. When embarking on what appears to be the long-term use of a dependence-causing or potentially addictive substance, it may be wise to hold a family conference and explain differences between physical dependence, tolerance and addiction.

STEP SIX

Maintain regular monitoring of the patient, including frequent physical monitoring. If the regimen is for prolonged need for the drug use it is very important to monitor the patient for the underlying condition which necessitates the drug and for the side effects of the drug itself. This is true no matter what type of controlled substance is used or to what schedule it belongs. It is very important to monitor the patient for the underlying condition which necessitates the use of controlled substances. It is also important to monitor the patient for side effects that may occur with the use of the selected controlled substance(s).

STEP SEVEN

The physician must keep detailed records of the type, dosage and amount of the drug prescribed. Prescribing physicians should also monitor and personally control all refills. One good way to accomplish this is to require the patient to return to obtain refill authorization, at least part of the time. Records of the cumulative dosage and average daily dosage are especially valuable. The patient should receive prescriptions from one physician and one pharmacy whenever possible. If the patient is at high risk for medication abuse or has a history of substance abuse, the physician should consider the use of a written agreement between physician and patient outlining patient responsibilities and checking on whether the patient is obtaining drugs from other physicians. Checking with pharmacies may indicate a patient is obtaining additional drugs or is doctor shopping. It is a felony in Georgia for a patient to fail to disclose to his physician that he has received controlled substances of a similar therapeutic use from another practitioner at the same time. If you are aware of these situations occurring, contact your local police or the Georgia Drug and Narcotics Agency.

STEP EIGHT

With the patient's permission, the patient's family may be a valuable source of information on the patient's response to the therapy regimen and the patient's functional status, and may provide more accurate and objective feedback than the patient alone.

Family may be a much better source of information on behavioral changes, especially dysfunctional behavior, than is the patient. Dysfunctional changes may be observable when the patient is taking the drug, or when the drug is discontinued. These changes, at the time, may be symptoms of dependency or addiction. Physicians should recognize that tolerance and physical dependence are normal consequences of sustained use of opioid analgesics and are not the same as addiction.

[CONTINUED ON NEXT PAGE]

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Encourages healthcare professionals to incorporate in their practice the evaluations of, and discussions with patients about, the potential benefits and risks of treatment with opioids, which can better ensure a clinical indication of such treatment so that opioids will be used for medical purposes.

(+) *CRITERION 7:*
Physical dependence or analgesic tolerance are not confused with "addiction"

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OTHER GOVERNMENTAL POLICY

Medical Board Guideline

[CONTINUED]

STEP NINE

Maintaining adequate records is extremely important. The physician who carefully manages pain treatment and maintains detailed records which reflect all the steps involved in the process will be able to assess and review the treatment course and progress.

STEP TEN

Document
Document
Document
Keep accurate and complete records to include:
The medical history and physical examination
Diagnostic, therapeutic and laboratory results
Evaluations and consultations
Treatment objectives
Medications (including date, type, dosage and quantity prescribed)
Instructions and agreements, pain contracts (where applicable)

Definitions:

Addiction—Addiction is a primary, chronic, neurobiologic disease, with genetic, psychosocial, and environmental factors influencing its development and manifestations. It is characterized by behaviors that include the following: impaired control over drug use, craving, compulsive use, and continued use despite harm. Physical dependence and tolerance are normal physiological consequences of extended opioid therapy for pain and are not the same as addiction.

Physical Dependence—Physical dependence is a state of adaptation that is manifested by drug class specific signs and symptoms that can be produced by abrupt cessation, rapid dose reduction, decreasing blood level of the drug, and/or administration of an antagonist. Physical dependence, by itself, does not equate with addiction.

Tolerance—Tolerance is a physiologic state resulting from regular use of a drug in which an increased dosage is needed to produce a specific effect, or a reduced effect is observed with a constant dose over time. Tolerance may or may not be evident during opioid treatment and does not equate with addiction.

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STATUTES

Homicide

O.C.G.A. § 16-5-5

§ 16-5-5. Assisted suicide; notification of licensing board regarding violation

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(c) The provisions of this Code section shall not apply to:

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(3) Any person prescribing, dispensing, or administering medications or medical procedures pursuant to, without limitation, a living will, a durable power of attorney for health care, an advance directive for health care, or a consent pursuant to ***Code Section 29-4-18*** or 31-9-2 when such actions are calculated or intended to relieve or prevent a patient's pain or discomfort but are not calculated or intended to cause such patient's death, even if the medication or medical procedure may have the effect of hastening or increasing the risk of death;

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(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT*:* Clarifies for physicians the important distinction between physician-assisted suicide and prescribing controlled substances for pain relief; this language identifies a clinical misperception that is pervasive in end-of-life care and attempts to lessen its impact on patient treatment, and the practitioners who provide it.

REGULATIONS

Hospice Services

Ga. Comp. R. & Regs. r. 290-9-43-.09

290-9-43-.09 Quality Management.

(1) The hospice shall appoint a multidisciplinary quality management committee that reflects the hospice's scope of services. The committee shall develop and implement a comprehensive and ongoing quality management, utilization, and peer review program that evaluates the quality and appropriateness of patient care provided, including the appropriateness of the level of service received by patients, and submits required patient incident reports to the Department.

(2) The quality management, utilization, and peer review program shall establish and use written criteria as the basis to evaluate the provision of patient care. The written criteria shall be based on accepted standards of care and shall include, at a minimum, systematic reviews of:

(a) Appropriateness of admissions, continued stay, and discharge;

(b) Appropriateness of professional services and level of care provided;

(c) Effectiveness of pain control and symptom relief;

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(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT*:* Establishes a mechanism (systematic reviews) for hospices to ensure that pain management is an essential part of patient care.

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STATUTES

- CONTROLLED SUBSTANCES ACT
  Division 1. Government; Title 19. Health; Chapter 329. Uniform Controlled Substances Act

- MEDICAL PRACTICE ACT
  Division 2. Business; Title 25. Professions and Occupations; Chapter 453. Medicine and Surgery

- PHARMACY PRACTICE ACT (*No provisions found*)
  Division 2. Business; Title 25. Professions and Occupations; Chapter 461. Pharmacists and Pharmacy

- PAIN PATIENT'S BILL OF RIGHTS
  Division 1. Government; Title 19. Health; Chapter 327H. Pain Patient's Bill of Rights

- INTRACTABLE PAIN TREATMENT ACT
  No policy found

REGULATIONS

- CONTROLLED SUBSTANCES REGULATIONS
  Title 23. Department of Public Safety; Subtitle 3. Law Enforcement; Chapter 200. Regulation of Controlled Substances

- MEDICAL BOARD REGULATIONS (*No provisions found*)
  Title 16. Department of Commerce and Consumer Affairs; Chapter 85. Medical Examiners

- OSTEOPATHIC BOARD REGULATIONS (*No provisions found*)
  Title 16. Department of Commerce and Consumer Affairs; Chapter 93. Osteopaths

- PHARMACY BOARD REGULATIONS (*No provisions found*)
  Title 16. Department of Commerce and Consumer Affairs; Chapter 95. Pharmacists and Pharmacies

OTHER GOVERNMENTAL POLICIES

- MEDICAL BOARD GUIDELINE
  Hawaii Board of Medical Examiners. *Hawaii Board of Medical Examiners Pain Management Guidelines*. Adopted: January, 2006.

RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY KEY WORD SEARCHES

No policies found

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STATUTES

Controlled Substances Act

HRS § 329-1

§ 329-1. Definitions.

As used in this chapter:

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"Practitioner" means: (1) A physician, dentist, veterinarian, scientific investigator, or other person licensed and registered under section 329-32 to distribute, dispense, or conduct research with respect to a controlled substance in the course of professional practice or research in this State.

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HRS § 329-38

§ 329-38. Prescriptions.

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(b) A schedule II controlled substance prescription shall:

(1) Be filled within seven days following the date the prescription was issued to the patient; and

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HRS § 329-40

§ 329-40. Methadone treatment programs

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The term "narcotic-dependent person" as used in this section means an individual who physiologically needs heroin or a morphine-like drug to prevent the onset of signs of withdrawal.

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(+) *CRITERION 3:*
Opioids are part of professional practice

(-) *CRITERION 11:*
Physical dependence or analgesic tolerance confused with "addiction"

(-) *CRITERION 13:*
Length of prescription validity is restricted

STATUTES

Medical Practice Act

HRS § 453-1.5

453-1.5. Pain management guidelines.

The Hawaii medical board may establish guidelines for physicians or osteopathic physicians with respect to patients' pain management. The guidelines shall apply to all patients with severe acute pain or severe chronic pain, regardless of the patient's prior or current chemical dependency or addiction, and may include standards and procedures for chemically dependent individuals.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (guidelines) for the board to ensure that pain management is an essential part of patient care.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY B:
Issues related to patients

COMMENT: Recognizes that a patient's prior history or current status of drug abuse does not necessarily contraindicate appropriate pain management.

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HAWAII

STATUTES

Pain Patient's Bill of Rights

HRS prec § 327H-1 – § 327H-2

[§ 327H-1.] Pain patient's bill of rights; findings.

The legislature finds that:

(1) Inadequate treatment of severe acute pain and severe chronic pain originating from cancer or noncancerous conditions is a significant health problem;

(2) For some patients, pain management is the single most important treatment a physician can provide;

(3) A patient who suffers from severe acute pain or severe chronic pain should have access to proper treatment of pain;

(4) Due to the complexity of their problems, many patients who suffer from severe acute pain or severe chronic pain may require referral to a physician with expertise in the treatment of severe acute pain and severe chronic pain. In some cases, severe acute pain and severe chronic pain is best treated by a team of clinicians to address the associated physical, psychological, social, and vocational issues;

(5) In the hands of knowledgeable, ethical, and experienced pain management practitioners, opiates administered for severe acute pain or severe chronic pain can be safe; and

(6) Opiates may be part of an overall treatment plan for a patient in severe acute pain or severe chronic pain who has not obtained relief from any other means of treatment.

§ 327H-2. Bill of rights.

(a) The pain patient's bill of rights includes the following:

(1) A patient who suffers from severe acute pain or severe chronic pain has the option to request or reject the use of any or all modalities to relieve the pain;

(2) A patient who suffers from severe acute pain or severe chronic pain has the option to choose from appropriate pharmacologic treatment options to relieve severe acute pain or severe chronic pain, including opiate medications, without first having to submit to an invasive medical procedure.

For purposes of this paragraph, "invasive medical procedure" means surgery, destruction of a nerve or other body tissue by manipulation, or the implantation of a drug delivery system or device;

(3) A patient's physician may refuse to prescribe opiate medication for a patient who requests a treatment for severe acute pain or severe chronic pain. However, that physician may inform the patient of physicians who are qualified to treat severe acute pain and severe chronic pain employing methods that include the use of opiates;

(4) A physician who uses opiate therapy to relieve severe acute pain or severe chronic pain may prescribe a dosage deemed medically necessary to relieve the pain;

(5) A patient may voluntarily request that the patient's physician provide an identifying notice of the prescription for purposes of emergency treatment or law enforcement identification; and

[CONTINUED ON NEXT PAGE]

(+) *CRITERION 2:*
Pain management is part of medical practice

(+) *CRITERION 4:*
Encourages pain management

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Recognizes that the goal of pain treatment should include improvements in patient functioning and quality of life.

(-) *CRITERION 16:*
Provisions that are ambiguous

CATEGORY B:
Unclear intent leading to possible misinterpretation

COMMENT: How does this qualify as a "Pain Patient's Bill of Rights"? This language falls short of providing any rights to specific treatment and may establish a false expectation for adequate pain management.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT*:* Recognizes the need for a multidisciplinary approach to pain management.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY B:
Issues related to patients

COMMENT*:* Recognizes the patient's right to request or reject different types of treatments.

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STATUTES

Pain Patient's Bill of Rights

[CONTINUED]

(6) With regard to pain patients, the application of this section shall be guided by the medical principle that physical tolerance and dependence are normal consequences of sustained use of opiate medication, distinguishable from psychological dependency or addiction that bears no relationship to pain experienced by a patient. For the purposes of this section, psychological dependency shall be characterized by a patient's compulsion to take a drug notwithstanding the fact that the patient knows the harmful and destructive effect of the drug on the patient. The distinction is one of treatment of pain as opposed to feeding a psychological need. A patient who suffers severe acute pain or severe chronic pain secondary to a diagnosis in any form of disease and chronic conditions may be entitled to receive a prescription of opiate medication for the treatment of the pain, if requested by that patient; provided that:

(A) The particular opiate is appropriate to the treatment of that pain; and

(B) The patient is not addicted to the opiate. For the purposes of this subparagraph, the term "addicted" refers to a psychological dependence, rather than a progressive physical tolerance for the opiate to relieve the pain; provided that the term does not include a narcotic-dependent person as defined in section 329-40.

(b) Nothing in this section shall be construed to:

(1) Expand the authorized scope of practice of any licensed physician;

(2) Limit any reporting or disciplinary provisions applicable to licensed physicians and surgeons who violate prescribing practices; and

(3) Prohibit the discipline or prosecution of a licensed physician for:

(A) Failing to maintain complete, accurate, and current records that document the physical examination and medical history of a patient, the basis for the clinical diagnosis of a patient, and the treatment plan for a patient;

(B) Writing false or fictitious prescriptions for controlled substances scheduled in the Federal Comprehensive Drug Abuse Prevention and Control Act of 1970, *21 United States Code 801* et seq. or in chapter 329;

(C) Prescribing, administering, or dispensing pharmaceuticals in violation of the provisions of the Federal Comprehensive Drug Abuse Prevention and Control Act of 1970, *21 United States Code 801* et seq. or of chapter 329;

(D) Diverting medications prescribed for a patient to the licensed physician's own personal use; and

(E) Causing, or assisting in causing, the suicide, euthanasia, or mercy killing of any individual; provided that it is not "causing, or assisting in causing, the suicide, euthanasia, or mercy killing of any individual" to prescribe, dispense, or administer medical treatment for the purpose of treating severe acute pain or severe chronic pain, even if the medical treatment may increase the risk of death, so long as the medical treatment is not also furnished for the purpose of causing, or the purpose of assisting in causing, death for any reason.

(+) *CRITERION 7:*
Physical dependence or analgesic tolerance are not confused with "addiction"

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Clarifies for physicians the important distinction between physician-assisted suicide and prescribing controlled substances for pain relief; this language identifies a clinical misperception that is pervasive in end-of-life care and attempts to lessen its impact on patient treatment, and the practitioners who provide it.

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HAWAII

REGULATIONS

Controlled Substances Regulations

WCHR 23-200

23-200. REGULATION OF CONTROLLED SUBSTANCES

§ 23-200-2 Definitions. The following definitions shall apply in the interpretation and enforcement of this chapter:

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"Practitioner" means:

(1) A physician, dentist, veterinarian, scientific investigator, or other person licensed and registered under *section 329-32, Hawaii Revised Statutes*, to distribute, dispense, prescribe or conduct research with respect to a controlled substance in the course of professional practice or research in this State but does not include midlevel practitioners.

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§ 23-200-15 Prescriptions.

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(g) Filling and refilling of prescriptions.

(1) The refilling of a prescription for a controlled substance listed in schedule II is prohibited;

(2) No prescription for a schedule II controlled substance shall be filled later than the third day following the day of issuance;

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(-) *CRITERION 16:*
Provisions that are ambiguous

Category C:
Conflicting or inconsistent policies or provisions

COMMENT: This provision is confusing, and even in conflict, when considered in conjunction with provision §329-38 of the state Controlled Substances Act, which indicates that a prescription for a Schedule II controlled substance is valid for seven days.

(+) *CRITERION 3:*
Opioids are part of professional practice

(-) *CRITERION 13:*
Length of prescription validity is restricted

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HAWAII

OTHER GOVERNMENTAL POLICY

Medical Board Guideline

Pursuant to section 453-1.5, Hawaii Revised Statutes, the Board of Medical Examiners ("Board") has established guidelines for physicians with respect to the care and treatment of patients with severe acute pain or severe chronic pain. These pain management guidelines are considerations that the Board will take into account in the proper treatment of pain.

HAWAII BOARD OF MEDICAL EXAMINERS
PAIN MANAGEMENT GUIDELINES

Section I: Introduction

The Board of Medical Examiners ("Board") recognizes that principles of quality medical practice dictate that the people of the State of Hawaii have access to appropriate and effective pain relief. The Board affirms that controlled substances may be necessary to relieve pain, and the medical use of opioid analgesics is recognized to be part of legitimate medical practice.

The diagnosis and treatment of pain is integral to the practice of medicine. The Board encourages physicians to view pain management as a part of quality medical practice for all patients with pain, acute or chronic, and it is especially urgent for patients who experience pain as a result of terminal illness. The Board believes that all physicians who treat patients directly should have sufficient knowledge about pain and its management to provide comfort for those in pain, or utilize consultations when possible to obtain necessary information to make treatment decisions for their patients. Accordingly, this policy has been developed to clarify the Board's position on pain management, particularly as related to the use of controlled substances.

The Board is obligated under the laws of the State of Hawaii to protect the public health and safety. The Board recognizes that the use of opioid analgesics for other than legitimate medical purposes poses a threat to the individual and society and that the inappropriate prescribing of controlled substances, including opioid analgesics, may lead to drug diversion and abuse by individuals who seek them for other than legitimate medical use. Accordingly, the Board expects that physicians incorporate safeguards into their practices to minimize the potential for the abuse and diversion of controlled substances. The Board considers acceptable the ordering, prescribing, dispensing or administration of controlled substances, including opioid analgesics, for a legitimate medical purpose to be acceptable particularly in the case of terminal illness. The Board considers the use of controlled substances for pain to be for a legitimate medical purpose if based on sound clinical judgment. To be within the usual course of professional practice, a physician-patient relationship must exist and the prescribing should be based on a diagnosis and documentation of unrelieved pain.

The Board will consider the inappropriate treatment of pain to be a departure from standards of practice and therefore investigate such allegations, recognizing that some types of pain cannot be completely relieved, and taking into account whether the treatment is appropriate to the diagnosis.

Section II: Evaluation of Physician Practice

The Board will judge the validity of the physician's treatment of the patient based on available documentation, rather than solely on the quantity and duration of medication administration. The goal is to control the patient's pain while effectively addressing other aspects of the patient's functioning, including physical, psychological, social and work-related factors.

Allegations of inappropriate pain management will be evaluated on a case-by-case basis. Deviation from this policy may be appropriate when contemporaneous medical records document reasonable cause for deviation.

In determining whether the physician has acted appropriately, the Board will consider the clinical outcome, whether drugs used are appropriate for the type of pain, and whether there is improvement in patient functioning and/or quality of life as factors.

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(+) CRITERION 4:
Encourages pain management

(+) CRITERION 2:
Pain management is part of healthcare practice

(+) CRITERION 8:
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT:
Acknowledges need for treatment flexibility for physicians to respond to individual clinical circumstances, as long as their prescribing maintains the standards of good medical practice.

(+) CRITERION 3:
Opioids are part of professional practice

(+) CRITERION 6:
Prescription amount alone does not determine legitimacy

(+) CRITERION 8:
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Recognizes that the goal of pain treatment should include improvements in patient functioning and quality of life.

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OTHER GOVERNMENTAL POLICY

Medical Board Guideline

[CONTINUED]

Section III: Practice Guidelines for Chronic Pain Management

Evaluation of the Patient – A medical history and physical examination should be performed and documented in the medical record. The medical record should document the nature and intensity of the pain, current and past treatments for pain, underlying or coexisting diseases or conditions, the effect of the pain on physical and psychological function, and history of substance abuse or other compulsive behaviors.

Treatment Plan – The written treatment plan should state objectives that will be used to determine treatment success, such as pain relief and improved physical and psychosocial function, and should indicate if any further diagnostic evaluations or other treatments are planned. The treatment plan should be adjusted and documented according to the individual needs of each patient.

Informed Consent and Agreement for Treatment – The physician should discuss the risks and benefits of the use of controlled substances with the patient, persons designated by the patient or with the patient's surrogate or guardian. The patient's pain medication should be managed by one physician and one pharmacy whenever possible. If the patient is at high risk for medication abuse or has a history of substance abuse, the physician should have written treatment agreements outlining the patient's responsibilities during treatment and should obtain informed consent before prescriptions are provided.

The treatment agreements may specify many of the following items:

- Urine or blood samples will be provided by patients upon request for urine/serum drugs of abuse screening and/or determining medication levels by their physicians;
- The number and frequency of all prescription refills may be limited at their physicians' discretion;
- Therapy with controlled substances may be discontinued by physicians under certain situations (e.g. significant violation of treatment agreements by patients);
- Physician/patient relationships may be discontinued under certain situations (e.g. violation of treatment agreements by patients);
- Medication refills will be provided under specified rules, within mutually agreed upon time-frames (e.g. early refills may not be allowed, lost medications may not be replaced, refills may only occur during regular business hours, etc.);
- All therapies may be provided on a time-limited basis to determine potential effectiveness, and may be discontinued if judged ineffective or unacceptably toxic;
- Referral of patients to substance abuse treatment programs will occur when use of controlled substances is determined to be due to underlying addiction and not pain.

Periodic Review - The physician should periodically review the course of pain treatment and any new information about the etiology of the pain or the patient's state of health. Continuation or modification of controlled substances for pain management therapy depends on the physician's evaluation of progress toward treatment objectives.

Use of consultation with pain management specialists, addiction medicine specialists, and other medical specialties is encouraged. Physicians should be willing to refer their patients as necessary for additional evaluations and therapies to achieve treatment objectives. Special attention should be given to those patients with pain who are at risk for medication misuse, abuse or diversion.

[CONTINUED ON NEXT PAGE]

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Encourages healthcare professionals to incorporate in their practice the evaluations of, and discussions with patients about, the potential benefits and risks of treatment with opioids, which can better ensure a clinical indication of such treatment so that opioids will be used for medical purposes.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY B:
Issues related to patients

COMMENT:
Acknowledges that a patient's prior history or current status of drug abuse does not necessarily contraindicate appropriate pain management.

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[CONTINUED]

Medical Records – The physician should keep accurate, current and complete medical records. Elements considered for completeness may include, but are not limited to the following:

1. An initial medical history and physical examination;
3. Diagnostic imaging, therapeutic and laboratory results;
4. Ongoing evaluations and consultations;
5. Establishment of treatment objectives;
6. Discussion and documentation of risks, benefits and alternatives;
7. Results of treatment(s) provided (changes in pain intensity and character, interference with activities of daily living), and management of side effects;
8. Intended use of medications (information about date, name of medication, dosage, quantity prescribed with instructions);
9. Treatment instructions and agreements provided; and
10. Evidence of ongoing periodic review process with treatment modification if necessary.

Compliance With Controlled Substances Laws and Rules – To prescribe, dispense or administer controlled substances, the physician must be licensed in the state and comply with applicable federal and state laws and rules.

Section IV: Definitions (as taken from the Federation of State Medical Boards)

For the purpose of these guidelines, the following terms are defined as follows:

Pain - An unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage.

Acute Pain – Acute pain is the normal, predicted physiological response to a noxious chemical, thermal or mechanical stimulus and typically is associated with an invasive procedure, trauma or disease. It is generally time-limited.

Chronic Pain – Chronic pain is a state in which pain persists beyond the usual course of an acute disease or healing of an injury, or that may or may not be associated with an acute or chronic pathologic process that causes continuous or intermittent pain over months or years.

Addiction – Addiction is a primary, chronic, neurobiologic disease, with genetic, psychosocial, and environmental factors influencing its development and manifestations. It is characterized by behaviors that include the following: impaired control over drug use, craving, compulsive use, and continued use despite harm. Physical dependence and tolerance are normal physiological consequences of extended opioid therapy for pain and are not the same as addiction.

Physical Dependence - Physical dependence is a state of adaptation that is manifested by drug class-specific signs and symptoms that can be produced by abrupt cessation, rapid dose reduction, decreasing blood level of the drug, and/or administration of an antagonist. Physical dependence, by itself, does not equate with addiction.

Tolerance - Tolerance is a physiological state resulting from regular use of a drug in which an increased dosage is needed to produce a specific effect, or a reduced effect is observed with a constant dose over time. Tolerance may or may not be evident during opioid treatment and does not equate with addiction.

Substance Abuse – Substance abuse is the use of any substance(s) for non-therapeutic purposes or use of medication for purposes other than those for which it is prescribed.

(+) CRITERION 8:
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT*:* Encourages healthcare professionals to understand and follow federal and state laws governing their practice, which can better ensure that practitioners follow the *balanced* approach represented by federal law and the laws in many states.

(+) CRITERION 7:
Physical dependence or analgesic tolerance are not confused with "addiction"

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STATUTES

- CONTROLLED SUBSTANCES ACT
  General Laws; Title 37. Food, Drugs, and Oil; Chapter 27. Uniform Controlled Substances

- MEDICAL PRACTICE ACT (*No provisions found*)
  General Laws; Title 54. Professions, Vocations, and Businesses; Chapter 18. Physicians and Surgeons; Medical Practice Act

- PHARMACY PRACTICE ACT
  General Laws; Title 54. Professions, Vocations, and Businesses; Chapter 17. Pharmacists

- INTRACTABLE PAIN TREATMENT ACT
  No policy found

REGULATIONS

- CONTROLLED SUBSTANCES REGULATIONS
  No policy found

- MEDICAL BOARD REGULATIONS (*No provisions found*)
  IDAPA 22. Board of Medicine

- PHARMACY BOARD REGULATIONS (*No provisions found*)
  IDAPA 27. Board of Pharmacy

OTHER GOVERNMENTAL POLICIES

- MEDICAL BOARD GUIDELINE
  Idaho State Board of Medicine. *Policy for the Use of Opioid Analgesics in the Treatment of Chronic Pain*. Adopted: September 6, 2013.

RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY KEY WORD SEARCHES

- HOMICIDE
  Penal Code; Title 18. Crimes and Punishments; Chapter 40. Homicide

- REQUIREMENTS FOR BEHAVIOR MANAGEMENT
  IDAPA 16. Department of Health and Welfare; Title 03. Division of Welfare; Chapter 22. Residential Care or Assisted Living Facilities in Idaho

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STATUTES

Controlled Substances Act

Idaho Code § 37-2701

§ 37-2701. Definitions

As used in this act:

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(aa) "Practitioner" means:

(1) A physician, dentist, veterinarian, scientific investigator, or other person licensed, registered or otherwise permitted to distribute, dispense, conduct research with respect to or to administer a controlled substance in the course of his professional practice or research in this state;

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(+) *CRITERION 3:*
Opioids are part of professional practice

STATUTES

Pharmacy Practice Act

Idaho Code § 54-1705

§ 54-1705. Definitions

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(32) "Practitioner" means a person licensed in this state and permitted by such license to dispense, conduct research with respect to or administer drugs in the course of professional practice or research in this state.

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(+) *CRITERION 3:*
Opioids are part of professional practice

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OTHER GOVERNMENTAL POLICY

Medical Board Guideline

Idaho State Board of Medicine
Policy for the Use of Opioid Analgesics in the Treatment of Chronic Pain

Section I: Preamble

The Idaho Board of Medicine is obligated under the laws of the State of Idaho to protect the public health and safety. The Idaho Board of Medicine recognizes that principles of high-quality medical practice dictate that the people of the State of Idaho have access to appropriate, safe and effective pain management. The application of up-to-date knowledge and treatment modalities can help to restore function and thus improve the quality of life of patients who suffer from pain, particularly chronic pain [4,8,26].

This policy has been developed to articulate the Board's position on the use of controlled substances for pain, particularly the use of opioid analgesics and with special attention to the management of chronic pain. The policy thus is intended to encourage physicians to be knowledgeable about best clinical practices as regards the prescribing of opioids and be aware of associated risks. For the purposes of this policy, inappropriate treatment of pain includes nontreatment, inadequate treatment, overtreatment, and continued use of ineffective treatments.

The Board recognizes that opioid analgesics are useful and can be essential in the treatment of acute pain that results from trauma or surgery, as well as in the management of certain types of chronic pain, whether due to cancer or non-cancer causes [20,26,28]. The Board will refer to current clinical practice guidelines and expert reviews in approaching allegations of possible mismanagement of pain [8,10,12,14,26-41,80].

Responsibility for Appropriate Pain Management: All physicians and other providers should be knowledgeable about assessing patients' pain and function, and familiar with methods of managing pain [4,16]. Physicians also need to understand and comply with federal and state requirements for prescribing opioid analgesics [3,12,19]. Whenever federal laws and regulations differ from those of a particular state, the more stringent rule is the one that should be followed [42].

Physicians should not fear disciplinary action from the Board for ordering, prescribing, dispensing or administering controlled substances, including opioid analgesics, for a legitimate medical purpose and in the course of professional practice, when current best clinical practices are met.

The Board will consider the use of opioids for pain management to be for a legitimate medical purpose if it is based on sound clinical judgment and current best clinical practices, is appropriately documented, and is of demonstrable benefit to the patient. To be within the usual course of professional practice, a legitimate physician-patient relationship must exist and the prescribing or administration of medications should be appropriate to the identified diagnosis, should be accompanied by careful follow-up monitoring of the patient's response to treatment as well as his or her safe use of the prescribed medication, and should demonstrate that the therapy has been adjusted as needed [7,38,43]. There should be documentation of appropriate referrals as necessary [36-37].

The medical management of pain should reflect current knowledge of evidence-based or best clinical practices for the use of pharmacologic and nonpharmacologic modalities, including the use of opioid analgesics and non-opioid therapies [14,16,27]. Such prescribing must be based on careful assessment of the patient and his or her pain (see the discussion on risk stratification, below) [33].

[CONTINUED ON NEXT PAGE]

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT*:* Recognizes that inadequate treatment of pain is subject to disciplinary action just as other substandard practices might be.

(+) *CRITERION 4:*
Encourages pain management

(+) *CRITERION 5:*
Addresses fear of regulatory scrutiny

(+) *CRITERION 3:*
Opioids are part of professional practice

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Medical Board Guideline

[CONTINUED]

Pain should be assessed and treated promptly, and the selection of therapeutic modalities (including the quantity and frequency of medication doses) should be adjusted according to the nature of the pain, the patient's response to treatment, and the patient's risk level relative to the use of medications with abuse potential [8,10,12,14,26-38].

Preventing Opioid Diversion and Abuse: The Board also recognizes that individuals' use of opioid analgesics for other than legitimate medical purposes poses a significant threat to the health and safety of the individual as well as to the public health [3]. The Board further recognizes that inappropriate prescribing of controlled substances by physicians may contribute to drug misuse and diversion by individuals who seek opioids for other than legitimate medical purposes [5,19,44]. Accordingly, the Board expects physicians to incorporate safeguards into their practices to minimize the risk of misuse and diversion of opioid analgesics and other controlled substances [19-23,38,45-46].

Allegations of inappropriate pain management will be evaluated on an individual basis. The Board may use a variety of sources to determine the appropriateness of treatment including prescribing information obtained from the State Prescription Drug Monitoring Program. The Board will not take disciplinary action against a physician for deviating from this Model Policy when contemporaneous medical records show reasonable cause for such a deviation.

The Board will judge the validity of the physician's treatment of a patient on the basis of available documentation, rather than solely on the quantity and duration of medication administered. The goal is the management of the patient's pain while effectively addressing other aspects of the patient's functioning, including physical, psychological, social and work-related factors, and mitigating risk of misuse, abuse, diversion and overdose [4,29].

The Board will consider the unsafe or otherwise inappropriate treatment of pain to be a departure from best clinical practice, taking into account whether the treatment is appropriate to the diagnosis and the patient's level of risk.

Section II: Guidelines

The Board has adopted the following criteria for use in evaluating a physician's management of a patient with pain, including the physician's prescribing of opioid analgesics:

Understanding Pain: The diagnosis and treatment of pain is integral to the practice of medicine [4,34-37]. In order to cautiously prescribe opioids, physicians must understand the relevant pharmacologic and clinical issues in the use of such analgesics, and carefully structure a treatment plan that reflects the particular benefits and risks of opioid use for each individual patient. Such an approach should be employed in the care of every patient who receives chronic opioid therapy [4,8].

Patient Evaluation and Risk Stratification: The medical record should document the presence of one or more recognized medical indications for prescribing an opioid analgesic [7] and reflect an appropriately detailed patient evaluation [38]. Such an evaluation should be completed before a decision is made as to whether to prescribe an opioid analgesic.

The nature and extent of the evaluation depends on the type of pain and the context in which it occurs. For example, meaningful assessment of chronic pain, including pain related to cancer or non-cancer origins, usually demands a more detailed evaluation than an assessment of acute pain. Assessment of the patient's pain typically would include the nature and intensity of the pain, past and current treatments for the pain, any underlying or co-occurring disorders and conditions, and the effect of the pain on the patient's physical and psychological functioning [31].

[CONTINUED ON NEXT PAGE]

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT*:*
Acknowledges need for treatment flexibility for physicians to respond to individual clinical circumstances, as long as their prescribing maintains the standards of good medical practice.

(+) *CRITERION 6:*
Prescription amount alone does not determine legitimacy

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Recognizes that the goal of pain treatment should include improvements in patient functioning and quality of life.

(+) *CRITERION 2:*
Pain management is part of healthcare practice

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Medical Board Guideline

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For every patient, the initial work-up should include a systems review and relevant physical examination, as well as laboratory investigations as indicated [33,36,48-53]. Such investigations help the physician address not only the nature and intensity of the pain, but also its secondary manifestations, such as its effects on the patient's sleep, mood, work, relationships, valued recreational activities, and alcohol and drug use.

Social and vocational assessment is useful in identifying supports and obstacles to treatment and rehabilitation; for example: Does the patient have good social supports, housing, and meaningful work? Is the home environment stressful or nurturing? [14].

Assessment of the patient's personal and family history of alcohol or drug abuse and relative risk for medication misuse or abuse also should be part of the initial valuation [11,14,21-23,45], and ideally should be completed prior to a decision as to whether to prescribe opioid analgesics [56-58]. This can be done through a careful clinical interview, which also should inquire into any history of physical, emotional or sexual abuse, because those are risk factors for substance misuse [31]. Use of a validated screening tool (such as the Screener and Opioid Assessment for Patients with Pain [SOAPP-R; 48] or the Opioid Risk Tool [ORT; 49]), or other validated screening tools, can save time in collecting and evaluating the information and determining the patient's level of risk.

All patients should be screened for depression and other mental health disorders, as part of risk evaluation. Patients with untreated depression and other mental health problems are at increased risk for misuse or abuse of controlled medications, including addiction, as well as overdose.

Patients who have a history of substance use disorder (including alcohol) are at elevated risk for failure of opioid analgesic therapy to achieve the goals of improved comfort and function, and also are at high risk for experiencing harm from this therapy, since exposure to addictive substances often is a powerful trigger of relapse [11,31,45]. Therefore, treatment of a patient who has a history of substance use disorder should, if possible, involve consultation with an addiction specialist before opioid therapy is initiated (and follow-up as needed). Patients who have an active substance use disorder should not receive opioid therapy until they are established in a treatment/recovery program [31] or alternatives are established such as co-management with an addiction professional. Physicians who treat patients with chronic pain should be encouraged to also be knowledgeable about the treatment of addiction, including the role of replacement agonists such as methadone and buprenorphine. For some physicians, there may be advantages to becoming eligible to treat addiction using office-based buprenorphine treatment.

Information provided by the patient is a necessary but insufficient part of the evaluation process. Reports of previous evaluations and treatments should be confirmed by obtaining records from other providers, if possible. Patients have occasionally provided fraudulent records, so if there is any reason to question the truthfulness of a patient's report, it is best to request records directly from the other providers [54-55].

If possible, the patient evaluation should include information from family members and/or significant others [22-23,49-50]. Where available, the state prescription drug monitoring program (PDMP) should be consulted to determine whether the patient is receiving prescriptions from any other physicians, and the results obtained from the PDMP should be documented in the patient record [34].

[CONTINUED ON NEXT PAGE]

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY B:
Issues related to patients

COMMENT:
Acknowledges that a patient's prior history or current status of drug abuse does not necessarily contraindicate appropriate pain management.

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(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Encourages healthcare professionals to incorporate in their practice the evaluations of, and discussions with patients about, the potential benefits and risks of treatment with opioids, which can better ensure a clinical indication of such treatment so that opioids will be used for medical purposes.

[CONTINUED]

Development of a Treatment Plan and Goals: The goals of pain treatment include reasonably attainable improvement in pain and function; improvement in pain-associated symptoms such as sleep disturbance, depression, and anxiety; and avoidance of unnecessary or excessive use of medications [4,8]. Effective means of achieving these goals vary widely, depending on the type and causes of the patient's pain, other concurrent issues, and the preferences of the physician and the patient.

The treatment plan and goals should be established as early as possible in the treatment process and revisited regularly, so as to provide clear-cut, individualized objectives to guide the choice of therapies [38]. The treatment plan should contain information supporting the selection of therapies, both pharmacologic (including medications other than opioids) and nonpharmacologic. It also should specify the objectives that will be used to evaluate treatment progress, such as relief of pain and improved physical and psychosocial function [14,36,47].

The plan should document any further diagnostic evaluations, consultations or referrals, or additional therapies that have been considered [21-23,45].

Informed Consent and Treatment Agreement: The decision to initiate opioid therapy should be a shared decision between the physician and the patient. The physician should discuss the risks and benefits of the treatment plan (including any proposed use of opioid analgesics) with the patient, with persons designated by the patient, or with the patient's surrogate or guardian if the patient is without medical decision-making capacity [32,35]. If opioids are prescribed, the patient (and possibly family members) should be counseled on safe ways to store and dispose of medications [3,37].

Use of a written informed consent and treatment agreement (sometimes referred to as a "treatment contract") is recommended [21-23,35,38].

Informed consent documents typically address:

- The potential risks and anticipated benefits of chronic opioid therapy.
- Potential side effects (both short- and long-term) of the medication, such as constipation and cognitive impairment.
- The likelihood that tolerance to and physical dependence on the medication will develop.
- The risk of drug interactions and over-sedation.
- The risk of impaired motor skills (affecting driving and other tasks).
- The risk of opioid misuse, dependence, addiction, and overdose.
- The limited evidence as to the benefit of long-term opioid therapy.
- The physician's prescribing policies and expectations, including the number and frequency of prescription refills, as well as the physician's policy on early refills and replacement of lost or stolen medications.
- Specific reasons for which drug therapy may be changed or discontinued (including violation of the policies and agreements spelled out in the treatment agreement).

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Treatment agreements outline the joint responsibilities of physician and patient [35-37] and are indicated for opioid or other abusable medications. They typically discuss:

- The goals of treatment, in terms of pain management, restoration of function, and safety.
- The patient's responsibility for safe medication use (e.g., by not using more medication than prescribed or using the opioid in combination with alcohol or other substances; storing medications in a secure location; and safe disposal of any unused medication).
- The patient's responsibility to obtain his or her prescribed opioids from only one physician or practice.
- The patient's agreement to periodic drug testing (as of blood, urine, hair, or saliva).
- The physician's responsibility to be available or to have a covering physician available to care for unforeseen problems and to prescribe scheduled refills.

Informed consent documents and treatment agreements can be part of one document for the sake of convenience.

Initiating an Opioid Trial: Generally, safer alternative treatments should be considered before initiating opioid therapy for chronic, non-malignant pain. Opioid therapy should be presented to the patient as a therapeutic trial or test for a defined period of time (usually no more than 90 days) and with specified evaluation points. The physician should explain that progress will be carefully monitored for both benefit and harm in terms of the effects of opioids on the patient's level of pain, function, and quality of life, as well as to identify any adverse events or risks to safety [51]. When initiating opioid therapy, the lowest dose possible should be given to an opioid naïve patient and titrate to affect. It is generally suggested to begin opioid therapy with a short acting opioid and rotate to a long acting/extended release if indicated.

A decision to continue opioid therapy beyond the trial period should reflect a careful evaluation of benefits versus adverse events [29] and/or potential risks.

Ongoing Monitoring and Adapting the Treatment Plan: The physician should regularly review the patient's progress, including any new information about the etiology of the pain or the patient's overall health and level of function [35,49-50]. When possible, collateral information about the patient's response to opioid therapy should be obtained from family members or other close contacts, and the state PDMP. The patient should be seen more frequently while the treatment plan is being initiated and the opioid dose adjusted [44-51]. As the patient is stabilized in the treatment regimen, follow-up visits may be scheduled less frequently. (However, if the patient is seen less than monthly and an opioid is prescribed, arrangements must be made for the patient to obtain a refill or new prescription when needed.)

At each visit, the results of chronic opioid therapy should be monitored by assessing what have been called the "5As" of chronic pain management; these involve a determination of whether the patient is experiencing a reduction in pain (**A**nalgesia), has demonstrated an improvement in level of function (**A**ctivity), whether there are significant **A**dverse effects, whether there is evidence of **A**berrant substance-related behaviors, and mood of the individual (**A**ffect) [38,52]. Validated brief assessment tools that measure pain and function, such as the three-question "Pain, Enjoyment and General Activity" (PEG) scale [47] or other validated assessment tools, may be helpful and time effective.

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Continuation, modification or termination of opioid therapy for pain should be contingent on the physician's evaluation of (1) evidence of the patient's progress toward treatment objectives and (2) the absence of substantial risks or adverse events, such as overdose or diversion [21-23,45]. A satisfactory response to treatment would be indicated by a reduced level of pain, increased level of function, and/or improved quality of life [29]. Information from family members or other caregivers should be considered in evaluating the patient's response to treatment [14,35-36]. Use of measurement tools to assess the patient's level of pain, function, and quality of life (such as a visual analog or numerical scale) can be helpful in documenting therapeutic outcomes [14,49].

Periodic Drug Testing: Periodic drug testing may be useful in monitoring adherence to the treatment plan, as well as in detecting the use of non-prescribed drugs [53-54]. Drug testing is an important monitoring tool because self-reports of medication use is not always reliable and behavioral observations may detect some problems but not others [55-59]. Patients being treated for addiction should be tested as frequently as necessary to ensure therapeutic adherence, but for patients being treated for pain, clinical judgment trumps recommendations for frequency of testing.

Urine may be the preferred biologic specimen for testing because of its ease of collection and storage and the cost-effectiveness of such testing [53]. When such testing is conducted as part of pain treatment, forensic standards are generally not necessary and not in place, so collection is not observed and chain-of-custody protocols are not followed. Initial testing may be done using class-specific immunoassay drug panels (point-of-care or laboratory-based), which typically do not identify particular drugs within a class unless the immunoassay is specific for that drug. If necessary, this can be followed up with a more specific technique, such as gas chromotography/mass spectrometry (GC/MS) or other chromatographic tests to confirm the presence or absence of a specific drug or its metabolites [53]. In drug testing in a pain practice, it is important to identify the specific drug not just the class of the drug.

Physicians need to be aware of the limitations of available tests (such as their limited sensitivity for many opioids) and take care to order tests appropriately [54]. For example, when a drug test is ordered, it is important to specify that it include the opioid being prescribed [53]. Because of the complexities involved in interpreting drug test results, it is advisable to confirm significant or unexpected results with the laboratory toxicologist or a clinical pathologist [59-60].

While immunoassay, point of care (POC) testing has its utility in the making of temporary and "on the spot" changes in clinical management, its limitations with regard to accuracy have recently been the subject of study. These limitations are such that the use of point of care testing for the making of more long term and permanent changes in management of people with the disease of addiction and other clinical situations may not be justified until the results of confirmatory testing with more accurate methods such as LC-MS/MS are obtained. A recent study on LC-MS/MS results following immunoassay POC testing in addiction treatment settings and found very high rates of "false negatives and positives" [53,81].

Test results that suggest opioid misuse should be discussed with the patient. It is helpful to approach such a discussion in a positive, supportive fashion, so as to strengthen the physician-patient relationship and encourage healthy behaviors (as well as behavioral change where that is needed). Both the test results and subsequent discussion with the patient should be documented in the medical record [53].

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OTHER GOVERNMENTAL POLICY

Medical Board Guideline

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Periodic pill counting is also a useful strategy to confirm medication adherence and to minimize diversion (e.g., selling, sharing or giving away medications). As noted earlier and where available, consulting the state's PDMP before prescribing opioids for pain and during ongoing use is highly recommended. A PDMP can be useful in monitoring compliance with the treatment agreement as well as identifying individuals obtaining controlled substances from multiple prescribers [21-23,55,62].

If the patient's progress is unsatisfactory, the physician must decide whether to revise or augment the treatment plan, whether other treatment modalities should be added to or substituted for the opioid therapy, or whether a different approach—possibly involving referral to a pain specialist or other health professional—should be employed [35-37,62-63].

Evidence of misuse of prescribed opioids demands prompt intervention by the physician [19,21-23,32,35]. Patient behaviors that require such intervention typically involve recurrent early requests for refills, multiple reports of lost or stolen prescriptions, obtaining controlled medications from multiple sources without the physician's knowledge, intoxication or impairment (either observed or reported), and pressuring or threatening behaviors [23]. The presence of illicit or unprescribed drugs, (drugs not prescribed by a physician) in drug tests similarly requires action on the part of the prescriber. Some aberrant behaviors are more closely associated with medication misuse than others [62-63]. Most worrisome is a pattern of behavior that suggests recurring misuse, such as unsanctioned dose escalations, deteriorating function, and failure to comply with the treatment plan [64].

Documented drug diversion or prescription forgery, obvious impairment, and abusive or assaultive behaviors require a firm, immediate response [22-23,38,46]. Indeed, failure to respond can place the patient and others at significant risk of adverse consequences, including accidental overdose, suicide attempts, arrests and incarceration, or even death [23,65-67]. For this reason, physicians who prescribe chronic opioid therapy should be knowledgeable in the diagnosis of substance use disorders and able to distinguish such disorders from physical dependence—which is expected in chronic therapy with opioids and many sedatives.

Consultation and Referral: The treating physician should seek a consultation with, or refer the patient to, a pain, psychiatry, addiction or mental health specialist as needed [37-38]. For example, a patient who has a history of substance use disorder or a co-occurring mental health disorder may require specialized assessment and treatment, if available [31,66].

Physicians who prescribe chronic opioid therapy should be familiar with treatment options for opioid addiction (including those available in licensed opioid treatment programs [OTPs]) and those offered by an appropriately credentialed and experienced physician through office-based opioid treatment [OBOT]), so as to make appropriate referrals when needed [23,31,37,39].

Discontinuing Opioid Therapy: Throughout the course of opioid therapy, the physician and patient should regularly weigh the potential benefits and risks of continued treatment and determine whether such treatment remains appropriate [46].

If opioid therapy is continued, the treatment plan may need to be adjusted to reflect the patient's changing physical status and needs, as well as to support safe and appropriate medication use [22-23].

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[CONTINUED]

Reasons for discontinuing opioid therapy include resolution of the underlying painful condition, emergence of intolerable side effects, inadequate analgesic effect, failure to improve the patient's quality of life despite reasonable titration, deteriorating function, or significant aberrant medication use [38, 45].

If opioid therapy is discontinued, the patient who has become physically dependent should be provided with a safely structured tapering regimen. Withdrawal can be managed either by the prescribing physician or by referring the patient to an addiction specialist [63]. The termination of opioid therapy should not mark the end of treatment, which should continue with other modalities, either through direct care or referral to other health care specialists, as appropriate [21-23].

Additionally, providers should not continue opioid treatment unless the patient has received a benefit, including demonstrated functional improvement.

Medical Records: Every physician who treats patients for chronic pain must maintain accurate and complete medical records. Information that should appear in the medical record includes the following [22-23,38,43-44]:

- Copies of the signed informed consent and treatment agreement.
- The patient's medical history.
- Results of the physical examination and all laboratory tests.
- Results of the risk assessment, including results of any screening instruments used.
- A description of the treatments provided, including all medications prescribed or administered (including the date, type, dose and quantity).
- Instructions to the patient, including discussions of risks and benefits with the patient and any significant others.
- Results of ongoing monitoring of patient progress (or lack of progress) in terms of pain management and functional improvement.
- Notes on evaluations by and consultations with specialists.
- Any other information used to support the initiation, continuation, revision, or termination of treatment and the steps taken in response to any aberrant medication use behaviors [21-23,30,38,45,68]. These may include actual copies of, or references to, medical records of past hospitalizations or treatments by other providers.
- Authorization for release of information to other treatment providers.

The medical record must include all prescription orders for opioid analgesics and other controlled substances, whether written or telephoned. In addition, written instructions for the use of all medications should be given to the patient and documented in the record [25]. The name, telephone number, and address of the patient's pharmacy also should be recorded to facilitate contact as needed [23]. Records should be up-to-date and maintained in an accessible manner so as to be readily available for review [25].

Good records demonstrate that a service was provided to the patient and establish that the service provided was medically necessary. Even if the outcome is less than optimal, thorough records protect the physician as well as the patient [23,38,45,68].

Compliance with Controlled Substance Laws and Regulations: To prescribe, dispense or administer controlled substances, the physician must be registered with the DEA, licensed by the state in which he or she practices, and comply with applicable federal and state regulations [25].

Physicians are referred to the *Physicians' Manual of the U.S. Drug Enforcement Administration* (and any relevant documents issued by the state medical Board) for specific rules and regulations governing the use of controlled substances. Additional resources are available on the DEA's website (at www.deadiversion.usdoj.gov), as well as from (*any relevant documents issued by the state medical board*).

[CONTINUED ON NEXT PAGE]

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Encourages healthcare professionals to understand and follow federal and state laws governing their practice, which can better ensure that practitioners follow the *balanced* approach represented by federal law and the laws in many states.

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[CONTINUED]

Section III: Definitions

For the purposes of this Model Policy, the following terms are defined as shown.

Aberrant Substance Use Behaviors: Behaviors that are outside the boundaries of the agreed-upon treatment plan may constitute aberrant substance use behaviors [22-23]. For example, obtaining prescriptions for the same or similar drugs from more than one physician or other health care provider without the treating physician's knowledge is aberrant behavior, as is use of illicit drugs.

Abuse: Abuse has been described as a maladaptive pattern of drug use that results in harm or places the individual at risk of harm [29]. Abuse of a prescription medication involves its use in a manner that deviates from approved medical, legal, and social standards, generally to achieve a euphoric state ("high") or to sustain opioid dependence that is opioid addiction or that is other than the purpose for which the medication was prescribed [28].

Addiction: A longstanding definition of addiction is that it is "a primary, chronic, neurobiologic disease, whose development and manifestations are influenced by genetic, psychosocial, and environmental factors" [28]. Addiction often is said to be characterized by behaviors that include impaired control over drug use, craving, compulsive use, and continued use despite harm [28].

A newer definition, adopted by the American Society of Addiction Medicine in 2011, describes addiction as "a primary, chronic disease of brain reward, motivation, memory and related circuitry. Dysfunction in these circuits leads to characteristic biological, psychological, social and spiritual manifestations. This is reflected in an individual pathologically pursuing reward and/or relief by substance use and other behaviors. Addiction is characterized by inability to consistently abstain, impairment in behavioral control, craving, diminished recognition of significant problems with one's behaviors and interpersonal relationships, and a dysfunctional emotional response. Like other chronic diseases, addiction often involves cycles of relapse and remission. Without treatment or engagement in recovery activities, addiction is progressive and can result in disability or premature death" [40].

(+) *CRITERION 7: Physical dependence or analgesic tolerance are not confused with "addiction"*

(As discussed below, physical dependence and tolerance are expected physiological consequences of extended opioid therapy for pain and in this context do not indicate the presence of addiction.)

Controlled Substance: A controlled substance is a drug that is subject to special requirements under the federal Controlled Substances Act of 1970 (CSA) [25], which is designed to ensure both the availability and control of regulated substances. Under the CSA, availability of regulated drugs for medical purposes is accomplished through a system that establishes quotas for drug production and a distribution system that closely monitors the importation, manufacture, distribution, prescribing, dispensing, administering, and possession of controlled drugs. Civil and criminal sanctions for serious violations of the statute are part of the government's control apparatus. The Code of Federal Regulations (Title 21, Chapter 2) implements the CSA.

The CSA provides that responsibility for scheduling controlled substances is shared between the Food and Drug Administration (FDA) and the DEA. In granting regulatory authority to these agencies, the Congress noted that both public health and public safety needs are important and that neither takes primacy over the other. To accomplish this, the Congress provided guidance in the form of factors that must be considered by the FDA and DEA when assessing public health and safety issues related to a new drug or one that is being considered for rescheduling or removal from control.

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The CSA does ***not*** limit the amount of drug prescribed, the duration for which it is prescribed, or the period for which a prescription is valid (although some states do impose such limits).

Most potent opioid analgesics are classified in ***Schedules II or III*** under the CSA, indicating that they have a significant potential for abuse and a currently accepted medical use in treatment in the U.S. (with certain restrictions), and that abuse of the drug may lead to severe psychological or physical dependence. Although the scheduling system provides a rough guide to abuse potential, it should be recognized that all controlled medications have some potential for abuse.

Dependence: Physical dependence is a state of biologic adaptation that is evidenced by a class-specific withdrawal syndrome when the drug is abruptly discontinued or the dose rapidly reduced, and/or by the administration of an antagonist [28]. It is important to distinguish addiction from the type of physical dependence that can and does occur within the context of good medical care, as when a patient on long-term opioid analgesics for pain becomes physically dependent on the analgesic. This distinction is reflected in the two primary diagnostic classification systems used by health care professionals: the ***International Classification of Mental and Behavioural Disorders, 10th Edition (ICD10)*** of the World Health Organization [70], and the ***Diagnostic and Statistical Manual (DSM)*** of the American Psychiatric Association [71]. In the DSM-IV-TR, a diagnosis of "substance dependence" meant addiction. In the upcoming DSM V, the term ***dependence*** is reestablished in its original meaning of physiological dependence. When symptoms are sufficient to meet criteria for substance misuse or addiction, the term "substance use disorder" is used, accompanied by severity ratings [69].

It may be important to clarify this distinction during the informed consent process, so that the patient (and family) understands that physical dependence and tolerance are likely to occur if opioids are taken regularly over a period of time, but that the risk of addiction is relatively low, although estimates do vary. Discontinuing chronic opioid therapy may be difficult, even in the absence of addiction. According to the World Health Organization, "The development of tolerance and physical dependence denote normal physiologic adaptations of the body to the presence of an opioid" [70]. Consequently, physical dependence alone is neither necessary nor sufficient to diagnose addiction [71,72].

Diversion: Drug diversion is defined as the intentional transfer of a controlled substance from authorized to unauthorized possession or channels of distribution [73-74]. The federal Controlled Substances Act (21 U.S.C. §§ 801 et seq.) establishes a closed system of distribution for drugs that are classified as controlled substances. Records must be kept from the time a drug is manufactured to the time it is dispensed. Health care professionals who are authorized to prescribe, dispense, and otherwise control access to such drugs are required to register with the DEA [25,75].

Pharmaceuticals that make their way outside this closed distribution system are said to have been "diverted" [75], and the individuals responsible for the diversion (including patients) are in violation of federal law.

Experience shows that the degree to which a prescribed medication is misused depends in large part on how easily it is redirected (diverted) from the legitimate distribution system [17,19,74].

Misuse: The term *misuse* (also called ***nonmedical use***) encompasses all uses of a prescription medication other than those that are directed by a physician and used by a patient within the law and the requirements of good medical practice [28].

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[CONTINUED]

Opioid: An opioid is any compound that binds to an opioid receptor in the central nervous system (CNS) [4]. The class includes both naturally occurring and synthetic or semi-synthetic opioid drugs or medications, as well as endogenous opioid peptides [35].

Most physicians use the terms "opiate" and "opioid" interchangeably, but toxicologists (who perform and interpret drug tests) make a clear distinction between them. "Opioid" is the broader term because it includes the entire class of agents that act at opioid receptors in the CNS, whereas "opiates" refers to natural compounds derived from the opium plant but not semisynthetic opioid derivatives of opiates or completely synthetic agents. Thus, drug tests that are "positive for opiates" have detected one of these compounds or a metabolite of heroin, 6-monoacetyl morphine (MAM). Drug tests that are "negative for opiates" have found no detectable levels of opiates in the sample, even though other opioids that were not tested for—including the most common currently used and misused prescription opioids—may be present in the sample that was analyzed [53,59-260].

Pain: An unpleasant and potentially disabling sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage.

Acute pain is the normal, predictable physiological response to a noxious chemical, thermal or mechanical stimulus and typically is associated with invasive procedures, trauma and disease. Acute pain generally is time-limited, lasting six weeks or less [4].

Chronic pain is a state in which pain persists beyond the usual course of an acute disease or healing of an injury (e.g., more than three months). It may or may not be associated with an acute or chronic pathologic process that causes continuous or intermittent pain over a period of months or years.

Chronic noncancer related pain is chronic pain that is not associated with active cancer and does not occur at the end of life [4,76].

Opioid-induced hyperalgesia may develop as a result of long-term opioid use in the treatment of chronic pain. *Primary hyperalgesia* is pain sensitivity that occurs directly in the damaged tissues, while *secondary hyperalgesia* occurs in surrounding undamaged tissues. Human and animal studies have demonstrated that primary or secondary hyperalgesia can develop in response to both chronic and acute exposure to opioids. Hyperalgesia can be severe enough to warrant discontinuation of opioid treatment [77].

Prescription Drug Monitoring Program: Almost all states have enacted laws that establish prescription drug monitoring programs (PDMPs) to facilitate the collection, analysis, and reporting of information on the prescribing and dispensing of controlled substances. Most such programs employ electronic data transfer systems, under which prescription information is transmitted from the dispensing pharmacy to a state agency, which collates and analyzes the information [3,24].

After analyzing the efficacy of PDMPs, the GAO concluded that such programs have the potential to help law enforcement and regulatory agencies rapidly identify and investigate activities that may involve illegal prescribing, dispensing or consumption of controlled substances. Where real-time data are available, PDMPs also can help to prevent prescription drug misuse and diversion by allowing physicians to determine whether a patient is receiving prescriptions for controlled substances from other physicians, as well as whether the patient has filled or refilled an order for an opioid the physician has prescribed [24,78-79].

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Tolerance: Tolerance is a state of physiologic adaptation in which exposure to a drug induces changes that result in diminution of one or more of the drug's effects over time. Tolerance is common in opioid treatment, has been demonstrated following a single dose of opioids, and is not the same as addiction [28].

Trial Period: A period of time during which the efficacy of an opioid for treatment of an individual's pain is tested to determine whether the treatment goals can be met in terms of reduction of pain and restoration of function. If the goals are not met, the opioid dose may be adjusted, a different opioid substituted, an adjunctive therapy added, or use of opioids discontinued and an alternative approach to pain management selected [36].

Universal Precautions: The concept of *universal precautions* is borrowed from an infectious disease model of the same name to underscore its comparability to practices in other areas of medicine. The concept recognizes that all patients have a level of risk that can only be estimated initially, with the estimate modified over time as more information is obtained. The 10 essential steps of universal precautions can be summarized as follows [38]:

1. Make a diagnosis with an appropriate differential.
2. Conduct a patient assessment, including risk for substance use disorders.
3. Discuss the proposed treatment plan with the patient and obtain informed consent.
4. Have a written treatment agreement that sets forth the expectations and obligations of both the patient and the treating physician.
5. Initiate an appropriate trial of opioid therapy, with or without adjunctive medications.
6. Perform regular assessments of pain and function.
7. Reassess the patient's pain score and level of function.
8. Regularly evaluate the patient in terms of the "5 A's": **A**nalgesia, **A**ctivity, **A**dverse effects, **A**berrant behaviors, and **A**ffect.
9. Periodically review the pain diagnosis and any comorbid conditions, including substance use disorders, and adjust the treatment regimen accordingly.
10. Keep careful and complete records of the initial evaluation and each follow-up visit.

By acknowledging the fact that there are no signs that invariably point to substance use disorder [41], the universal precautions encourage a consistent and respectful approach to the assessment and management of pain patients, thereby minimizing stigma, improving patient care, and reducing overall risk [38].

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STATUTES

Homicide

Idaho Code § 18-4017

§ 18-4017. Causing a suicide -- Assisting in a suicide -- Injunctive relief -- Revocation of license -- Exceptions

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(5) The following shall not be deemed a violation of the provisions of this section:

(a) A health care professional who administers, prescribes or dispenses medications or procedures to relieve another person's pain or discomfort, even if any such medication or procedure may hasten or increase the risk of death, unless such medications or procedures are knowingly and intentionally administered, prescribed or dispensed to cause death.

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(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT*:* Clarifies for physicians the important distinction between physician-assisted suicide and prescribing controlled substances for pain relief; this language identifies a clinical misperception that is pervasive in end-of-life care and attempts to lessen its impact on patient treatment, and the practitioners who provide it.

REGULATIONS

Requirements for Behavior Management

IDAPA 16.03.22.225

225. REQUIREMENTS FOR BEHAVIOR MANAGEMENT.

The facility must identify and evaluate behavioral symptoms that are distressing to the resident or infringe on other residents' rights. Effective Date: (3-30-06)

01. Evaluation for Behavior Management. The facility evaluation must include the following; Effective Date: (3-30-06)

a. Identification if the resident behavior is transitory or permanent; Effective Date: (3-30-06)

b. Review of the resident's previous behaviors and activities; Effective Date: (3-30-06)

c. Review of baseline data including intensity, duration and frequency of the resident behavior; Effective Date: (3-30-06)

d. Identification of recent changes in the resident's life, such as death in the family, change in resident's daily routine, or changes in the Resident's Negotiated Service Agreement; Effective Date: (3-30-06)

e. Identification of environmental causes that could contribute to the resident's behavior such as excessive heat, noise, overcrowding, hunger, staffing; Effective Date: (3-30-06)

f. Rule out possible medical causes such as pain, constipation, fever, infection, or medication side effects; and Effective Date: (3-30-06)

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(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT*:* Establishes a mechanism (behavior management evaluation) for residential care or assisted living facilities to ensure that pain management is an essential part of patient care.

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ILLINOIS

STATUTES

- CONTROLLED SUBSTANCES ACT
  Chapter 720. Criminal Offenses; Offenses Against the Public; Illinois Controlled Substances Act

- MEDICAL PRACTICE ACT (*No provisions found*)
  Chapter 225. Professions and Occupations; Health; Medical Practice Act of 1987

- OSTEOPATHIC PRACTICE ACT (*No provisions found*)
  Chapter 225. Professions and Occupations; Health; Osteopathic and Allopathic Healthcare Discrimination Act

- PHARMACY PRACTICE ACT (*No provisions found*)
  Chapter 225. Professions and Occupations; Health; Pharmacy Practice Act

- INTRACTABLE PAIN TREATMENT ACT
  No policy found

REGULATIONS

- CONTROLLED SUBSTANCES REGULATIONS
  Title 77. Public Health; Chapter XV. Department of Professional Regulation; Part 3100. Illinois Controlled Substances Act

- MEDICAL BOARD REGULATIONS (*No provisions found*)
  Title 68. Professions and Occupations; Chapter VII. Department of Financial and Professional Regulation; Subchapter b. Professions and Occupations; Part 1285. Medical Practice Act of 1987

- PHARMACY BOARD REGULATIONS (*No provisions found*)
  Title 68. Professions and Occupations; Chapter VII. Department of Financial and Professional Regulation; Subchapter b. Professions and Occupations; Part 1330. Pharmacy Practice Act

OTHER GOVERNMENTAL POLICIES

No policies found

RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY KEY WORD SEARCHES

- HOSPICE SERVICES
  Title 77. Public Health; Chapter I. Department of Public Health; Subchapter b. Hospitals and Ambulatory Care Facilities; Part 280. Hospice Programs; Subpart B. Hospice Services

- ELECTRONIC PRESCRIPTION MONITORING PROGRAM
  Title 77. Public Health; Chapter X. Department of Human Services; Subchapter e. Controlled Substances Activities; Part 2080. Electronic Prescription Monitoring Program

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ILLINOIS

STATUTES

Controlled Substances Act

720 ILCS 570/102

§ 720 ILCS 570/102. Definitions

Sec. 102. Definitions. As used in this Act, unless the context otherwise requires:

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(kk) "Practitioner" means a physician licensed to practice medicine in all its branches, dentist, optometrist, podiatrist, veterinarian, scientific investigator, pharmacist, physician assistant, advanced practice nurse, licensed practical nurse, registered nurse, hospital, laboratory, or pharmacy, or other person licensed, registered, or otherwise lawfully permitted by the United States or this State to distribute, dispense, conduct research with respect to, administer or use in teaching or chemical analysis, a controlled substance in the course of professional practice or research.

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(+) *CRITERION 3:*
Opioids are part of professional practice

REGULATIONS

Controlled Substances Regulations

77 Ill. Adm. Code 3100.400

§ 3100.400 Requirement of Prescription.

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b) An individual practitioner may administer or dispense directly a controlled substance listen in Schedule II in the course of his professional practice subject to the Act and this Part.

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(+) *CRITERION 3:*
Opioids are part of professional practice

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ILLINOIS

REGULATIONS

Hospice Services

77 Ill. Adm. Code 280.2070

§ 280.2070 Medical Director and Physician Services

a) The hospice program shall have a medical director who shall be a doctor of medicine or osteopathy and licensed to practice medicine in all of its branches. (Section 8(d) of the Act) In his/her absence, the medical director or governing

b) The medical director shall have overall responsibility for medical direction of the patient care component of the hospice program and shall consult and cooperate with the patient's attending physician. (Section 8(d) of the Act)

c) Duties of the medical director shall include but not be limited to:

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9) Approving written guidelines for symptom control, i.e., pain, nausea, vomiting, or other symptoms.

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(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (written guidelines) for hospices to ensure that pain management is an essential part of patient care.

REGULATIONS

Electronic Prescription Monitoring Program

77 Ill. Adm. Code 2080.70

§ 2080.70 Schedule II Drug Prescription Requirements

a) A dispenser may fill a prescription for a Schedule II drug upon receipt of a written, facsimile or verbal order of a physician unless otherwise specifically exempted or allowed by federal or State law.

b) A prescription for a Schedule II drug shall:

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9) Not be filled more than seven days after the date of issue;

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(-) *CRITERION 13:*
Length of prescription validity is restricted

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INDIANA

STATUTES

- CONTROLLED SUBSTANCES ACT
  Title 35. Criminal Law and Procedure; Article 48. Controlled Substances

- MEDICAL PRACTICE ACT
  Title 25. Professions and Occupations; Article 22.5. Physicians

- PHARMACY PRACTICE ACT (*No provisions found*)
  Title 25. Professions and Occupations; Article 26. Pharmacists and Pharmacies or Drugstores

- INTRACTABLE PAIN TREATMENT ACT
  No policy found

REGULATIONS

- CONTROLLED SUBSTANCES REGULATIONS (*Part of Pharmacy Board Regulations*)
  Title 856. Indiana Board of Pharmacy; Article 2. Controlled Substances

- MEDICAL BOARD REGULATIONS
  Title 844. Medical Licensing Board of Indiana;

- PHARMACY BOARD REGULATIONS (*No provisions found*)
  Title 856. Indiana Board of Pharmacy

OTHER GOVERNMENTAL POLICIES

No policies found

RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY KEY WORD SEARCHES

- HOMICIDE
  Title 35. Criminal Law and Procedure; Article 42. Offenses Against the Person; Chapter 1. Homicide

- OPIOID TREATMENT PROGRAMS
  Title 440. Division of Mental Health and Addiction; Article 10. Minimum Standards for the Provision of Services by Opioid Treatment Facilities and Programs; Rule 4. Specific Approval of Opioid Treatment Programs

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INDIANA

STATUTES

Controlled Substances Act

Burns Ind. Code Ann. § 35-48-1-24

§ 35-48-1-24. Practitioner

"Practitioner" means a physician, dentist, veterinarian, scientific investigator, pharmacy, hospital, or other institution or individual licensed, registered, or otherwise permitted to distribute, dispense, conduct research with respect to, or administer a controlled substance in the course of professional practice or research in Indiana.

(+) *CRITERION 3:*
Opioids are part of professional practice

Burns Ind. Code Ann. § 35-48-7-8.1

35-48-7-8.1. Advisory board to provide for controlled substance prescription monitoring program -- Components of program.

(a) The board shall provide for a controlled substance prescription monitoring program that includes the following components:

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(4) The board may require that prescriptions for controlled substances be written on a one (1) part form that cannot be duplicated. However, the board may not apply such a requirement to prescriptions filled at a pharmacy with a Type II permit (as described in *IC 25-26-13-17*) and operated by a hospital licensed under IC 16-21, or prescriptions ordered for and dispensed to bona fide enrolled patients in facilities licensed under IC 16-28. The board may not require multiple copy prescription forms for any prescriptions written. The board may not require different prescription forms for any individual drug or group of drugs. Prescription forms required under this subdivision must be approved by the Indiana board of pharmacy established by *IC 25-26-13-3*.

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(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Recognizes characteristics of prescription monitoring programs that are believed to impede the appropriate medical use of Schedule II controlled substances.

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STATUTES

Controlled Substances Act

Burns Ind. Code Ann. § 35-48-7-11.1

35-48-7-11.1. Information received by INSPECT program confidential -- Release of confidential information -- Procedures for release of confidential information -- Use of information as evidence -- Civil immunity.

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(g) The board may release to:

(1) a member of the board or another governing body that licenses practitioners;

(2) an investigator for the consumer protection division of the office of the attorney general, a prosecuting attorney, the attorney general, a deputy attorney general, or an investigator from the office of the attorney general; or

(3) a law enforcement officer who is:

(A) authorized by the state police department to receive the type of information released; and

(B) approved by the board to receive the type of information released;

confidential information generated from computer records that identifies practitioners who are prescribing or dispensing large quantities of a controlled substance.

(h) The information described in subsection (g) may not be released until it has been reviewed by:

(1) a member of the board who is licensed in the same profession as the prescribing or dispensing practitioner identified by the data; or

(2) the board's designee;

and until that member or the designee has certified that further investigation is warranted. However, failure to comply with this subsection does not invalidate the use of any evidence that is otherwise admissible in a proceeding described in subsection (i).

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(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT*:* Establishes a mechanism (review by advisory committee member with the same professional license) to determine from prescription monitoring program information whether further investigation for a particular case of improper prescribing is warranted.

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INDIANA

STATUTES

Medical Practice Act

Burns Ind. Code Ann. § 25-22.5-1-1.1

§ 25-22.5-1-1.1. Definitions

As used in this article:

(a) "Practice of medicine or osteopathic medicine" means any one (1) or a combination of the following:

(1) Holding oneself out to the public as being engaged in:

(A) the diagnosis, treatment, correction, or prevention of any disease, ailment, defect, injury, infirmity, deformity, pain, or other condition of human beings;

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(+) CRITERION 2:
Pain management is part of healthcare practice

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INDIANA

REGULATIONS

Controlled Substances Regulations

856 IAC 2-1-1

856 IAC 2-1-1 Definitions

Sec. 1. Definitions. As used herein, the following terms shall have the meanings specified:

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(h) The term "individual practitioner" means a physician, dentist, veterinarian, or other individual licensed, registered or otherwise permitted by the State of Indiana or the United States, to dispense a controlled substance in the course of professional practice, but does not include a pharmacist, a pharmacy, or an institutional practitioner.

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856 IAC 2-6-3

856 IAC 2-6-3 Purpose of prescription; prohibitions

Sec. 3. Purpose of issue of prescription. (a) A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose in a reasonable quantity by an individual practitioner acting in the usual course of his professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription. An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription, within the meaning and intent of IC 1971, 35-24.1-3-8 [Repealed by Acts 1976, P.L. 148, SECTION 24; Acts 1977, P.L. 26, SECTION 25. See IC 35-48.] as amended, and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.

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(+) *CRITERION 3:*
Opioids are part of professional practice

(-) *CRITERION 16:*
Provisions that are ambiguous

CATEGORY A:
Arbitrary standards for legitimate prescribing

COMMENT: Although it is reasonable to expect practitioners to avoid contributing to diversion, "reasonable" implies there is a known standard, but the standard is not specified.

REGULATIONS

Medical Board Regulations

844 IAC 5-1-1

844 IAC 5-1-1 Definitions

Sec. 1. For purposes of this article and IC 25-1-9, the following definitions apply:

(1) "Addict" means a person who is physiologically and/or psychologically dependent upon a drug that is classified as a narcotic, controlled substance, or dangerous drug.

(2) "Habitue" means a person who: (A) is physiologically and/or psychologically dependent upon any narcotic, drug classified as a narcotic, dangerous drug, or controlled substance under Indiana law; or (B) consumes, on a regular basis and without any medically justifiable purpose, a narcotic drug classified as a narcotic, dangerous drug, or controlled substance under Indiana law, whether or not such person has developed a physiological or psychological dependence upon such substance.

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(-) *CRITERION 11:*
Physical dependence or analgesic tolerance confused with "addiction"

2013

Pain & Policy Studies Group
University of Wisconsin Carbone Cancer Center
Madison, Wisconsin

INDIANA

REGULATIONS

Medical Board Regulations

EMERGENCY RULE

SECTION 1. This document establishes standards and protocols for physicians in the prescribing of controlled substances for pain management treatment. It is adopted under the authority of IC 25-22.5-13-2.

SECTION 2. (a) The definition in this SECTION apply throughout this document.

(b) "Chronic Pain" means a state in which pain persists beyond the usual course of an acute disease or healing of an injury, or that may or may not be associated with an acute or chronic pathologic process that causes continuous or intermittent pain over months or years.

(c) "Controlled substances: has the meaning set forth in IC 35-48-1-9.

(d) "Morphine Equivalent Dose" means a conversion of various opioids to a standardized dose of morphine by the use of accepted conversion tables.

(e) "Opioid" means any of various narcotics containing opium or one or more of its natural or synthetic derivatives.

(f) "Outset of an opioid treatment plan" means that a patient has been prescribed opioids as described in SECTION 3(c) of this document and therefore the provisions stated in SECTION 3(a) of this document become applicable to that patient.

(g) "Terminal" means a condition caused by injury, disease, or illness from which, to a reasonable degree of medical certainty:

(1) there can be no recovery; and

(2) progression to death can be anticipated as an eventual consequence of that condition.

SECTION 3. (a) This SECTION and SECTIONS 4 through 11 of this document establish requirements concerning the use of opioids for chronic pain management for patients.

(b) Notwithstanding subsection (a), this SECTION and SECTIONS 4 through 11 of this document shall not apply to the use of opioids for chronic pain management for the following:

(1) Patients with a terminal condition.

(2) Residents of a health facility licensed under IC 16-28.

(3) Patients enrolled in a hospice program licensed under IC 16-25.

(4) Patients enrolled in an inpatient or outpatient palliative care program of a hospital licensed under IC 16-21 or a hospice licensed under IC 16-25.

However, a period of time that a patient who was, but is no longer, a resident or patient as described in subdivisions (2) through (4), shall be included in the calculations under subsection (c).

(c) The requirements in the SECTIONS identified in subsection (a) only apply if a patient has been prescribed:

(1) more than sixty (60) opioid-containing pills a month; or

(2) a morphine equivalent dose of more than fifteen (15) milligrams per day; for more than three (3) consecutive months.

(d) Because the requirements in the SECTIONS identified in subsection (a) do not apply until the time stated in subsection (c), the initial evaluation of the patient for the purposes of SECTIONS 4, 7(a) and 8(a) shall not be required to take place until that time.

(e) Notwithstanding subsection (d), the physician may undertake those actions earlier than required if the physician deems it medically appropriate and if those actions meet the requirements a further initial evaluation is not required. If the physicians conducts actions earlier than required under this subsection, any subsequent requirements are determined by when the initial evaluation would have been required and not at the earlier date it actually was conducted.

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REGULATIONS

Medical Board Regulations

(CONTINUED)

SECTION 4. (a) The physician shall do the physician's own evaluation and risk stratification of the patient by doing the following in the initial evaluation of the patient: (1) Performing an appropriately focused history and physical exam and obtain or order appropriate tests, as indicated.

(2) Making a diligent effort to obtain and review records from previous health care providers to supplement the physicians understanding of the patient's chronic pain problem, including past treatments, and documenting this effort.

(3) Asking the patient to complete an objective pain assessment tool to document and better understand the patient's specific pain concerns.

(4) Assessing both the patient's mental health status and risk for substance abuse using available validated screening tools.

(5) After completing the initial evaluation, establishing a working diagnosis and tailoring a treatment plan to meaningful and functional goals with the patient reviewing them from time to time.

(b) Where medically appropriate, the physician shall utilize non-opioid options instead of or in addition to prescribing opioids.

SECTION 5. The physician shall discuss with the patient the potential risks and benefits of opioid treatment for chronic pain, as well as expectations related to prescription requests and proper medication use. In doing so, the physician shall:

(1) Where alternative modalities to opioids for managing pain exist for a patient, discuss them with the patient.

(2) Provide a simple and clear explanation to help patients understand the key elements of their treatment plan.

(3) Counsel women between the ages of 14 and 55 with child bearing potential about the risks to the fetus when the mother has been taking opioids while pregnant. Such described risks shall include fetal opioid dependency and neonatal abstinence syndrome (NAS).

(4) Together with the patient, review and sign a "Treatment Agreement", which shall include at least the following:

(A) The goals of the treatment.

(B) The patient's consent to drug monitoring testing.

(C) The physician's prescribing policies which must include at least:

(i) a requirement that the patient take the medication as prescribed; and

(ii) a prohibition of sharing medication with other individuals.

(D) A requirement that the patient inform the physician about any other controlled substances prescribed or taken.

(E) The granting of permission to the physician to conduct random pill counts.

(F) Reasons the opioid therapy may be changed or discontinued by the physician.

A copy of the treatment agreement shall be retained in the patient's chart.

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(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Encourages healthcare professionals to incorporate in their practice the evaluations of, and discussions with patients about, the potential benefits and risks of treatment with opioids, which can better ensure a clinical indication of such treatment so that opioids will be used for medical purposes.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Recognizes that the goal of pain treatment should include improvements in patient functioning and quality of life.

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REGULATIONS

Medical Board Regulations

(CONTINUED)

SECTION 6. (a) Physicians shall not prescribe opioids for patients without periodic scheduled visits. Visits for patients with a stable medication regimen and treatment plan shall occur face to face at least once every four (4) months. More frequent visits may be appropriate for patients working with the physician to achieve optimal management. For patients requiring changes to the medication and treatment plan, if changes are prescribed by the physician, the visits required by this subsection shall be scheduled at least once every two (2) months until the medication and treatment has been stabilized.

(b) During the visits required by subsection (a) the physician shall evaluate patient progress and compliance with the patient's treatment plan regularly and set clear expectations along the way (such as, attending physical therapy, counseling or other treatment options).

SECTION 7. At the outset of an opioid treatment plan, and at least annually thereafter, a physician prescribing opioids for a patient shall run an INSPECT report on that patient under IC 35-48-7-11.1(d)(4) and document in the patient's chart whether the INSPECT report is consistent with the physician's knowledge of the patient's controlled substance use history.

SECTION 8. (a) At the outset of an opioid treatment plan, and at least annually thereafter, a physician prescribing opioids for a patient shall perform or order a drug monitoring test, which must include a confirmatory test, on the patient.

(b) If the test required under subsection (a) reveals inconsistent medication use patterns or the presence of illicit substances, a review of the current treatment plan shall be required.
Documentation of the revised plan and discussion with the patient must be recorded in the patient's chart.

SECTION 9. When a patient's opioid dose reaches a morphine equivalent dose of more than sixty (60) milligrams per day, a face-to-face review of the treatment plan and patient evaluation must be scheduled, including consideration of referral to a specialist. If the physician elects to continue providing opioid therapy at a morphine equivalent dose of more than sixty (60) milligrams per day, the physician must develop a revised assessment and plan for ongoing treatment. The revised assessment and plan must be documented in the patient's chart, including an assessment of increased risk for adverse outcomes, including death, if the physician elects to provide ongoing opioid treatment.

SECTION 10. (a) IC 25-27.5-5 addresses the scope of practice of physician assistants in their dependent practice under supervising physicians including limiting the duties and responsibilities of physician assistants to those that are delegated by the supervising physician and that are within the supervising physician's scope of practice. IC 25-27.5-6 addresses supervisory responsibilities of the supervising physician, or when applicable, a physician designee. The prescribing of opioids for chronic pain management as regulated by this document falls within the requirements on supervising physicians, or when applicable, on physicians designees, under IC 25-27.5-5 and IC 25-27.5-6 including appropriate delegating of duties and responsibilities to physician assistants and appropriate supervision of physician assistants.

(b) IC 25-23-1-19.4 through IC 25-23-1-19.8, and 848 IAC 5, address the practice of advanced practice nurses with prescriptive authority in collaboration with a physician. The prescribing of opioids for chronic pain management as regulated by this document fails within the requirements on collaborating physicians regarding the prescriptive authority for advanced practice nurses under IC 25-23-1-19.4 through IC 25-23-1-19.8 and 848 IAC 5.

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SECTION 11. (a) Initial running of an INSPECT report as required under SECTION 7 of this document shall not be required for any patient who fell within the scope of SECTION 3(c) of this document before December 15, 2013. Initial conducting of a drug monitoring test as required under SECTION 8(a) of this document shall not be required for any patient who fell within the scope of SECTION 3(c) of this document before January 1, 2015. However, all other requirements of this document apply to these patients; that is, every requirement except for the initial running of the INSPECT report and the initial or annual conducting of a drug monitoring test.

(b) Notwithstanding subsection (a) and SECTION 7 of this document, the first running of an annual INSPECT report under SECTION 7 of this document shall not be required to be conducted before November 1, 2014. Nothing about this subsection shall be construed to prohibit a physician from running a report sooner than required by this subsection.

(c) Notwithstanding SECTION 8(a) of this document, the first conducting of an annual drug monitoring test under SECTION 8(a) of this document shall not be required to be conducted before January 1, 2015. Nothing about this subsection shall be construed to prohibit a physician from conducting a test sooner than required by this subsection.

SECTION 12. SECTIONS 1 through 11 of this document take effect December 15, 2013.

Pain & Policy Studies Group
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Madison, Wisconsin

INDIANA

STATUTES

Homicide

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT*:* Clarifies for physicians the important distinction between physician-assisted suicide and prescribing controlled substances for pain relief; this language identifies a clinical misperception that is pervasive in end-of-life care and attempts to lessen its impact on patient treatment, and the practitioners who provide it.

Burns Ind. Code Ann. § 35-42-1-2.5

§ 35-42-1-2.5. Assisting suicide

(a) This section does not apply to the following:

(1) A licensed health care provider who administers, prescribes, or dispenses medications or procedures to relieve a person's pain or discomfort, even if the medication or procedure may hasten or increase the risk of death, unless such medications or procedures are intended to cause death.

(2) The withholding or withdrawing of medical treatment or life-prolonging procedures by a licensed health care provider, including pursuant to IC 16-36-4 (living wills and life-prolonging procedures), IC 16-36-1 (health care consent), or IC 30-5 (power of attorney).

(b) A person who has knowledge that another person intends to commit or attempt to commit suicide and who intentionally does either of the following commits assisting suicide, a Class C felony:

(1) Provides the physical means by which the other person attempts or commits suicide.

(2) Participates in a physical act by which the other person attempts or commits suicide.

REGULATIONS

Opioid Treatment Programs

440 IAC 10-4-2o

440 IAC 10-4-20 Medical history and physical examination

Sec. 20. (a) An OTP shall conduct a physical examination of each patient at the following times:

(1) Prior to admission to an OTP.

(2) Annually thereafter.

(b) The OTP shall fully document the nature, extent, and results of the physical examination in the patient's record.

(c) The physical examination shall be performed by either of the following:

(1) A program physician.

(2) An authorized health care professional.

(d) The physical examination shall include at least the following:

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(4) A pain evaluation using a standard pain scale.

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(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY B:
Issues related to patients

COMMENT*:* Acknowledges that a patient's prior history or current status of drug abuse does not necessarily contraindicate appropriate pain management.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT*:* Establishes a responsibility for OTP staff to assess methadone-maintained patients for pain.

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STATUTES

- CONTROLLED SUBSTANCES ACT
  Title IV. Public Health; Subtitle 1. Alcoholic Beverages and Controlled Substances; Chapter 124. Controlled Substances

- MEDICAL PRACTICE ACT *(No provisions found)*
  Title IV. Public Health; Subtitle 3. Health-Related Professions; Chapter 148. Medicine and Surgery and Osteopathic Medicine and Surgery

- PHARMACY PRACTICE ACT
  Title IV. Public Health; Subtitle 3. Health-Related Professions; Chapter 155A. Pharmacy

- INTRACTABLE PAIN TREATMENT ACT
  No policy found

REGULATIONS

- CONTROLLED SUBSTANCES REGULATIONS (*Part of Pharmacy Board Regulations*) (*No provisions found*)
  Pharmacy Board; Chapter 10. Controlled Substances

- MEDICAL BOARD REGULATIONS (Governs Osteopathic *Board*)
  Medicine Board

- PHARMACY BOARD REGULATIONS
  Pharmacy Board

OTHER GOVERNMENTAL POLICIES

- JOINT BOARD POLICY STATEMENT
  A Joint Policy Statement on Pain by the Iowa Boards of Medicine, Nursing, Pharmacy and Physician Assistants. Adopted by Boards between August 2008 and January 2009.

RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY BOOLEAN (KEY WORD) SEARCHES

- ASSISTING SUICIDE
  Title XVI. Criminal Law and Procedure; Subtitle 1. Crime Control and Criminal Acts; Chapter 707A. Assisting Suicide

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STATUTES

Controlled Substances Act

Iowa Code § 124.101

124.101 Definitions.

As used in this chapter:

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26. *"Practitioner"* means either:

a. A physician, dentist, podiatric physician, veterinarian, scientific investigator or other person licensed, registered or otherwise permitted to distribute, dispense, conduct research with respect to or to administer a controlled substance in the course of professional practice or research in this state.

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Iowa Code § 124.551

124.551 Information program for drug prescribing and dispensing.

Contingent upon the receipt of funds pursuant to section 124.557 sufficient to carry out the purposes of this division, the board, in conjunction with the advisory council created in section 124.555, shall establish and maintain an information program for drug prescribing and dispensing. The program shall collect from pharmacies dispensing information for controlled substances identified pursuant to section 124.554, subsection 1, paragraph *"g"*. The information collected shall be used by prescribing practitioners and pharmacists on a need-to-know basis for purposes of improving patient health care by facilitating early identification of patients who may be at risk for addiction, or who may be using, abusing, or diverting drugs for unlawful or otherwise unauthorized purposes at risk to themselves and others, or who may be appropriately using controlled substances lawfully prescribed for them but unknown to the practitioner. For purposes of this division, *"prescribing practitioner"* means a practitioner who has prescribed or is contemplating the authorization of a prescription for the patient about whom information is requested, and *"pharmacist"* means a practicing pharmacist who is actively engaged in and responsible for the pharmaceutical care of the patient about whom information is requested. The board shall collect, store, and disseminate program information consistent with security criteria established by rule, including use of appropriate encryption or other industry-recognized security technology. The board shall seek any federal waiver necessary to implement the provisions of the program.

(+) *CRITERION 3:*
Opioids are part of professional practice

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Recognizes that prescription monitoring programs may identify patients who are appropriately using controlled substances that are lawfully prescribed, but are obtained from more than one practitioner; such information could be used to address inadequate treatment and improve patient care.

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University of Wisconsin Carbone Cancer Center
Madison, Wisconsin

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STATUTES

Pharmacy Practice Act

(+) *CRITERION 3:*
Opioids are part of professional practice

Iowa Code § 155A.3

155A.3 Definitions.

As used in this chapter, unless the context otherwise requires:

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35. *"Practitioner"* means a physician, dentist, podiatric physician, veterinarian, or other person licensed or registered to distribute or dispense a prescription drug or device in the course of professional practice in this state or a person licensed by another state in a health field in which, under Iowa law, licensees in this state may legally prescribe drugs.

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REGULATIONS

Medical Board Regulations

653 IAC 1.1(17A,147)

653-1.1(17A,147) Definitions.

The following definitions shall be applicable to the rules of the board of medicine:

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"The practice of medicine and surgery" shall mean holding one's self out as being able to diagnose, treat, operate or prescribe for any human disease, pain, injury, deformity or physical or mental condition and who shall either offer or undertake, by any means or methods, to diagnose, treat, operate or prescribe for any human disease, pain, injury, deformity or physical or mental condition. This rule shall not apply to licensed podiatrists, chiropractors, physical therapists, nurses, dentists, optometrists, acupuncturists, pharmacists and other licensed health professionals who are exclusively engaged in the practice of their respective professions.

(+) *CRITERION 2:*
Pain management is part of healthcare practice

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653 IAC 11.4(272C)

653-11.4(272C) Continuing education and training requirements for renewal or reinstatement.

A licensee shall meet the requirements in this rule to qualify for renewal of a permanent or special license or reinstatement of a permanent license.

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d. Training for chronic pain management for permanent or special license renewal. The licensee shall complete the training for chronic pain management as part of a category 1 credit. The licensee may utilize category 1 credit received for this training during the license period in which the training occurred to meet continuing education requirements in paragraph 11.4(1)"a."

(1) A licensee who regularly provides primary health care to patients in Iowa must complete at least two hours of category 1 credit for chronic pain management every five years. "A licensee who regularly provides primary health care to patients" means all emergency physicians, family physicians, general practice physicians, internists, neurologists, pain medicine specialists, psychiatrists, and any other physician who regularly provides primary health care to patients.

(2) A licensee who had a permanent license on August 17, 2011, has until August 17, 2016, to complete the chronic pain management training, and shall then complete the training once every five years thereafter.

e. Training for end-of-life care for permanent or special license renewal. The licensee shall complete the training for end-of-life care as part of a category 1 credit. The licensee may utilize category 1 credit received for this training during the license period in which the training occurred to meet continuing education requirements in paragraph 11.4(1)"a."

(1) A licensee who regularly provides primary health care to patients in Iowa must complete at least two hours of category 1 credit for end-of-life care every five years. "A licensee who regularly provides primary health care to patients" means all emergency physicians, family physicians, general practice physicians, internists, neurologists, pain medicine specialists, psychiatrists, and any other physician who regularly provides primary health care to patients.

(2) A licensee who had a permanent license on August 17, 2011, has until August 17, 2016, to complete the end-of-life care training, and shall then complete the training once every five years thereafter.

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(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT*:* Establishes a mechanism (mandatory continuing education) to provide practitioners information/education about pain management and end-of-life care.

2013

Pain & Policy Studies Group
University of Wisconsin Carbone Cancer Center
Madison, Wisconsin

IOWA

REGULATIONS

Medical Board Regulations

653 IAC 13.2(148,272C)

653-13.2(148,272C) Standards of practice--appropriate pain management.

This rule establishes standards of practice for the management of acute and chronic pain. The board encourages the use of adjunct therapies such as acupuncture, physical therapy and massage in the treatment of acute and chronic pain. This rule focuses on prescribing and administering controlled substances to provide relief and eliminate suffering for patients with acute or chronic pain.

1. This rule is intended to encourage appropriate pain management, including the use of controlled substances for the treatment of pain, while stressing the need to establish safeguards to minimize the potential for substance abuse and drug diversion.

2. The goal of pain management is to treat each patient's pain in relation to the patient's overall health, including physical function and psychological, social and work-related factors. At the end of life, the goals may shift to palliative care.

3. The board recognizes that pain management, including the use of controlled substances, is an important part of general medical practice. Unmanaged or inappropriately treated pain impacts patients' quality of life, reduces patients' ability to be productive members of society, and increases patients' use of health care services.

4. Physicians should not fear board action for treating pain with controlled substances as long as the physicians' prescribing is consistent with appropriate pain management practices. Dosage alone is not the sole measure of determining whether a physician has complied with appropriate pain management practices. The board recognizes the complexity of treating patients with chronic pain or a substance abuse history. Generally, the board is concerned about a pattern of improper pain management or a single occurrence of willful or gross overtreatment or undertreatment of pain.

5. The board recognizes that the undertreatment of pain is a serious public health problem that results in decreases in patients' functional status and quality of life, and that adequate access by patients to proper pain treatment is an important objective of any pain management policy.

6. Inappropriate pain management may include nontreatment, undertreatment, overtreatment, and the continued use of ineffective treatments. Inappropriate pain management is a departure from the acceptable standard of practice in Iowa and may be grounds for disciplinary action.

13.2(1) Definitions. For the purposes of this rule, the following terms are defined as follows:

"Acute pain" means the normal, predicted physiological response to a noxious chemical, thermal or mechanical stimulus and typically is associated with invasive procedures, trauma and disease. Generally, acute pain is self-limited, lasting no more than a few weeks following the initial stimulus.

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(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Represents the principle of Balance, which states that the regulation of controlled substances should not interfere with legitimate medical use.

(+) *CRITERION 3:*
Opioids are part of professional practice

(+) *CRITERION 6:*
Prescription amount alone does not determine legitimacy

(+) CRITERION 4:
Encourages pain management

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Recognizes that the goal of pain treatment should include improvements in patient functioning and quality of life.

(+) *CRITERION 5:*
Addresses fear of regulatory scrutiny

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Recognizes that inadequate treatment of pain is subject to disciplinary action just as other substandard practices might be.

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Medical Board Regulations

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"Addiction" means a primary, chronic, neurobiologic disease, with genetic, psychosocial, and environmental factors influencing its development and manifestations. It is characterized by behaviors that include the following: impaired control over drug use, craving, compulsive use, and continued use despite harm. Physical dependence and tolerance are normal physiological consequences of extended opioid therapy for pain and are not the same as addiction.

"Chronic pain" means persistent or episodic pain of a duration or intensity that adversely affects the functioning or well-being of a patient when (1) no relief or cure for the cause of pain is possible; (2) no relief or cure for the cause of pain has been found; or (3) relief or cure for the cause of pain through other medical procedures would adversely affect the well-being of the patient. If pain persists beyond the anticipated healing period of a few weeks, patients should be thoroughly evaluated for the presence of chronic pain.

"Pain" means an unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage. Pain is an individual, multifactorial experience influenced by culture, previous pain events, beliefs, mood and ability to cope.

"Physical dependence" means a state of adaptation that is manifested by drug class-specific signs and symptoms that can be produced by abrupt cessation, rapid dose reduction, decreasing blood level of the drug, or administration of an antagonist. Physical dependence, by itself, does not equate with addiction.

"Pseudoaddiction" means an iatrogenic syndrome resulting from the misinterpretation of relief-seeking behaviors as though they are drug-seeking behaviors that are commonly seen with addiction. The relief-seeking behaviors resolve upon institution of effective analgesic therapy.

"Substance abuse" means the use of a drug, including alcohol, by the patient in an inappropriate manner that may cause harm to the patient or others, or the use of a drug for an indication other than that intended by the prescribing clinician. An abuser may or may not be physically dependent on or addicted to the drug.

"Tolerance" means a physiological state resulting from regular use of a drug in which an increased dosage is needed to produce a specific effect, or a reduced effect is observed with a constant dose over time. Tolerance may or may not be evident during opioid treatment and does not equate with addiction.

"Undertreatment of pain" means the failure to properly assess, treat and manage pain or the failure to appropriately document a sound rationale for not treating pain.

13.2(2) Laws and regulations governing controlled substances. Nothing in this rule relieves a physician from fully complying with applicable federal and state laws and regulations governing controlled substances.

13.2(3) Undertreatment of pain. The undertreatment of pain is a departure from the acceptable standard of practice in Iowa. Undertreatment may include a failure to recognize symptoms and signs of pain, a failure to treat pain within a reasonable amount of time, a failure to allow interventions, e.g., analgesia, to become effective before invasive steps are taken, a failure to address pain needs in patients with reduced cognitive status, a failure to use controlled substances for terminal pain due to the physician's concern with addicting the patient, or a failure to use an adequate level of pain management.

13.2(4) Assessment and treatment of acute pain. Appropriate assessment of the etiology of the pain is essential to the appropriate treatment of acute pain. Acute pain is not a diagnosis; it is a symptom. Prescribing controlled substances for the treatment of acute pain should be based on clearly diagnosed and documented pain. Appropriate management of acute pain should include an assessment of the mechanism, type and intensity of pain. The patient's medical record should clearly document a medical history, a pain history, a clinical examination, a medical diagnosis and a treatment plan.

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(+) *CRITERION 7:*
Physical dependence or analgesic tolerance are not confused with "addiction"

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Encourages healthcare professionals to understand and follow federal and state laws governing their practice, which can better ensure that practitioners follow the *balanced* approach represented by federal law and the laws in many states.

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13.2(5) Effective management of chronic pain. Prescribing controlled substances for the treatment of chronic pain should only be accomplished within an established physician-patient relationship and should be based on clearly diagnosed and documented unrelieved pain. To ensure that chronic pain is properly assessed and treated, a physician who prescribes or administers controlled substances to a patient for the treatment of chronic pain shall exercise sound clinical judgment and establish an effective pain management plan in accordance with the following:

a. Patient evaluation. A patient evaluation that includes a physical examination and a comprehensive medical history shall be conducted prior to the initiation of treatment. The evaluation shall also include an assessment of the pain, physical and psychological function, diagnostic studies, previous interventions, including medication history, substance abuse history and any underlying or coexisting conditions. Consultation/referral to a physician with expertise in pain medicine, addiction medicine or substance abuse counseling or a physician who specializes in the treatment of the area, system, or organ perceived to be the source of the pain may be warranted depending upon the expertise of the physician and the complexity of the presenting patient. Interdisciplinary evaluation is strongly encouraged.

b. Treatment plan. The physician shall establish a comprehensive treatment plan that tailors drug therapy to the individual needs of the patient. To ensure proper evaluation of the success of the treatment, the plan shall clearly state the objectives of the treatment, for example, pain relief or improved physical or psychosocial functioning. The treatment plan shall also indicate if any further diagnostic evaluations or treatments are planned and their purposes. The treatment plan shall also identify any other treatment modalities and rehabilitation programs utilized. The patient's short- and long-term needs for pain relief shall be considered when drug therapy is prescribed. The patient's ability to request pain relief as well as the patient setting shall be considered. For example, nursing home patients are unlikely to have their pain control needs assessed on a regular basis, making prn (on an as-needed basis) drugs less effective than drug therapy prescribed for routine administration that can be supplemented if pain is found to be worse. The patient should receive prescriptions for controlled substances from a single physician and a single pharmacy whenever possible.

c. Informed consent. The physician shall document discussion of the risks and benefits of controlled substances with the patient or person representing the patient.

d. Periodic review. The physician shall periodically review the course of drug treatment of the patient and the etiology of the pain. The physician should adjust drug therapy to the individual needs of each patient. Modification or continuation of drug therapy by the physician shall be dependent upon evaluation of the patient's progress toward the objectives established in the treatment plan. The physician shall consider the appropriateness of continuing drug therapy and the use of other treatment modalities if periodic reviews indicate that the objectives of the treatment plan are not being met or that there is evidence of diversion or a pattern of substance abuse. Long-term opioid treatment is associated with the development of tolerance to its analgesic effects. There is also evidence that opioid treatment may paradoxically induce abnormal pain sensitivity, including hyperalgesia and allodynia. Thus, increasing opioid doses may not improve pain control and function.

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(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Encourages healthcare professionals to incorporate in their practice the evaluations of, and discussions with patients about, the potential benefits and risks of treatment with opioids, which can better ensure a clinical indication of such treatment so that opioids will be used for medical purposes.

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Medical Board Regulations

(CONTINUED)

e. Consultation/referral. A specialty consultation may be considered at any time if there is evidence of significant adverse effects or lack of response to the medication. Pain, physical medicine, rehabilitation, general surgery, orthopedics, anesthesiology, psychiatry, neurology, rheumatology, oncology, addiction medicine, or other consultation may be appropriate. The physician should also consider consultation with, or referral to, a physician with expertise in addiction medicine or substance abuse counseling, if there is evidence of diversion or a pattern of substance abuse. The board encourages a multidisciplinary approach to chronic pain management, including the use of adjunct therapies such as acupuncture, physical therapy and massage.

f. Documentation. The physician shall keep accurate, timely, and complete records that detail compliance with this subrule, including patient evaluation, diagnostic studies, treatment modalities, treatment plan, informed consent, periodic review, consultation, and any other relevant information about the patient's condition and treatment.

g. Pain management agreements. A physician who treats patients for chronic pain with controlled substances shall consider using a pain management agreement with each patient being treated that specifies the rules for medication use and the consequences for misuse. In determining whether to use a pain management agreement, a physician shall evaluate each patient, taking into account the risks to the patient and the potential benefits of long-term treatment with controlled substances. A physician who prescribes controlled substances to a patient for more than 90 days for treatment of chronic pain shall utilize a pain management agreement if the physician has reason to believe a patient is at risk of drug abuse or diversion. If a physician prescribes controlled substances to a patient for more than 90 days for treatment of chronic pain and chooses not to use a pain management agreement, then the physician shall document in the patient's medical records the reason(s) why a pain management agreement was not used. Use of pain management agreements is not necessary for hospice or nursing home patients. A sample pain management agreement and prescription drug risk assessment tools may be found on the board's Web site at www.medicalboard.iowa.gov.

h. Substance abuse history or comorbid psychiatric disorder. A patient's prior history of substance abuse does not necessarily contraindicate appropriate pain management. However, treatment of patients with a history of substance abuse or with a comorbid psychiatric disorder may require extra care and communication with the patient, monitoring, documentation, and consultation with or referral to an expert in the management of such patients. The board strongly encourages a multidisciplinary approach for pain management of such patients that incorporates the expertise of other health care professionals.

i. Drug testing. A physician who prescribes controlled substances to a patient for more than 90 days for the treatment of chronic pain shall consider utilizing drug testing to ensure that the patient is receiving appropriate therapeutic levels of prescribed medications or if the physician has reason to believe that the patient is at risk of drug abuse or diversion.

j. Termination of care. The physician shall consider termination of patient care if there is evidence of noncompliance with the rules for medication use, drug diversion, or a repeated pattern of substance abuse.

(CONTINUED ON NEXT PAGE)

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY B:
Issues related to patients

COMMENT: Acknowledges that a patient's prior history or current status of drug abuse does not contraindicate appropriate pain management.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Recognizes the need for a multidisciplinary approach to pain management.

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Pain & Policy Studies Group
University of Wisconsin Carbone Cancer Center
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REGULATIONS

Medical Board Regulations

(CONTINUED)

13.2(6) Pain management for terminal illness. The provisions of this subrule apply to patients who are at the stage in the progression of cancer or other terminal illness when the goal of pain management is comfort care. When the goal of treatment shifts to comfort care rather than cure of the underlying condition, the board recognizes that the dosage level of opiates or controlled substances to control pain may exceed dosages recommended for chronic pain and may come at the expense of patient function. The determination of such pain management should involve the patient, if possible, and others the patient has designated for assisting in end-of-life care.

13.2(7) Prescription monitoring program. The Iowa board of pharmacy has established a prescription monitoring program pursuant to ***Iowa Code sections 124.551*** to ***124.558*** to assist prescribers and pharmacists in monitoring the prescription of controlled substances to patients. The board recommends that physicians utilize the prescription monitoring program when prescribing controlled substances to patients if the physician has reason to believe that a patient is at risk of drug abuse or diversion. A link to the prescription monitoring program may be found at the board's Web site at www.medicalboard.iowa.gov.

13.2(8) Pain management resources. The board strongly recommends that physicians consult the following resources regarding the proper treatment of chronic pain. This list is provided for the convenience of licensees, and the publications included are not intended to be incorporated in the rule by reference.

a. American Academy of Hospice and Palliative Medicine or AAHPM is the American Medical Association-recognized specialty society of physicians who practice in hospice and palliative medicine in the United States. The mission of the AAHPM is to enhance the treatment of pain at the end of life.

b. American Academy of Pain Medicine or AAPM is the American Medical Association-recognized specialty society of physicians who practice pain medicine in the United States. The mission of the AAPM is to enhance pain medicine practice by promoting a climate conducive to the effective and efficient practice of pain medicine.

c. American Pain Society or APS is the national chapter of the International Association for the Study of Pain, an organization composed of physicians, nurses, psychologists, scientists and other professionals who have an interest in the study and treatment of pain. The mission of the APS is to serve people in pain by advancing research, education, treatment and professional practice.

d. DEA Policy Statement: Dispensing Controlled Substances for the Treatment of Pain. On August 28, 2006, the Drug Enforcement Agency (DEA) issued a policy statement establishing guidelines for practitioners who dispense controlled substances for the treatment of pain. This policy statement may be helpful to practitioners who treat pain with controlled substances.

e. Interagency Guideline on Opioid Dosing for Chronic Non-cancer Pain. In March 2007, the Washington State Agency Medical Directors' Group published an educational pilot to improve care and safety of patients with chronic, noncancer pain who are treated with opioids. The guidelines include opioid dosing recommendations.

f. Responsible Opioid Prescribing: A Physician's Guide. In 2007, in collaboration with author Scott Fishman, M.D., the Federation of State Medical Boards' (FSMB) Research and Education Foundation published a book on responsible opioid prescribing based on the FSMB Model Policy for the Use of Controlled Substances for the Treatment of Pain.

g. World Health Organization: Pain Relief Ladder. Cancer pain relief and palliative care. Technical report series 804. Geneva: World Health Organization.

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Madison, Wisconsin

IOWA

REGULATIONS

Pharmacy Board Regulations

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT*:* Represents the principle of Balance, which states that the regulation of controlled substances should not interfere with legitimate medical use.

657 IAC 37.1(124)

657-37.1(124) Purpose.

These rules establish a prescription monitoring program that compiles a central database of reportable prescriptions dispensed to patients in Iowa. An authorized health care practitioner may, but is not required to, access prescription monitoring program (PMP) information regarding the practitioner's patient to assist in determining appropriate treatment options and to improve the quality of patient care. The PMP is intended to provide a health care practitioner with a resource for information regarding a patient's use of controlled substances. This database will assist the practitioner in identifying any potential diversion, misuse, or abuse of controlled substances without impeding the appropriate medical use of controlled substances.

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Madison, Wisconsin

IOWA

OTHER GOVERNMENTAL POLICY

Joint Board Policy Statement

A Joint Statement on Pain by the Iowa Boards of Medicine, Nursing, Pharmacy and Physician Assistants

Adopted by the Iowa Boards of Medicine 8/28/08, Nursing 9/11/08, Pharmacy 10/7/08, and Physician Assistant 1/21/09

This policy statement is not a legally binding opinion of the Boards, but is only intended to provide guidance to the public. The Board may make formal policy only through administrative rules, declaratory orders or contested case decisions.

The Iowa Boards of Medicine, Nursing, Pharmacy and Physician Assistants join together in a commitment to improve the pain management services for all Iowa residents.

Health care practitioners, i.e., medical doctors, osteopathic physicians, advanced practice nurses, registered nurses, licensed practical nurses, pharmacists and physician assistants care for patients regularly who have pain. Patients deserve to have their pain well managed, whether it's acute or chronic, mild or severe. Health care practitioners should, within their legal scope of practice, attend to patients' pain.

The goal of pain management is to treat each patient's pain in relation to the patient's overall health, including physical function and psychological, social and work-related factors. Although pain management is not an exact science, the Boards recognize that much can be done to treat pain more appropriately. Unmanaged or inappropriately treated pain impacts patients' quality of life, reduces patients' ability to be productive members of society and increases patients' use of health care services.

To effectively assist patients in managing their pain, health care practitioners should, within their legal scope of practice:

1. Routinely assess all patients for pain. All pain should be evaluated with an appropriate history and physical and with laboratory and diagnostic testing, if indicated.
2. Draw on the expertise that other health care practitioners offer in treating patients' pain and work cooperatively with them to balance between pain relief and sedation, keeping in mind each patient's level of pain, overall health and need to attend to family and other responsibilities. Utilize non-pharmacological and pharmacological approaches to the treatment of pain and suffering.
3. Regularly evaluate the effectiveness of the treatment plan and work together to alter the plan or seek consultation/referrals if the treatment is not providing optimal pain relief.
4. Document the assessment, plan of care and response to care in a clear, consistent, thorough and accurate manner. Patients should be informed of the risks and benefits when controlled substances or highly abusable drugs are prescribed in the ambulatory care setting. Documentation should be sufficiently detailed so that other practitioners can understand the original practitioner's findings and thought processes.
5. Anticipate and effectively manage side effects of pain medication, e.g., nausea, constipation, fatigue, depression and anxiety.
6. Become knowledgeable about effective pain management.
7. Learn about addiction. Patients with addictions deserve to have their pain treated effectively. Patients in recovery from addiction who have pain should have their pain treated effectively while minimizing the recurrence of their addiction.
8. Minimize the risk of diversion of drugs by using a pain management contract for chronic pain patients prescribed controlled substances and other abusable drugs.

A licensed health care practitioner involved in the care of a patient in pain should not be at risk of disciplinary action from their respective licensing board for prescribing, dispensing or administering controlled substances, including opioid analgesics, for a legitimate medical purpose, based on accepted scientific knowledge, sound clinical judgment and adequate documentation.

(+) *CRITERION 4:*
Encourages pain management

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT*:* Recognizes that the goals of pain treatment should include improvements in patient functioning and quality of life.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY B:
Issues related to patients

COMMENT*:* Acknowledges that a patient's prior history or current status of drug abuse does not necessarily contraindicate appropriate pain management.

(+) *CRITERION 5:*
Addresses fear of regulatory scrutiny

(+) *CRITERION 2:*
Pain management is part of healthcare practice

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT*:* Recognizes the need for a multidisciplinary approach to pain management.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Encourages healthcare professionals to incorporate in their practice the evaluations of, and discussions with patients about, the potential benefits and risks of treatment with opioids, which can better ensure a clinical indication of such treatment so that opioids will be used for medical purposes.

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University of Wisconsin Carbone Cancer Center
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IOWA

STATUTES

Assisting Suicide

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Clarifies for physicians the important distinction between physician-assisted suicide and prescribing controlled substances for pain relief; this language identifies a clinical misperception that is pervasive in end-of-life care and attempts to lessen its impact on patient treatment, and the practitioners who provide it.

Iowa Code § 707A.3

707A.3 Acts or omissions not considered assisting suicide

1. A licensed health care professional who administers, prescribes, or dispenses medications or who performs or prescribes procedures to relieve another person's pain or discomfort, even if the medication or procedure may hasten or increase the risk of death, does not violate section 707A.2 unless the medications or procedures are intentionally or knowingly administered, prescribed, or dispensed with the primary intention of causing death.

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KANSAS

STATUTES

- CONTROLLED SUBSTANCES ACT *(No provisions found)*
  Chapter 65. Public Health; Article 41. Controlled Substances; Uniform Controlled Substances Act

- MEDICAL PRACTICE ACT
  Chapter 65. Public Health; Article 28. Healing Arts; Kansas Healing Arts Act

- PHARMACY PRACTICE ACT *(No provisions found)*
  Chapter 65. Public Health; Article 16. Regulation of Pharmacists

- INTRACTABLE PAIN TREATMENT ACT
  No policy found

REGULATIONS

- CONTROLLED SUBSTANCES REGULATIONS (*Part of Pharmacy Board Regulations*) (*No provisions found*)
  Agency 68. Kansas State Board of Pharmacy; Article 20. Controlled Substances

- MEDICAL BOARD REGULATIONS *(No provisions found)*
  Agency 100. Kansas State Board of Healing Arts

- PHARMACY BOARD REGULATIONS (*No provisions found*)
  Agency 68. Kansas State Board of Pharmacy

OTHER GOVERNMENTAL POLICIES

- MEDICAL BOARD GUIDELINE
  Kansas State Board of Healing Arts. *Guidelines for the Use of Controlled Substances for the Treatment of Pain*. Adopted: October 17, 1998.

- JOINT BOARD POLICY STATEMENT
  Kansas State Boards of Healing Arts, Nursing, and Pharmacy. *Joint Policy Statement by the Boards of Healing Arts, Nursing, and Pharmacy on the Use of Controlled Substances for the Treatment of Pain*. Adopted: July 17, 2002.

RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY KEY WORD SEARCHES

- PREVENTION OF ASSISTED SUICIDE
  Chapter 60. Procedure, Civil; Article 44. Prevention of Assisted Suicide

- PAIN PATIENT'S QUALITY OF CARE
  Chapter 65. Public Health; Article 49. Health Care Providers

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KANSAS

STATUTES

Medical Practice Act

K.S.A. § 65-2838

65-2838. Disciplinary action against licensee; procedure; stipulations; temporary suspension or limitation; emergency proceedings; guidelines for use of controlled substances for treatment of pain; written advisory opinions.

(a) The board shall have jurisdiction of proceedings to take disciplinary action authorized by *K.S.A. 65-2836* and amendments thereto against any licensee practicing under this act. Any such action shall be taken in accordance with the provisions of the Kansas administrative procedure act.

(b) Either before or after formal charges have been filed, the board and the licensee may enter into a stipulation which shall be binding upon the board and the licensee entering into such stipulation, and the board may enter its findings of fact and enforcement order based upon such stipulation without the necessity of filing any formal charges or holding hearings in the case. An enforcement order based upon a stipulation may order any disciplinary action authorized by *K.S.A. 65-2836* and amendments thereto against the licensee entering into such stipulation.

(c) The board may temporarily suspend or temporarily limit the license of any licensee in accordance with the emergency adjudicative proceedings under the Kansas administrative procedure act if the board determines that there is cause to believe that grounds exist under *K.S.A. 65-2836* and amendments thereto for disciplinary action authorized by *K.S.A. 65-2836* and amendments thereto against the licensee and that the licensee's continuation in practice would constitute an imminent danger to the public health and safety.

(d) The board shall adopt guidelines for the use of controlled substances for the treatment of pain.

(e) Upon request of another regulatory or enforcement agency, or a licensee, the board may render a written advisory opinion indicating whether the licensee has prescribed, dispensed, administered or distributed controlled substances in accordance with the treatment of pain guidelines adopted by the board.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (board guidelines) to provide practitioners information/education about pain management.

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Madison, Wisconsin

KANSAS

OTHER GOVERNMENTAL POLICY

Medical Board Guideline

GUIDELINES FOR THE USE OF CONTROLLED SUBSTANCES
FOR THE TREATMENT OF PAIN

Section 1: Preamble

The Kansas State Board of Healing Arts recognizes that principles of quality medical practice dictate that the people of the State of Kansas have access to appropriate and effective pain relief. The appropriate application of up-to-date knowledge and treatment modalities can serve to improve the quality of life for those patients who suffer from pain as well as reduce the morbidity and costs associated with untreated or inappropriately treated pain. The Board encourages physicians to view effective pain management as a part of quality medical practice for all patients with pain, acute or chronic, and it is especially important for patients who experience pain as a result of terminal illness. All physicians should become knowledgeable about effective methods of pain treatment.

Inadequate pain control may result from physicians' lack of knowledge about pain management or an inadequate understanding of addiction. Fears of investigation or sanction by federal, state and local regulatory agencies may also result in inappropriate or inadequate treatment of chronic pain patients. Accordingly, these guidelines have been developed to clarify the Board's position on pain control, specifically as related to the use of controlled substances, to alleviate physician uncertainty and to encourage better pain management.

The Board recognizes that controlled substances, including opioid analgesics, may be essential in the treatment of acute pain due to trauma or surgery and chronic pain, whether due to cancer or non-cancer origins. The medical management of pain should be based on current knowledge and research and include the use of both pharmacologic and non-pharmacologic modalities. Pain should be assessed and treated promptly, and the quantity and frequency of doses should be adjusted according to the intensity and duration of pain. Physicians should recognize that tolerance and physical dependence are normal consequences of sustained use of opioid analgesics and are not synonymous with addiction.

The Kansas State Board of Healing Arts is obligated under the laws of the State of Kansas to protect the public health and safety. The Board recognizes that inappropriate prescribing of controlled substances, including opioid analgesics, may lead to drug diversion and abuse by individuals who seek them for other than legitimate medical use. Physicians should be diligent in preventing the diversion of drugs for illegitimate purposes.

Physicians should not fear disciplinary action from the Board for prescribing, dispensing or administering controlled substances, including opioid analgesics, for a legitimate medical purpose and in the usual course of professional practice. The Board will consider prescribing, ordering, administering or dispensing controlled substances for pain to be for a legitimate medical purpose based on sound clinical grounds. All such prescribing must be based on clear documentation of unrelieved pain and in compliance with these guidelines. If such prescribing meets these criteria, the Board will support physicians whose use of controlled substances has been questioned by another regulatory or enforcement agency.

Allegations of improper prescribing of controlled substances for pain will be evaluated on a case-by-case basis. The board will not take disciplinary action against a physician for failing to adhere strictly to the provisions of these guidelines, if good cause is shown for such deviation. The physician's conduct will be evaluated to a great extent by the treatment outcome, taking into account whether the drug used is medically and/or pharmacologically recognized to be appropriate for the diagnosis, the patient's individual needs - including any improvement in functioning - and recognizing that some types of pain cannot be completely relieved.

(CONTINUED ON NEXT PAGE)

(+) *CRITERION 2:*
Pain management is part of healthcare practice

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Identifies the potential impact of important barriers on the provision of effective pain care.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT:
Acknowledges the need for treatment flexibility for physicians to respond to individual clinical circumstances, as long as their prescribing maintains the standards of good medical practice.

(+) *CRITERION 4:*
Encourages pain management

(+) *CRITERION 7:*
Physical dependence or analgesic tolerance are not confused with "addiction"

(+) *CRITERION 5:*
Addresses fear of regulatory scrutiny

(+) *CRITERION 3:*
Opioids are part of professional practice

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Madison, Wisconsin

KANSAS

OTHER GOVERNMENTAL POLICY

Medical Board Guideline

(+) *CRITERION 6:*
Prescription amount alone does not determine legitimacy

[CONTINUED]

The Board will judge the validity of prescribing based on the physician's treatment of the patient and on available documentation, rather than on the quantity and chronicity of prescribing. The goal is to control the patient's pain for its duration while effectively addressing other aspects of the patient's functioning, including physical, psychological, social and work-related factors. The following guidelines are not intended to define complete or best practice, but rather to communicate what the Board considers to be within the boundaries of professional practice.

Section II: Guidelines

The Board has adopted the following guidelines when evaluating the use of controlled substances for pain control:

1. Evaluation of the Patient

The medical record should document the nature and intensity of the pain, current and past treatments for pain, underlying or coexisting diseases or conditions, the effect of pain on physical and psychological function, and history of substance abuse. The medical record also should document the presence of one or more recognized medical indications for the use of a controlled substance.

2. Treatment Plan

The written treatment plan should state objectives that will be used to determine treatment success, such as pain relief and improved physical and psychosocial function, and should indicate if any further diagnostic evaluations or other treatments are planned. After treatment begins, the physician should adjust drug therapy to the individual medical needs of each patient. Other treatment modalities or a rehabilitation program may be necessary depending on the etiology of the pain and the extent to which pain is associated with physical and psychosocial impairment.

3. Informed Consent and Agreement for Treatment

The physician should discuss the risks and benefits of the use of controlled substances with the patient, persons designated by the patient or with the patient's surrogate or guardian if the patient is incompetent. The patient should receive prescriptions from one physician and one pharmacy where possible. If the patient is determined to be at high risk for medication abuse or have a history of substance abuse, the physician may employ the use of a written agreement between physician and patient outlining patient responsibilities, including

- urine/serum medication levels screening when requested;
- number and frequency of all prescription refills; and
- reasons for which drug therapy may be discontinued (i.e., violation of agreement).

4. Periodic Review

At reasonable intervals based on the individual circumstances of the patient, the physician should review the course of treatment and any new information about the etiology of the pain. Continuation or modification of therapy should depend on the physician's evaluation of progress toward stated treatment objectives, such as improvement in patient's pain intensity and improved physical and / or psychosocial function, i.e., ability to work, need of health care resources, activities of daily living and quality of social life. If treatment goals are not being achieved, despite medication adjustments, the physician should reevaluate the appropriateness of continued treatment. The physician should monitor patient compliance in medication usage and related treatment plans.

[CONTINUED ON NEXT PAGE]

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Encourages healthcare professionals to incorporate in their practice the evaluations of, and discussions with patients about, the potential benefits and risks of treatment with opioids, which can better ensure a clinical indication of such treatment so that opioids will be used for medical purposes.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Recognizes that the goal of pain treatment should include improvements in patient functioning and quality of life.

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OTHER GOVERNMENTAL POLICY

Medical Board Guideline

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY B:
Issues related to patients

COMMENT: Acknowledges that a patient's prior history or current status of drug abuse does not necessarily contraindicate appropriate pain management.

[CONTINUED]

5. Consultation

The physician should be willing to refer the patient as necessary for additional evaluation and treatment in order to achieve treatment objectives. Special attention should be given to those pain patients who are at risk for misusing their medications and those whose living arrangement pose a risk for medication misuse or diversion. The management of pain in patients with a history of substance abuse or with a co-morbid psychiatric disorder may require extra care, monitoring, documentation and consultation with or referral to an expert in the management of such patients.

6. Medical Records

The physician should comply with and meet the requirements of K.A.R. 100-24-1 in the maintenance of an adequate record for each patient.

7. Compliance With Controlled Substances Laws and Regulations

To prescribe, dispense or administer controlled substances, the physician must be licensed in the state and comply with applicable federal and state regulations.

Section III: Definitions

For the purposes of these guidelines, the following terms are defined as follows:

Acute Pain

Acute pain is the normal, predicted physiological response to an adverse chemical, thermal or mechanical stimulus and is associated with surgery, trauma and acute illness. It is generally time-limited and is responsive to opioid therapy, among other therapies.

Addiction

Addiction is a neuro-behavioral syndrome with genetic and environmental influences that results in psychological dependence on the use of substances for their psychic effects and is characterized by compulsive use despite harm. Addiction may also be referred to by terms such as "drug dependence" and "psychological dependence." Physical dependence and tolerance are normal physiological consequences of extended opioid therapy for pain and should not be considered addiction.

Analgesic Tolerance

Analgesic tolerance is the need to increase the dose of opioid to achieve the same level of analgesia. Analgesic tolerance may or may not be evident during opioid treatment and does not equate with addiction.

Chronic Pain

A pain state which is persistent and in which the cause of the pain cannot be removed or otherwise treated. Chronic pain may be associated with a long-term incurable or intractable medical condition or disease.

[CONTINUED ON NEXT PAGE]

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Encourages healthcare professionals to understand and follow federal and state laws governing their practice, which can better ensure that practitioners follow the *balanced* approach represented by federal law and the laws in many states.

Pain & Policy Studies Group
University of Wisconsin Carbone Cancer Center
Madison, Wisconsin

OTHER GOVERNMENTAL POLICY

Medical Board Guideline

[CONTINUED]

Pain

An unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage.

Physical Dependence

Physical dependence on a controlled substance is a physiologic state of neuro-adaptation which is characterized by the emergence of a withdrawal syndrome if drug use is stopped or decreased abruptly, or if an antagonist is administered. Physical dependence is an expected result of opioid use. Physical dependence, by itself, does not equate with addiction.

Pseudo-Addiction

Pattern of drug-seeking behavior of pain patients who are receiving inadequate pain management that can be mistaken for addiction.

Substance Abuse

Substance abuse is the use of any substance(s) for non-therapeutic purposes or use of medication for purposes other than those for which it is prescribed.

Tolerance

Tolerance is a physiologic state resulting from regular use of a drug in which an increased dosage is needed to produce the same effect, or a reduced effect is observed with a constant dose.

Pain & Policy Studies Group
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Madison, Wisconsin

KANSAS

OTHER GOVERNMENTAL POLICY

Joint Board Policy Statement

JOINT POLICY STATEMENT BY THE BOARDS OF HEALING ARTS, NURSING, AND PHARMACY ON THE USE OF CONTROLLED SUBSTANCES FOR THE TREATMENT OF PAIN

Section 1: Preamble

The Kansas Legislature created the Board of Healing Arts, the Board of Nursing, and the Board of Pharmacy to protect the public health, safety and welfare. Protection of the public necessitates reasonable regulation of health care providers who order, administer, or dispense drugs. The boards adopt this statement to help assure health care providers and patients and their families that it is the policy of this state to encourage competent comprehensive care for the treatment of pain. Guidelines by individual boards are appropriate to address issues related to particular professions.

The appropriate application of current knowledge and treatment modalities improves the quality of life for those patients who suffer from pain, and reduces the morbidity and costs associated with pain that is inappropriately treated. All health care providers who treat patients in pain, whether acute or chronic, and whether as a result of terminal illness or non-life-threatening injury or disease, should become knowledgeable about effective methods of pain treatment. The management of pain should include the use of both pharmacologic and non-pharmacologic modalities.

Inappropriate treatment of pain is a serious problem in the United States. Inappropriate treatment of pain includes nontreatment, undertreatment, overtreatment, and ineffective treatment. All persons who are experiencing pain should expect the appropriate assessment and management of pain while retaining the right to refuse treatment. A person's report of pain is the optimal standard upon which all pain management interventions are based. The goal of pain management is to reduce the individual's pain to the lowest level possible, while simultaneously increasing the individual's level of functioning to the greatest extent possible. The exact nature of these goals is determined jointly by the patient and the health care provider.

Prescribing, administering or dispensing controlled substances, including opioid analgesics, to treat pain is considered a legitimate medical purpose if based upon sound clinical grounds. Health care providers authorized by law to prescribe, administer or dispense drugs, including controlled substances, should recognize that tolerance and physical dependence are normal consequences of sustained use of opioid analgesics and are not synonymous with addiction.

A board is under a duty to make an inquiry when it receives information contending that a health care provider treated pain inappropriately. Proper investigation is necessary in order to obtain relevant information. A health care provider should not construe any request for information as a presumption of misconduct. Prior to the filing of any allegations, the results of the investigation will be evaluated by the health care provider's peers who are familiar with this policy statement. Health care providers who competently treat pain should not fear disciplinary action from their licensing board.

The following guidelines are not intended to define complete or best practice, but rather to communicate what the boards consider to be within the boundaries of professional practice. This policy statement is not intended to interfere with any healthcare provider's professional duty to exercise that degree of learning and skill ordinarily possessed by competent members of the healthcare provider's profession.

Section II: Principles

The boards approve the following principles when evaluating the use of controlled substances for pain control

(CONTINUED ON NEXT PAGE)

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Recognizes that inadequate treatment of pain is subject to disciplinary action just as other substandard practices might be.

(+) *CRITERION 3:*
Opioids are part of professional practice

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT:
Acknowledges the need for treatment flexibility for physicians to respond to individual clinical circumstances, as long as their prescribing maintains the standards of good medical practice.

(+) *CRITERION 4:*
Encourages pain management

(+) *CRITERION 2:*
Pain management is part of healthcare practice

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY B:
Issues related to patients

COMMENT*:* Recognizes the patient's right to request or reject different types of treatments.

(+) *CRITERION 7:*
Physical dependence or analgesic tolerance are not confused with "addiction"

(+) *CRITERION 5:*
Addresses fear of regulatory scrutiny

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Pain & Policy Studies Group
University of Wisconsin Carbone Cancer Center
Madison, Wisconsin

KANSAS

OTHER GOVERNMENTAL POLICY

Joint Board Policy Statement

[CONTINUED]

1. Assessment of the Patient
Pain should be assessed and reassessed as clinically indicated. Interdisciplinary communications regarding a patient's report of pain should include adoption of a standardized scale for assessing pain.

2. Treatment Plan
The written treatment plan should state objectives that will be used to determine treatment success, such as pain relief and improved physical and psychosocial function, and should indicate if any further diagnostic evaluations or other treatments are planned. After treatment begins, the drug therapy plan should be adjusted to the individual medical needs of each patient. The nurse's skill is best utilized when an order for drug administration uses dosage and frequency parameters that allow the nurse to adjust (titrate) medication dosage. Other treatment modalities or a rehabilitation program may be necessary depending on the etiology of the pain and the extent to which the pain is associated with physical and psychosocial impairment. If, in a healthcare provider's sound professional judgement, pain should not be treated as requested by the patient, the healthcare provider should inform the patient of the basis for the treatment decisions and document the substance of this communication.

3. Informed Consent
The physician retains the ultimate responsibility for obtaining informed consent to treatment from the patient. All health care providers share the role of effectively communicating with the patient so that the patient is apprised of the risks and benefits of using controlled substances to treat pain.

4. Agreement for Treatment of High-Risk Patients
If the patient is determined to be at high risk for medication abuse or to have a history of substance abuse, the health care provider should consider requiring a written agreement by the patient outlining patient responsibilities, including:
- Submitting to screening of urine/serum medication levels when requested;
- Limiting prescription refills only to a specified number and frequency;
- Requesting or receiving prescription orders from only one health care provider;
- Using only one pharmacy for filling prescriptions; and
- Acknowledging reasons for which the drug therapy may be discontinued (i.e., violation of agreement).

5. Periodic Review
At reasonable intervals based on the individual circumstances of the patient, the course of treatment and any new information about the etiology of the pain should be evaluated. Communication among health care providers is essential to review of the medical plan of care. The health care providers involved with the management of pain should evaluate progress toward meeting treatment objectives in light of improvement in patient's pain intensity and improved physical or psychosocial function, i.e., ability to work, need of health care resources, activities of daily living and quality of social life. If treatment goals are not being achieved despite medication adjustments, the health care provider's should reevaluate the appropriateness of continued treatment.

6. Consultation
The health care provider should be willing to refer the patient as necessary for additional evaluation and treatment in order to achieve treatment objectives. Special attention should be given to those pain patients who are at risk for misusing their medications and those whose living arrangement poses a risk for medication misuse or diversion. The management of pain in patients with a history of substance abuse or with a co-morbid psychiatric disorder may require extra care, monitoring, documentation and consultation with or referral to an expert in the management of such patients.

[CONTINUED ON NEXT PAGE]

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Recognizes the need for a multidisciplinary approach to pain management.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY B:
Issues related to patients

COMMENT:
Acknowledges that a patient's prior history or current status of drug abuse does not necessarily contraindicate appropriate pain management.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Encourages healthcare professionals to incorporate in their practice the evaluations of, and discussions with patients about, the potential benefits and risks of treatment with opioids, which can better ensure a clinical indication of such treatment so that opioids will be used for medical purposes.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Recognizes that the goal of pain treatment should include improvements in patient functioning and quality of life.

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University of Wisconsin Carbone Cancer Center
Madison, Wisconsin

KANSAS

OTHER GOVERNMENTAL POLICY

Joint Board Policy Statement

[CONTINUED]

7. Medical Records
The medical record should document the nature and intensity of the pain and contain pertinent information concerning the patient's health history, including treatment for pain or other underlying or coexisting conditions. The medical record also should document the presence of one or more recognized medical indications for the use of a controlled substance.

8. Compliance With Controlled Substances Laws and Regulations
To prescribe, dispense or administer controlled substances within this state, the health care provider must be licensed according to the laws of this state and comply with applicable federal and state laws.

Section III: Definitions

For the purposes of these guidelines, the following terms are defined as follows:

Acute pain is the normal, predicted physiological response to an adverse chemical, thermal or mechanical stimulus and is associated with surgery, trauma and acute illness. It is generally time-limited and is responsive to opioid therapy, among other therapies

Addiction is a neuro-behavioral syndrome with genetic and environmental influences that results in psychological dependence on the use of substances for their psychic effects and is characterized by compulsive use despite harm. Addiction may also be referred to as "psychological dependence." Physical dependence and tolerance are normal physiological consequences of extended opioid therapy for pain and should not be considered addiction. Addiction must be distinguished from pseudoaddiciton, which is a pattern of drug-seeking behavior of pain patients who are receiving inadequate pain management that can be mistaken for addiction.

Analgesic tolerance is the need to increase the dose of opioid to achieve the same level of analgesia. Analgesic tolerance may or may not be evident during opioid treatment and does not equate with addiction.

Chronic pain is a pain state which is persistent beyond the usual course of an acute disease or a reasonable time for an injury to heal, or that is associated with a chronic pathologic process that causes continuous pain or pain that recurs at intervals for months or years.

Pain is an unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage.

Physical dependence on a controlled substance is a physiologic state of neuro-adaptation which is characterized by the emergence of a withdrawal syndrome if drug use is stopped or decreased abruptly, or if an antagonist is administered. Physical dependence is an expected result of opioid use. Physical dependence, by itself, does not equate with addiction.

Substance abuse is the use of any substance(s) for non-therapeutic purposes or use of medication for purposes other than those for which it is prescribed.

Tolerance is a physiologic state resulting from regular use of a drug in which an increased dosage is needed to produce the same effect, or a reduced effect is observed with a constant dose.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Encourages healthcare professionals to understand and follow federal and state laws governing their practice, which can better ensure that practitioners follow the *balanced* approach represented by federal law and the laws in many states.

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Madison, Wisconsin

KANSAS

STATUTES

Prevention of Assisted Suicide

K.S.A. § 60-4403

60-4403. Standard of conduct of licensed health care professional related to assisting suicide; family member conduct; spiritual treatment.

(a) A licensed health care professional who administers, prescribes or dispenses medications or procedures to relieve another person's pain or discomfort does not violate *K.S.A. 2011 Supp. 21-5407*, and amendments thereto unless the medications or procedures are knowingly administered, prescribed or dispensed with the intent to cause death. A mid-level practitioner as defined in *K.S.A. 65-1626*, and amendments thereto, who prescribes medications or procedures to relieve another person's pain or discomfort does not violate *K.S.A. 2011 Supp. 21-5407*, and amendments thereto unless the medications or procedures are knowingly prescribed with the intent to cause death.

(b) A licensed health care professional, family member or other legally authorized person who participates in the act of, or the decision making process which results in the withholding or withdrawal of a life-sustaining procedure does not violate *K.S.A. 2011 Supp. 21-5407*, and amendments thereto.

(c) Providing spiritual treatment through prayer alone, in lieu of medical treatment, does not violate *K.S.A. 2011 Supp. 21-5407*, and amendments thereto.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Clarifies for physicians the important distinction between physician-assisted suicide and prescribing controlled substances for pain relief; this language identifies a clinical misperception that is pervasive in end-of-life care and attempts to lessen its impact on patient treatment, and the practitioners who provide it.

Pain & Policy Studies Group
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Madison, Wisconsin

KANSAS

STATUTES

Pain Patient's Quality of Care

K.S.A. § 65-4976

65-4976. Legislative findings on pain treatment.

The legislature finds and declares that pain is a significant health problem, and that the diagnosis and treatment of pain is complex, and can involve several therapeutic modalities. The treatment of pain may require the use of controlled substances in appropriate circumstances. In order to promote the public health, safety and welfare, the state has a duty to restrict the inappropriate use of controlled substances while supporting a physician's or other health care provider's ability to provide appropriate pain treatment consistent with patient needs and sound clinical judgment.

(+) *CRITERION 3:*
Opioids are part of professional practice

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Represents the principle of Balance, which states that the regulation of controlled substances should not interfere with legitimate medical use.

K.S.A. § 65-4976

65-4977. Persons suffering from pain; use of controlled substances for pain treatment.

(a) A person suffering from pain:

(1) Should be an active participant in decisions about the assessment, diagnosis and treatment of their pain.

(2) May accept or reject the use of any or all diagnostic and therapeutic modalities which may be recommended to treat such person's pain.

(3) Should accurately, completely, and honestly report all symptoms and concerns to physicians and other health care professionals conducting assessment and treatment of such person's pain.

(b) Nothing in this act shall be construed to prevent, restrict or limit a physician or other person authorized to prescribe drugs from prescribing, dispensing, administering, or distributing a controlled substance to a patient for the treatment of pain, when it is for a valid medical purpose and based on appropriate clinical indications.

(c) Nothing in this act shall be construed to require a physician or other person authorized to prescribe drugs to prescribe, dispense, administer, or distribute a controlled substance to a patient for the treatment of pain if in the judgment of the prescriber the use of a controlled substance is not clinically indicated or the most appropriate therapeutic modality.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY B:
Issues related to patients

COMMENT: Recognizes the patient's right to request or reject different types of treatments.

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Madison, Wisconsin

KENTUCKY

STATUTES

- CONTROLLED SUBSTANCES ACT
  Title XVIII. Public Health; Chapter 218A. Controlled Substances

- MEDICAL PRACTICE ACT
  Title XXVI. Occupations and Professions; Chapter 311. Practice of Medicine and Osteopathy

- PHARMACY PRACTICE ACT *(No provisions found)*
  Title XXVI. Occupations and Professions; Chapter 315. Pharmacists and Pharmacies

- INTRACTABLE PAIN TREATMENT ACT
  No policy found

REGULATIONS

- CONTROLLED SUBSTANCES REGULATIONS *(No provisions found)*
  Title 902. Cabinet for Health and Family Services Department for Public Health; Chapter 55. Controlled Substances

- MEDICAL BOARD REGULATIONS
  Title 201. General Government Cabinet; Chapter 9. Board of Medical Licensure

- PHARMACY BOARD REGULATIONS (*No provisions found*)
  Title 201. General Government Cabinet; Chapter 2. Board of Pharmacy

OTHER GOVERNMENTAL POLICIES

- MEDICAL BOARD OPINION
  Kentucky Board of Medical Licensure. Opinion Regarding *the Use of Controlled Substances in Pain Treatment*. Adopted: October 10, 2008.

RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY KEY WORD SEARCHES

- SUICIDE ASSISTANCE
  Title XVII. Public Health; Chapter 216. Health Facilities and Services; Suicide Assistance

- PAIN MANAGEMENT FACILITIES
  Title 902. Cabinet for Health and Family Services Department for Public Health; Chapter 20. Health Services and Facilities

Pain & Policy Studies Group
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Madison, Wisconsin

KENTUCKY

STATUTES

Controlled Substances Act

KRS § 218A.010

218A.010. Definitions for chapter.

As used in this chapter:

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(33) "Practitioner" means a physician, dentist, podiatrist, veterinarian, scientific investigator, optometrist as authorized in *KRS 320.240*, or other person licensed, registered, or otherwise permitted to distribute, dispense, conduct research with respect to, or to administer a controlled substance in the course of professional practice or research in this state. "Practitioner" also includes a physician, dentist, podiatrist, or veterinarian who is a resident of and actively practicing in a state other than Kentucky and who is licensed and has prescriptive authority for controlled substances under the professional licensing laws of another state, unless the person's Kentucky license has been revoked, suspended, restricted, or probated, in which case the terms of the Kentucky license shall prevail.

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(+) *CRITERION 3:*
Opioids are part of professional practice

Pain & Policy Studies Group
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Madison, Wisconsin

KENTUCKY

STATUTES

Controlled Substances Act

KRS § 218A.172

218A.172. Administrative regulations on prescribing or dispensing of Schedule II controlled substance or Schedule III controlled substance containing hydrocodone -- Continuing course of treatment -- Recordkeeping -- Exemptions.

(1) Administrative regulations promulgated under *KRS 218A.205(3)* shall require that, prior to the initial prescribing or dispensing of any Schedule II controlled substance or a Schedule III controlled substance containing hydrocodone to a human patient, a practitioner shall:

(a) Obtain a medical history and conduct a physical or mental health examination of the patient, as appropriate to the patient's medical complaint, and document the information in the patient's medical record;

(b) Query the electronic monitoring system established in *KRS 218A.202* for all available data on the patient for the twelve (12) month period immediately preceding the patient encounter and appropriately utilize that data in the evaluation and treatment of the patient;

(c) Make a written plan stating the objectives of the treatment and further diagnostic examinations required;

(d) Discuss the risks and benefits of the use of controlled substances with the patient, the patient's parent if the patient is an unemancipated minor child, or the patient's legal guardian or health care surrogate, including the risk of tolerance and drug dependence; and

(e) Obtain written consent for the treatment.

(2) (a) Administrative regulations promulgated under *KRS 218A.205(3)* shall require that a practitioner prescribing or dispensing additional amounts of Schedule II controlled substances or Schedule III controlled substances containing hydrocodone for the same medical complaint and related symptoms shall:

1. Review, at reasonable intervals based on the patient's individual circumstances and course of treatment, the plan of care;

2. Provide to the patient any new information about the treatment; and

3. Modify or terminate the treatment as appropriate.

(b) If the course of treatment extends beyond three (3) months, the administrative regulations shall also require that the practitioner:

1. Query the electronic monitoring system established in *KRS 218A.202* no less than once every three (3) months for all available data on the patient for the twelve (12) month period immediately preceding the query; and

2. Review that data before issuing any new prescription or refills for the patient for any Schedule II controlled substance or a Schedule III controlled substance containing hydrocodone.

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(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: :
Encourages healthcare professionals to incorporate in their practice the evaluations of, and discussions with patients about, the potential benefits and risks of treatment with opioids, which can better ensure a clinical indication of such treatment so that opioids will be used for medical purposes.

Pain & Policy Studies Group
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Madison, Wisconsin

KENTUCKY

STATUTES

Controlled Substances Act

KRS § 218A.205

218A.205. Reports of improper, inappropriate, or illegal prescribing or dispensing of controlled substances -- Administrative regulations for prescribing and dispensing protocols and licensure actions and requirements -- Complaint procedure.

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(2) (a) When a reporting agency or a law enforcement agency receives a report of improper, inappropriate, or illegal prescribing or dispensing of a controlled substance it may, to the extent otherwise allowed by law, send a copy of the report within three (3) business days to every other reporting agency.

(b) A county attorney or Commonwealth's attorney shall notify the Office of the Attorney General and the appropriate state licensing board within three (3) business days of an indictment or a waiver of indictment becoming public in his or her jurisdiction charging a licensed person with a felony offense relating to the manufacture of, trafficking in, prescribing, dispensing, or possession of a controlled substance.

(3) Each state licensing board shall by September 1, 2012, establish the following by administrative regulation for those licensees authorized to prescribe or dispense controlled substances:

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(h) Continuing education requirements beginning with the first full educational year occurring after July 1, 2012, that specify that at least seven and one-half percent (7.5%) of the continuing education required of the licensed practitioner relate to the use of the electronic monitoring system established in KRS 218A.202, pain management, or addiction disorders.

(4) A state licensing board shall employ or obtain the services of a specialist in the treatment of pain and a specialist in drug addiction to evaluate information received regarding a licensee's prescribing or dispensing practices related to controlled substances if the board or its staff does not possess such expertise, to ascertain if the licensee under investigation is engaging in improper, inappropriate, or illegal practices.

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(-) *CRITERION 16:*
Provisions that are ambiguous

CATEGORY A:
Arbitrary standards for legitimate prescribing

COMMENT: Although it is reasonable to expect physicians to avoid contributing to diversion, "improper or inappropriate" implies there is a known standard, but the standard is not specified.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT*:* Requires an expertise in pain management on a state licensing board to evaluate prescribing or dispensing practices.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT*:* Establishes a mechanism (continuing education) for healthcare licensees to ensure that pain management is an essential part of patient care.

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Madison, Wisconsin

KENTUCKY

STATUTES

Medical Practice Act

KRS § 311.597

§ 311.597. Acts declared to constitute dishonorable, unethical, or unprofessional conduct

As used in KRS 311.595(9), "dishonorable, unethical, or unprofessional conduct of a character likely to deceive, defraud, or harm the public or any member thereof" shall include, but not be limited to, the following acts by a licensee:

(1) Prescribes or dispenses any medication:

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(d) In such amounts that the licensee knows or has reason to know, under the attendant circumstances, that said amounts so prescribed or dispensed are excessive under accepted and prevailing medical practice standards.

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(-) *CRITERION 16:*
Provisions that are ambiguous

CATEGORY A:
Arbitrary standards for legitimate prescribing

COMMENT: Although it is reasonable to expect physicians to avoid contributing to diversion, "excessive" implies there is a known standard, but the standard is not specified.

Pain & Policy Studies Group
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Madison, Wisconsin

KENTUCKY

REGULATIONS

Medical Board Regulations

201 KAR 9:250

201 KAR 9:250. Registration and oversight of pain management facilities.

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Section 5. Identification and Qualifications of Prescribers Employed by the Facility; Notification of Changes. (1) As part of its initial or annual registration, the facility shall identify each practitioner, who is employed by the facility in any capacity, who will be prescribing or dispensing controlled substances to patients of the facility.

(2) Each licensed physician who will prescribe or dispense controlled substances to patients of the facility as part of the employment arrangement with the facility shall successfully complete a minimum of ten (10) hours of Category I continuing medical education in pain management during each registration period throughout the employment agreement with the facility. This continuing medical education requirement shall satisfy the requirement of *201 KAR 9:310*.

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201 KAR 9:260

201 KAR 9:260. Professional standards for prescribing and dispensing controlled substances.

Section 1. Applicability. (1) A physician who is authorized to prescribe or dispense a controlled substance shall comply with the standards of acceptable and prevailing medical practice for prescribing and dispensing a controlled substance established in this administrative regulation.

(2) The professional standards established in this administrative regulation shall not apply to a physician prescribing or dispensing a controlled substance:

(a) To a patient as part of the patient's hospice or end-of-life treatment;

(b) To a patient admitted to a licensed hospital as an inpatient, outpatient, or observation patient, during and as part of a normal and expected part of the patient's course of care at that hospital;

(c) To a patient for the treatment of pain associated with cancer or with the treatment of cancer;

(d) To a patient who is a registered resident of a long-term-care facility as defined in *KRS 216.510*;

(e) During the effective period of any period of disaster or mass casualties which has a direct impact upon the physician's practice;

(f) In a single dose prescribed or dispensed to relieve the anxiety, pain, or discomfort experienced by that patient submitting to a diagnostic test or procedure; or

(g) That has been classified as a Schedule V controlled substance.

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(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Establishes a mechanism (continuing medical education) for pain management facilities to provide practitioners information/education about pain management.

(+) CRITERION 3:
Opioids are part of professional practice

Pain & Policy Studies Group
University of Wisconsin Carbone Cancer Center
Madison, Wisconsin

KENTUCKY

REGULATIONS

Medical Board Regulations

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT:
Acknowledges need for treatment flexibility for physicians to respond to individual clinical circumstances, as long as their prescribing maintains the standards of good medical practice.

(CONTINUED)

Section 2. Professional Standards for Documentation of Patient Assessment, Education, Treatment Agreement and Informed Consent, Action Plans, Outcomes and Monitoring. (1) Each physician prescribing or dispensing a controlled substance shall obtain and document all relevant information in a patient's medical record in a legible manner and in sufficient detail to enable the board to determine whether the physician is conforming to professional standards for prescribing or dispensing controlled substances and other relevant professional standards.

(2) If a physician is unable to conform to professional standards for prescribing or dispensing controlled substances due to circumstances beyond the physician's control, or the physician makes a professional determination that it is not appropriate to comply with a specific standard, based upon the individual facts applicable to a specific patient's diagnosis and treatment, the physician shall document those circumstances in the patient's record and only prescribe or dispense a controlled substance to the patient if the patient record appropriately justifies the prescribing or dispensing of a controlled substance under the circumstances.

Section 3. Professional Standards for the Prescribing or Dispensing of Controlled Substances for the Treatment of Pain and Related Symptoms Associated with a Primary Medical Complaint. Prior to the initial prescribing or dispensing of any controlled substance for pain or other symptoms associated with the same primary medical complaint, the first physician prescribing or dispensing a controlled substance shall:

(1) Obtain an appropriate medical history relevant to the medical complaint, including a history of present illness, and:

(a) If the complaint does not relate to a psychiatric condition, conduct a physical examination of the patient relevant to the medical complaint and related symptoms and document the information in the patient's medical record; or

(b) If the complaint relates to a psychiatric condition, perform, or have performed by a psychiatrist or other designated mental health provider, an evaluation appropriate to the presenting complaint and document the relevant findings;

(2) Obtain and review a KASPER report for that patient for the twelve (12) month period immediately preceding the patient encounter, and appropriately utilize that information in the evaluation and treatment of the patient;

(3) After examining the benefits and risks of prescribing or dispensing a controlled substance to the patient, including nontreatment or other treatment, make a deliberate decision that it is medically appropriate to prescribe or dispense the controlled substance in the amount specified;

(4) Not prescribe or dispense a long-acting or controlled-release opioid (e.g. OxyContin, fentanyl patches, or methadone) for acute pain that is not directly related to and close in time to a specific surgical procedure;

(5) Explain to the patient that a controlled substance used to treat an acute medical complaint is for time-limited use, and that the patient should discontinue the use of the controlled substance when the condition requiring the controlled substance use has resolved; and

(6) Explain to the patient how to safely use and properly dispose of any unused controlled substance.

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Madison, Wisconsin

KENTUCKY

REGULATIONS

Medical Board Regulations

(CONTINUED)

Section 4. Professional Standards for Commencing Long Term Use of Prescribing or Dispensing of Controlled Substances for the Treatment of Pain and Related Symptoms Associated with a Primary Medical Complaint. (1) Before a physician commences to prescribe or dispense any controlled substance to a patient sixteen (16) years or older for pain or other symptoms associated with the same primary medical complaint for a total period of longer than three (3) months, the physician shall comply with the mandatory professional standards established in subsection (2) of this section. These standards may be accomplished by different licensed practitioners in a single group practice at the direction of or on behalf of the prescribing physician if:

(a) Each practitioner involved has lawful access to the patient's medical record;

(b) There is compliance with all applicable standards; and

(c) Each practitioner performing an action to meet the required standards is acting within the practitioner's legal scope of practice.

(2)(a) The physician shall obtain the following information from the patient and record all relevant information in the patient's medical record:

1. History of present illness;

2. Past medical history;

3. History of substance use and any prior treatment for that use by the patient, and history of substance abuse by first degree relatives of the patient;

4. Past family history of relevant illnesses and treatment; and

5. Psychosocial history.

(b) The physician shall conduct an appropriate physical examination of the patient sufficient to support the medical indications for prescribing or dispensing a controlled substance on a long-term basis.

(c) The physician shall perform appropriate baseline assessments to establish beginning values to assist in establishing and periodically evaluating the functional goals of any treatment plan.

(d) If a specific or specialized evaluation is necessary for the formulation of a working diagnosis or treatment plan, the physician shall only continue the use of a controlled substance after determining that continued use of the controlled substance is safe and medically appropriate in the absence of that information.

(e) If the physician determines that the patient has previously received medical treatment for the presenting medical complaint or related symptoms and that review of the prior treatment records is necessary to justify long-term prescribing of a controlled substance, the physician shall obtain those prior medical records and incorporate the information therein into the evaluation and treatment of the patient.

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(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Recognizes that the goal of pain treatment should include improvements in patient functioning and quality of life.

Pain & Policy Studies Group
University of Wisconsin Carbone Cancer Center
Madison, Wisconsin

KENTUCKY

REGULATIONS

Medical Board Regulations

(CONTINUED)

(f)1. Based upon consideration of all information available, the physician shall promptly formulate and document a working diagnosis of the source of the patient's medical complaint and related symptoms without simply describing or listing the related symptoms.

2. If the physician is unable, despite best efforts, to formulate a working diagnosis, the physician shall consider the usefulness of additional information, such as a specialized evaluation or assessment, referral to an appropriate specialist, and the usefulness of further observation and evaluation, before attempting again to formulate a working diagnosis.

3. If the physician is unable to formulate a working diagnosis, despite the use of an appropriate specialized evaluation or assessment, the physician shall only prescribe long term use of a controlled substance after establishing that its use at a specific level is medically indicated and appropriate.

(g)1. To the extent that functional improvement is medically expected based upon the patient's condition, the physician shall formulate an appropriate treatment plan.

2. The treatment plan shall include specific and verifiable goals of treatment, with a schedule for periodic evaluations.

(h)1. The physician shall utilize appropriate screening tools to screen each patient to determine if the patient:

a. Is presently suffering from another medical condition which may impact the prescribing or dispensing of a controlled substance; or

b. Presents a significant risk for illegal diversion of a controlled substance.

2. If, after screening, the physician determines that there is a reasonable likelihood that the patient suffers from substance abuse or dependence, or a psychiatric or psychological condition, the physician shall take the necessary actions to facilitate a referral to an appropriate treatment program or provider. The physician shall appropriately incorporate the information from the treatment program or provider into the evaluation and treatment of the patient.

3. If, after screening, the physician determines that there is a risk that the patient may illegally divert a controlled substance, but determines to continue long term prescribing of the controlled substance, the physician shall use a prescribing agreement that meets professional standards. The prescribing agreement and informed consent document may be combined into one (1) document.

4. The physician shall obtain and document a baseline drug screen.

5. If, after screening, the physician determines that the controlled substance prescribed to the patient will be used or is likely to be used other than medicinally or other than for an accepted therapeutic purpose, the physician shall not prescribe any controlled substance to that patient.

(i) After explaining the risks and benefits of long-term use of a controlled substance, the physician shall obtain the written informed consent of the patient in a manner that meets professional standards.

(j) The physician shall initially attempt, to the extent possible, or establish and document a previous attempt by another physician, of a trial of noncontrolled modalities and lower doses of a controlled substance in increasing order to treat the pain and related symptoms associated with the primary medical complaint, before continuing with long term prescribing of a controlled substance at a given level.

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(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: :
Encourages healthcare professionals to incorporate in their practice the evaluations of, and discussions with patients about, the potential benefits and risks of treatment with opioids, which can better ensure a clinical indication of such treatment so that opioids will be used for medical purposes.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY B:
Issues related to patients

COMMENT:
Acknowledges that a patient's prior history or current status of drug abuse does not necessarily contraindicate appropriate pain management.

2013

Pain & Policy Studies Group
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KENTUCKY

REGULATIONS

Medical Board Regulations

(CONTINUED)

Section 5. Professional Standards for Continuing Long Term Prescribing or Dispensing of Controlled Substances for the Treatment of Pain and Related Symptoms Associated with a Primary Medical Complaint. (1) If a physician continues to prescribe or dispense a controlled substance beyond three (3) months to a patient sixteen (16) years or older for pain and related symptoms associated with the primary medical complaint, the physician shall comply with the professional standards established in subsection (2) of this section. These standards may be accomplished by different licensed practitioners in a single group practice at the direction of or on behalf of the prescribing physician as established in Section 4(1) of this administrative regulation.

(2)(a)1. The physician shall ensure that the patient is seen at least once a month initially for evaluation and review of progress. The physician may determine that the patient is to be evaluated less frequently, on a schedule determined by the physician's professional judgment after the physician has determined:

a. The controlled substance prescribed or dispensed has been titrated to the level appropriate and necessary to treat the medical complaint and related symptoms;

b. The controlled substance prescribed or dispensed is not causing unacceptable side effects; and

c. There is sufficient monitoring in place to minimize the likelihood that the patient will use the controlled substance in an improper or inappropriate manner or divert it for an improper or inappropriate use.

(b) At appropriate intervals, the physician shall:

1. Ensure that a current history is obtained from the patient;

2. Ensure that a focused physical examination is considered, and performed, if appropriate; and

3. Perform appropriate measurable examinations as indicated in the treatment plan.

(c) At appropriate intervals, the physician shall evaluate the working diagnosis and treatment plan based upon the information gained to determine whether there has been functional improvement or any change in baseline measures. The physician shall modify the diagnosis, treatment plan, or controlled substance therapy, as appropriate.

(d) If the physician determines that the patient presents a significant risk of diversion or improper use of a controlled substance, the physician shall discontinue the use of the controlled substance or justify its continued use in the patient record.

(e) If the medical complaint and related symptoms continue with no significant improvement in function despite treatment with a controlled substance, and if improvement is medically expected, the physician shall obtain appropriate consultative assistance to determine whether there are undiagnosed conditions to be addressed in order to resolve the medical complaint.

(f) For a patient exhibiting symptoms suggestive of a mood, anxiety, or psychotic disorder, the physician shall obtain a psychiatric or psychological consultation for intervention if appropriate.

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KENTUCKY

REGULATIONS

Medical Board Regulations

(CONTINUED)

(g) If a patient reports experiencing episodes of breakthrough pain, the physician shall:

1. Attempt to identify the trigger or triggers for each episode;

2. Determine whether the breakthrough pain may be adequately treated through noncontrolled treatment; and

3. If the physician determines that the nonmedication treatments do not adequately address the triggers, and after considering the risks and benefits, determines to add an as-needed controlled substance to the regimen, take appropriate steps to minimize the improper or illegal use of the additional controlled substance.

(h) At least once a year, the physician shall perform or shall ensure that the patient's primary treating physician performs a preventive health screening and physical examination appropriate to the patient's gender, age, and medical condition.

(i)1. At least once every three (3) months, the physician shall obtain and review a current KASPER report, for the twelve (12) month period immediately preceding the request, and appropriately use that information in the evaluation and treatment of the patient.

2. If the physician obtains or receives specific information that the patient is not taking the controlled substance as directed, is diverting a controlled substance, or is engaged in any improper or illegal use of a controlled substance, the physician shall immediately obtain and review a KASPER report and appropriately use the information in the evaluation and treatment of the patient.

3. If a KASPER report discloses that the patient is obtaining a controlled substance from another practitioner without the physician's knowledge and approval, in a manner that raises suspicion of illegal diversion, the physician shall promptly notify the other practitioner of the relevant information from the KASPER review.

4. The physician shall obtain consultative assistance from a specialist if appropriate.

(j) If appropriate, the physician shall conduct random pill counts and appropriately use that information in the evaluation and treatment of the patient.

(k)1. During the course of long-term prescribing or dispensing of a controlled substance, the physician shall utilize drug screens, appropriate to the controlled substance and the patient's condition, in a random and unannounced manner at appropriate times. If the drug screen or other information available to the physician indicates that the patient is noncompliant, the physician shall:

a. Do a controlled taper;

b. Stop prescribing or dispensing the controlled substance immediately; or

c. Refer the patient to an addiction specialist, mental health professional, pain management specialist, or drug treatment program, depending upon the circumstances.

2. The physician shall discontinue controlled substance treatment or refer the patient to addiction management if:

a. There has been no improvement in function and response to the medical complaint and related symptoms, if improvement is medically expected;

b. Controlled substance therapy has produced significant adverse effects; or

c. The patient exhibits inappropriate drug-seeking behavior or diversion.

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KENTUCKY

REGULATIONS

Medical Board Regulations

201 KAR 9:310

201 KAR 9:310. Continuing medical education.

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Section 6. (1) For each three (3) year continuing education cycle beginning on January 1, 2015, a licensee who is authorized to prescribe or dispense controlled substances within the Commonwealth at any time during that cycle shall complete at least four and one-half (4.5) hours of approved continuing education hours relating to the use of KASPER, pain management, addiction disorders, or a combination of two (2) or more of those subjects. A licensee may satisfy this requirement by completing a single approved program of four and one-half (4.5) hours or longer or by completing multiple approved programs for a total of four and one-half (4.5) hours or longer for that cycle.

(2) Each physician licensed to practice medicine or osteopathy within the Commonwealth of Kentucky who is authorized to prescribe or dispense controlled substances within the Commonwealth from July 20, 2012 through the end of the three (3) year continuing education cycle beginning on January 1, 2012 and ending on December 31, 2014 shall complete at least four and one-half (4.5) hours of approved Category I Credit continuing medical education hours relating to the use of KASPER, pain management, addiction disorders, or a combination of two (2) or more of those subjects on or before December 31, 2014. The licensee may satisfy this requirement by completing a single approved program of four and one-half (4.5) hours or longer or by completing multiple approved programs for a total of four and one-half (4.5) hours or longer for this cycle.

(3) Each physician licensed to practice medicine or osteopathy within the Commonwealth of Kentucky who is authorized to prescribe or dispense controlled substances during the calendar years 2013 and 2014, but not during any portion of 2012, shall complete at least three (3) hours of approved Category I Credit continuing medical education hours relating to the use of KASPER, pain management, addiction disorders, or a combination of two (2) or more of those subjects on or before December 31, 2014. The licensee may satisfy this requirement by completing a single approved program of three (3) hours or longer or by completing multiple approved programs for a total of three (3) hours or longer for those two (2) years.

(4) Each physician licensed to practice medicine or osteopathy within the Commonwealth of Kentucky who is authorized to prescribe or dispense controlled substances during calendar year 2014, but not during any portion of 2012 or 2013, shall complete at least one and one-half (1.5) hours of approved Category I Credit continuing medical education hours relating to the use of KASPER, pain management, addiction disorders, or a combination of two (2) or more of those subjects on or before December 31, 2014. The licensee may satisfy this requirement by completing a single approved program of one and one-half (1.5) hours or longer or by completing multiple approved programs for a total of one and one-half (1.5) hours or longer for that calendar year.

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(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Establishes a mechanism (continuing medical education) to provide practitioners information/education about pain management.

Pain & Policy Studies Group
University of Wisconsin Carbone Cancer Center
Madison, Wisconsin

KENTUCKY

OTHER GOVERNMENTAL POLICY

Medical Board Opinion

Opinion Regarding the Use of Controlled Substances in Pain Treatment Legal Authority

This is a Board opinion issued pursuant to the Board's statute, KRS 311.602, to assist licensees in determining what actions would constitute unacceptable conduct under the provisions of KRS 311.595. The Board has decided to publish this opinion because it addresses issues of significant public and medical interest. This opinion is not a statute or administrative regulation, and does not have the force of law.

The Board has determined that the following principles constitute the standards of acceptable and prevailing medical practice relating to a physician's use of controlled substances in the treatment of chronic, non-malignant pain. If the Board should receive a grievance that a physician has departed from the acceptable and prevailing standards of medical practice, the Board and its Hearing Officer will consider the grievance in light of these standards, the actual patient records and expert testimony specific to the physician's practice.

Introduction

The Kentucky Board of Medical Licensure (KBML) recognizes that principles of quality medical practice dictate that the people of Kentucky have access to appropriate and effective pain relief. The appropriate application of state-of-the-art treatment modalities can serve not only to improve the quality of life for those patients who suffer from pain, but also can reduce the morbidity and costs associated with inappropriately treated pain. The Board encourages physicians to view effective pain management as a part of quality medical practice for all patients with pain, acute or chronic. Pain management is particularly important for patients who experience pain as a result of terminal illness and can be difficult for patients with chronic non-terminal pain. It is imperative that physicians become knowledgeable about effective methods of pain treatment, as well as statutory requirements for prescribing controlled substances.

Inadequate pain control may result either from physicians' lack of knowledge about pain management or their misunderstanding of addiction. Fears of investigation or sanction by federal, state and local regulatory agencies may also result in inappropriate or inadequate treatment of the pain patient. Accordingly, **this Opinion has been developed to clarify the Board's position on pain control, especially as related to the use of controlled substances for non-terminal/non-malignant chronic pain, in order to alleviate physician uncertainty and to encourage better pain management.**

The Board recognizes that controlled substances (including opioid analgesics, benzodiazapines and stimulants) may be essential in the treatment of acute pain and chronic pain, whether due to cancer or non-cancer origins. The medical management of pain should be based on current knowledge and research and includes the use of both pharmacological and non-pharmacological modalities. Pain should be assessed and treated promptly, and the quantity and frequency of doses should be adjusted according to the intensity and duration of the pain. Physicians should recognize that *tolerance* and *physical dependence* are normal consequences of sustained use of opioid analgesics and are not synonymous with *addiction*. *Addiction* refers to both dependence on the use of substances for the drugs' psychic effects and compulsive use of the drug despite consequences.

The KBML is obligated under the laws of the state of Kentucky to protect the public health and safety. The Board recognizes that the inappropriate prescribing of controlled substances may lead to drug diversion and abuse by individuals who seek the drugs for other than legitimate medical use. Physicians must be diligent in preventing the diversion of drugs for illegitimate purposes. The Board believes the adoption of this Opinion will protect legitimate medical uses of controlled substances, while helping to prevent drug diversion and eliminating inappropriate prescribing practices.

(CONTINUED ON NEXT PAGE)

(+) CRITERION 2:
Pain management is part of healthcare practice

(+) CRITERION 7:
Physical dependence or analgesic tolerance are not confused with "addiction"

(+) CRITERION 8:
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Identifies the potential impact of important barriers on the provision of effective pain care.

(+) CRITERION 8:
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Represents the principle of Balance, which states that the regulation of controlled substances should not interfere with legitimate medical use.

2013

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University of Wisconsin Carbone Cancer Center
Madison, Wisconsin

KENTUCKY

OTHER GOVERNMENTAL POLICY

Medical Board Opinion

(+) CRITERION 5:
Addresses fear of regulatory scrutiny

(+) CRITERION 3:
Opioids are part of professional practice

(+) CRITERION 6:
Prescription amount alone does not determine legitimacy

(CONTINUED)

Physicians should not fear disciplinary action from the Board for prescribing controlled substances for a legitimate medical purpose and in the usual course of professional practice. The Board will consider the prescribing of controlled substances for pain a legitimate medical purpose, if such prescribing is (1) based on accepted scientific knowledge of pain treatment and (2) if based on sound clinical grounds. All such prescribing must be grounded in clear documentation of unrelieved pain and in compliance with applicable state or federal law.

Each case of prescribing for pain will be evaluated on an individual basis if and when brought to the Board's attention. The Board does not take disciplinary action against a physician who fails to adhere strictly to the provisions of this Opinion, if good cause is shown for such deviation. The physician's conduct will be evaluated to a great extent by the treatment outcome, taking into account: (1) whether or not the drug used is medically and/or pharmacologically recognized to be appropriate for the diagnosis; (2) the patient's individual needs – including improvement in functioning; and (3) a recognition that some types of pain cannot be completely relieved.

The Board will judge the validity of prescribing based on the physician's treatment of the patient and on available documentation, rather than only the quantity and chronicity of prescribing. The goal is to control the patient's pain for its duration while effectively addressing other aspects of the patient's functioning, including physical, psychological, social and work-related factors. The following Opinion is not intended to define complete or best practice, but rather to communicate what the Board considers to be within acceptable boundaries of professional practice when prescribing for recurrent or persistent chronic pain. An Opinion regarding the prescribing for acute pain would be appropriately less stringent but, in principle, the same.

Board Opinion
The Kentucky Board of Medical Licensure has adopted the following Opinion for evaluating the use of controlled substances for control of **recurrent or chronic pain.**

1. Evaluation of the Patient
A complete medical history and physical examination must be conducted and documented in the medical record. A Family History should be documented with particular reference to any history of first degree relative with chemical dependence problems. The medical record should document the nature and intensity of the pain, current and past treatments for pain, underlying or coexisting diseases or conditions, the effect of the pain on physical and psychological function, and history of any substance abuse. The medical record also should document the presence of one or more recognized medical indication(s) for the use of a controlled substance.

By definition, pain is a *subjective* statement of a patient's perception of actual or potential tissue damage. The distinction between pain and suffering should be established. A patient may suffer due to pain, but may have other reasons for suffering as well. The assessment of a patient's overall condition should be made at the initial evaluation and thereafter. It is the goal of the physician to assist in the relief of suffering no matter the cause. Financial, emotional, mental, physical, and spiritual factors may contribute to the patient's suffering. Relief of the underlying reasons for suffering as well as the pain will lead to optimal treatment and utilization of controlled substances.

Before beginning a regiment of controlled drugs, the physician must determine, through actual clinical trial or through patient records and history that non-addictive medication regimens have been inadequate or are unacceptable for solid clinical reasons. Speaking with the patient's significant other or conducting a family conference can be helpful if there is any doubt regarding the patient's integrity. Utilizing the Kentucky All Schedule Prescription Electronic Reporting [i.e., KASPER Report] initially can also aid in documenting the patient's history of drug utilization.

(CONTINUED ON NEXT PAGE)

(+) CRITERION 8:
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT*:*
Acknowledges the need for treatment flexibility for physicians to respond to individual clinical circumstances, as long as their prescribing maintains the standards of good medical practice.

(+) CRITERION 8:
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Recognizes that the goal of pain treatment should include improvements in patient functioning and quality of life.

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Madison, Wisconsin

KENTUCKY

OTHER GOVERNMENTAL POLICY

Medical Board Opinion

(CONTINUED)

2. Treatment Plan
The written treatment plan should state objectives that will be used to determine treatment success, such as pain relief and improved physical and psychosocial function, and should indicate if any further diagnostic evaluations, consultations or other treatments are planned. After treatment begins, the physician should adjust drug therapy to the individual medical needs of each patient. Other treatment modalities or a rehabilitation program may be necessary depending on the etiology of the pain and the extent to which the pain is associated with physical and psychosocial impairment.

3. Informed Consents and Treatment Agreements
The physician should discuss the risks and benefits of the use of controlled substances with the patient or his/her surrogate, including the risk of tolerance and drug dependence. If the patient is determined to be at *high risk* for medication abuse or have a history of substance abuse, the physician may employ the use of a written *agreement* between physician and patient outlining patient responsibilities, including:

- One prescribing doctor and one designated pharmacy.
- Urine/serum drug screening when request.
- No early refills and no medications called in. If medications are lost or stolen, then a police report could be required before considering additional prescriptions.
- The reasons for which drug therapy may be discontinued such as violation of a documented doctor-patient *agreement*.

4. Periodic Review
At reasonable intervals based on the individual circumstances of the patient, the physician should review the course of treatment and any new information about the etiology of the pain. Continuation or modification of therapy should depend on the physician's evaluation of progress toward stated treatment objectives such as reduction in patient's pain intensity and improved physical and/or psychosocial function (i.e., ability to work), need of health care resources, activities of daily living, and quality of social life. If treatment goals are not being achieved despite medication adjustments, the physician should reevaluate the appropriateness of continued treatment. The physician should monitor patient compliance in medication usage and related treatment plans. Periodic requests for a **KASPER Report** could be utilized.

5. Consultation
The physician should be willing to refer the patient as clinically indicated for additional evaluation and in order to achieve treatment objectives. Special attention should be given to those pain patients who are at risk for misusing their medications and those whose living arrangement pose a risk for medication misuse or diversion. The management of pain in patients with a history of substance abuse or with a coexisting psychiatric disorder may require extra care, monitoring, documentation, and consultation with or referral to an expert in the management of such patients.

(CONTINUED ON NEXT PAGE)

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Encourages healthcare professionals to incorporate in their practice the evaluations of, and discussions with patients about, the potential benefits and risks of treatment with opioids, which can better ensure a clinical indication of such treatment so that opioids will be used for medical purposes.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY B:
Issues related to patients

COMMENT:
Acknowledges that a patient's prior history or current status of drug abuse does not necessarily contraindicate appropriate pain management.

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KENTUCKY

OTHER GOVERNMENTAL POLICY

Medical Board Opinion

(CONTINUED)

6. Medical Records
The physician should keep accurate and complete records to include:

- The medical history and physical examination;
- Diagnostic, therapeutic, and laboratory results;
- Evaluations and consultations;
- Treatment objectives;
- Discussion of risk, benefits, and limitations of treatments;
- Treatments;
- Medications (including date, type, dosage, and quantity prescribed);
- Instructions and agreements;
- Periodic reviews; and
- Records should remain current and be maintained in an accessible manner and readily available for review.

Initial or periodic **KASPER Report(s)** should *not* be part of the patient's records and should not be released to the patient or a third party.

7. Compliance With Controlled Substances Laws and Regulations
To prescribe, dispense, or administer controlled substances, the physician must have an active license in the state and comply with applicable federal and state regulations.

Physicians should studiously **avoid** prescribing scheduled drugs for themselves, immediate family, or staff in accordance with the American Medical Association's Code of Medical Ethics and the KRS Medical Practice Act.

Conclusion: **By publishing this Opinion, the KBML wishes to encourage physicians to utilize adequate medications to treat their patients with serious pain complaints without undue fear of legal or licensure repercussions. Concurrently the Board strives to prevent, as much as possible, drug diversion and inappropriate prescribing practices.**

(+) CRITERION 8:
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Encourages healthcare professionals to understand and follow federal and state laws governing their practice, which can better ensure that practitioners follow the *balanced* approach represented by federal law and the laws in many states.

(+) CRITERION 4:
Encourages Pain Management

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KENTUCKY

STATUTES

Suicide Assistance

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Clarifies for physicians the important distinction between physician-assisted suicide and prescribing controlled substances for pain relief; this language identifies a clinical misperception that is pervasive in end-of-life care and attempts to lessen its impact on patient treatment, and the practitioners who provide it.

KRS § 216.304

§ 216.304. Actions of licensed health care professional that are not violative of KRS 216.302

(1) A licensed health care professional who administers, prescribes, or dispenses medications or procedures to relieve another person's pain or discomfort, even if the medication or procedure may hasten or increase the risk of death, shall not be deemed to have violated KRS 216.302 unless the medications or procedures are knowingly and intentionally administered, prescribed, or dispensed to cause death.

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KENTUCKY

REGULATIONS

Pain Management Facilities

902 KAR 20:420

902 KAR 20:420. Pain management facilities

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Section 7. Administration

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(10) In-service training.

(a) All personnel shall participate in orientation and annual in-service training programs relating to their respective job activities.

(b) All licensed prescribers in a pain management facility shall comply with the professional standards established by their respective licensing boards for the completion of continuing professional education. Each licensed physician who prescribes or dispenses a controlled substance to a patient in the facility as part of his or her employment agreement with the facility shall successfully complete a minimum of ten (10) hours of Category I continuing medical education in pain management during each registration period throughout his or her employment agreement with the facility.

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(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT*:* Establishes a mechanism (continuing medical education) to provide practitioners information/education about pain management.

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Madison, Wisconsin

LOUISIANA

STATUTES

- CONTROLLED SUBSTANCES ACT
  Louisiana Revised Statutes; Title 40. Public Health and Safety; Chapter 4. Food and Drugs; Part 10. Uniform Controlled Substances Law

- MEDICAL PRACTICE ACT *(No provisions found)*
  Louisiana Revised Statutes; Title 37. Professions and Occupations; Chapter 15. Physicians, Surgeons, and Midwives

- PHARMACY PRACTICE ACT
  Louisiana Revised Statutes; Title 37. Professions and Occupations; Chapter 14. Louisiana Pharmacy Practice Act

- INTRACTABLE PAIN TREATMENT ACT
  No policy found

REGULATIONS

- CONTROLLED SUBSTANCES REGULATIONS (*Part of Pharmacy Board Regulations*)
  Title 46. Professional and Occupational Standards; Part LIII. Pharmacists; Chapter 27. Controlled Dangerous Substances

- MEDICAL BOARD REGULATIONS
  Title 46. Professional and Occupational Standards; Part XLV. Medical Professions

- PHARMACY BOARD REGULATIONS (*No provisions found*)
  Title 46. Professional and Occupational Standards; Part LIII. Pharmacists

OTHER GOVERNMENTAL POLICIES

No policies found

RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY KEY WORD SEARCHES

- SUICIDE
  Louisiana Revised Statutes; Title 14. Criminal Law; Chapter 1. Criminal Code; Part 2. Offenses Against the Person; Subpart A-2. Suicide

- PAIN MANAGEMENT CLINICS
  Louisiana Revised Statutes; Title 40. Public Health and Safety; Chapter 11. State Department of Hospitals; Part 12-A. Pain Management Clinics

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LOUISIANA

STATUTES

Controlled Substances Act

La. R.S. 40:961

§ 40:961. Definitions

As used in this Part, the following terms shall have the meaning ascribed to them in this Section unless the context clearly indicates otherwise:

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(18) "Drug dependent person" means a person who is using a controlled dangerous substance and who is in a state of psychic or physical dependence, or both, arising from administration of that controlled dangerous substance on a continuous basis. Drug dependence is characterized by behavioral and other responses which include a strong compulsion to take the substance on a continuous basis in order to experience its psychic effects, or to avoid the discomfort of its absence.

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(31) "Practitioner" means a physician, dentist, veterinarian, scientific investigator, pharmacy, hospital, or other person licensed, registered, or otherwise permitted to distribute, dispense, conduct research with respect to, or administer a controlled dangerous substance in the course of professional practice or research in this state.

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(38) "Substance abuse" or "addiction" means a compulsive disorder in which an individual becomes preoccupied with obtaining and using a substance, despite adverse social, psychological, or physical consequences, the continued use of which results in a decreased quality of life. The development of controlled dangerous substance tolerance or physical dependence does not equate with substance abuse or addiction.

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La. R.S. 40:1002

§ 40:1002. Purpose

The purpose of this Part is to authorize the development, implementation, operation, and evaluation of an electronic system for the monitoring of controlled substances and other drugs of concern that are dispensed in the state or dispensed to an address within the state. The goal of the program is to improve the state's ability to identify and inhibit the diversion of controlled substances and drugs in an efficient and cost-effective manner and in a manner that shall not impede the appropriate utilization of these drugs for legitimate medical purposes.

(-) *CRITERION 11:*
Physical dependence or analgesic tolerance confused with "addiction"

(+) *CRITERION 3:*
Opioids are part of professional practice

(+) *CRITERION 7:*
Physical dependence or analgesic tolerance are not confused with "addiction"

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Represents the principle of Balance, which states that the regulation of controlled substances should not interfere with legitimate medical use.

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LOUISIANA

STATUTES

Pharmacy Practice Act

La. R.S. 37:1164

§ 37:1164. Definitions

As used in this Chapter, the following terms have the meaning ascribed to them by this Section:

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(43) "Practitioner" means an individual currently licensed, registered, or otherwise authorized by the appropriate licensing board to prescribe and administer drugs in the course of professional practice.

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(+) *CRITERION 3:*
Opioids are part of professional practice

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LOUISIANA

REGULATIONS

Controlled Substances Regulations

LAC 46:LIII.2701

§ 2701. Definitions

A. Words not defined in this Chapter shall have their common usage and meaning as stated in the Merriam-Webster's Collegiate Dictionary--Tenth Edition, as revised, and other similarly accepted reference texts. As used in this Chapter, the following terms shall have the meaning ascribed to them in this Section unless the context clearly indicates otherwise.

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Practitioner--an individual currently licensed, registered, or otherwise authorized by the appropriate licensing board to prescribe and administer drugs in the course of professional practice.

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(+) *CRITERION 3:*
Opioids are part of professional practice

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REGULATIONS

Medical Board Regulations

LAC 46:XLV 6915-6923 (non-seq)

§ 6915. Scope of Subchapter

The rules of this subchapter govern physician responsibility for providing effective and safe pain control for patients with noncancer-related chronic or intractable pain.

§ 6917. Definitions

As used in this subchapter, unless the content clearly states otherwise, the following terms and phrases shall have the meanings specified:

Board--the Louisiana State Board of Medical Examiners.

Chronic Pain--pain which persists beyond the usual course of a disease, beyond the expected time for healing from bodily trauma, or pain associated with a long-term incurable or intractable medical illness or disease.

Controlled Substance--any substance defined, enumerated, or included in federal or state statute or regulations 21 C.F.R. §§ 1308.11-15 or R.S. 40:964, or any substance which may hereafter be designated as a controlled substance by amendment or supplementation of such regulations and statute.

Diversion--the conveyance of a controlled substance to a person other than the person to whom the drug was prescribed or dispensed by a physician.

Intractable Pain--a chronic pain state in which the cause of the pain cannot be eliminated or successfully treated without the use of controlled substance therapy and, which in the generally accepted course of medical practice, no cure of the cause of pain is possible or no cure has been achieved after reasonable efforts have been attempted and documented in the patient's medical record.

Noncancer-Related Pain--that pain which is not directly related to symptomatic cancer.

Physical Dependence–the physiological state of neuroadaptation to controlled substance which is characterized by the emergence of a withdrawal syndrome if the controlled substance use is stopped or decreased abruptly, or if an antagonist is administered. Withdrawal may be relieved by readministration of the controlled substance.

Physician--physicians and surgeons licensed by the Board.

Protracted Basis--utilization of any controlled substance for the treatment of noncancer-related chronic or intractable pain for a period in excess of 12 weeks during any 12-month period.

Substance Abuse (may also be referred to by the term Addiction)– a compulsive disorder in which an individual becomes preoccupied with obtaining and using a substance, despite adverse social, psychological, and/or physical consequences, the continued use of which results in a decreased quality of life. The development of controlled substance tolerance or physical dependence does not equate with substance abuse or addiction.

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(+) CRITERION 7: Physical dependence or analgesic tolerance are not confused with "addiction"

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REGULATIONS

Medical Board Regulations

(CONTINUED)

Tolerance–refers to the physiologic state resulting from regular use of a drug in which an increased dosage is needed to produce the same effect or a reduced effect is observed with a constant dose. Controlled substance tolerance refers to the need to increase the dose of the drug to achieve the same level of analgesia. Controlled substance tolerance may or may not be evident during controlled substance treatment.

§ 6919. General Conditions/Prohibitions

The treatment of noncancer-related chronic or intractable pain with controlled substances constitutes legitimate medical therapy when provided in the course of professional medical practice and when fully documented in the patient's medical record. A physician duly authorized to practice medicine in Louisiana and to prescribe controlled substances in this state shall not, however, prescribe, dispense, administer, supply, sell, give, or otherwise use for the purpose of treating such pain, any controlled substance unless done in strict compliance with applicable state and federal laws and the rules enumerated in this subchapter.

§ 6921. Use of Controlled Substances, Limitations

A. Requisite Prior Conditions. In utilizing any controlled substance for the treatment of noncancer-related chronic or intractable pain on a protracted basis, a physician shall comply with the following rules:

1. Evaluation of the Patient. Evaluation of the patient shall initially include relevant medical, pain, alcohol and substance abuse histories, an assessment of the impact of pain on the patient's physical and psychological functions, a review of previous diagnostic studies, previously utilized therapies, an assessment of coexisting illnesses, diseases, or conditions, and an appropriate physical examination.

2. Medical Diagnosis. A medical diagnosis shall be established and fully documented in the patient's medical record, which indicates not only the presence of noncancer-related chronic or intractable pain, but also the nature of the underlying disease and pain mechanism if such are determinable.

3. Treatment Plan. An individualized treatment plan shall be formulated and documented in the patient's medical record which includes medical justification for controlled substance therapy. Such plan shall include documentation that other medically reasonable alternative treatments for relief of the patient's noncancer-related chronic or intractable pain have been considered or attempted without adequate or reasonable success. Such plan shall specify the intended role of controlled substance therapy within the overall plan, which therapy shall be tailored to the individual medical needs of each patient.

4. Informed Consent. A physician shall ensure that the patient and/or his guardian is informed of the benefits and risks of controlled substance therapy. Discussions of risks and benefits should be noted in some format in the patient's record.

B. Controlled Substance Therapy. Upon completion and satisfaction of the conditions prescribed in §6921.A, and upon a physician's judgment that the prescription, dispensation, or administration of a controlled substance is medically warranted, a physician shall adhere to the following rules.

(CONTINUED ON NEXT PAGE)

(+) *CRITERION 2:*
Pain management is part of healthcare practice

(+) *CRITERION 3:*
Opioids are part of professional practice

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Recognizes that the goal of pain treatment should include improvements in patient functioning and quality of life.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Encourages healthcare professionals to incorporate in their practice the evaluations of, and discussions with patients about, the potential benefits and risks of treatment with opioids, which can better ensure a clinical indication of such treatment so that opioids will be used for medical purposes.

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LOUISIANA

REGULATIONS

Medical Board Regulations

(CONTINUED)

1. Assessment of Treatment Efficacy and Monitoring. Patients shall be seen by the physician at appropriate intervals, not to exceed 12 weeks, to assess the efficacy of treatment, assure that controlled substance therapy remains indicated, and evaluate the patient's progress toward treatment objectives and any adverse drug effects. Exceptions to this interval shall be adequately documented in the patient's record. During each visit, attention shall be given to the possibility of decreased function or quality of life as a result of controlled substance treatment. Indications of substance abuse or diversion should also be evaluated. At each visit, the physician should seek evidence of under treatment of pain.

2. Drug Screen. If a physician reasonably believes that the patient is suffering from substance abuse or that he is diverting controlled substances, the physician shall obtain a drug screen on the patient. It is within the physician's discretion to decide the nature of the screen and which type of drug(s) to be screened.

3. Responsibility for Treatment. A single physician shall take primary responsibility for the controlled substance therapy employed by him in the treatment of a patient's noncancer-related chronic or intractable pain.

4. Consultation. The physician should be willing to refer the patient as necessary for additional evaluation and treatment in order to achieve treatment objectives. Special attention should be given to those pain patients who are at risk for misusing their medications and those whose living arrangements pose a risk for medication misuse or diversion. The management of pain in patients with a history of substance abuse or with a comorbid psychiatric disorder may require extra care, monitoring, documentation, and consultation with or referral to an expert in the management of such patients.

5. Medications Employed. A physician shall document in the patient's medical record the medical necessity for the use of more than one type or schedule of controlled substance employed in the management of a patient's noncancer-related chronic or intractable pain.

6. Treatment Records. A physician shall document and maintain in the patient's medical record, accurate and complete records of history, physical and other examinations and evaluations, consultations, laboratory and diagnostic reports, treatment plans and objectives, controlled substance and other medication therapy, informed consents, periodic assessments, and reviews and the results of all other attempts at analgesia which he has employed alternative to controlled substance therapy.

7. Documentation of Controlled Substance Therapy. At a minimum, a physician shall document in the patient's medical record the date, quantity, dosage, route, frequency of administration, the number of controlled substance refills authorized, as well as the frequency of visits to obtain refills.

C. Termination of Controlled Substance Therapy. Evidence or behavioral indications of substance abuse or diversion of controlled substances shall be followed by tapering and discontinuation of controlled substance therapy. Such therapy shall be reinitiated only after referral to and written concurrence of the medical necessity of continued controlled substance therapy by an addiction medicine specialist, a pain management specialist, a psychiatrist, or other substance abuse specialist based upon his physical examination of the patient and a review of the referring physician's medical record of the patient.

§ 6923. Effect of Violation

Any violation of or failure of compliance with the provisions of this subchapter, §§6915-6923, shall be deemed a violation of R.S. 37:1285(A)(6) and (14), providing cause for the board to suspend or revoke, refuse to issue, or impose probationary or other restrictions on any license held or applied for by a physician to practice medicine in the state of Louisiana culpable of such violation.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY B:
Issues related to patients

COMMENT:
Acknowledges that a patient's prior history or current status of drug abuse does not necessarily contraindicate appropriate pain management.

2013

Pain & Policy Studies Group
University of Wisconsin Carbone Cancer Center
Madison, Wisconsin

LOUISIANA

STATUTES

Suicide

La. R.S. 14:32.12

§ 14:32.12. Criminal assistance to suicide

A. Criminal assistance to suicide is:

(1) The intentional advising or encouraging of another person to commit suicide or the providing of the physical means or the knowledge of such means to another person for the purpose of enabling the other person to commit or attempt to commit suicide.

(2) The intentional advising, encouraging, or assisting of another person to commit suicide, or the participation in any physical act which causes, aids, abets, or assists another person in committing or attempting to commit suicide.

B. For the purposes of this Section, "suicide" means the intentional and deliberate act of taking one's own life through the performance of an act intended to result in death.

C. The provisions of this Section shall not apply to any licensed physician or other authorized licensed health care professional who either:

(1) Withholds or withdraws medical treatment in accordance with the provisions of *R.S. 40:1299.58.8*.

(2) Prescribes, dispenses, or administers any medication, treatment, or procedure if the intent is to relieve the patient's pain or suffering and not to cause death.

D. Whoever commits the crime of criminal assistance to suicide shall be imprisoned, with or without hard labor, for not more than ten years or fined not more than ten thousand dollars, or both.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT*:* Clarifies for physicians the important distinction between physician-assisted suicide and prescribing controlled substances for pain relief; this language identifies a clinical misperception that is pervasive in end-of-life care and attempts to lessen its impact on patient treatment, and the practitioners who provide it.

STATUTES

Pain Management Clinics

La. R.S. 40:2198.12

§ 40:2198.12. Licensure of pain management clinics; rules and regulations

A. Except as provided in Subsection D of this Section, all pain management clinics shall be owned and operated by a physician certified in the subspecialty of pain management by a member board of the American Boards of Medical Specialties.

B. (1) The department shall prescribe and publish minimum standards, rules, and regulations as necessary to effectuate the provisions of this Section. Such rules and regulations shall include but not be limited to all of the following:

(a) Operational and personnel requirements.

(b) Practice standards to assure quality of care, including the requirement that prescriptions may be written for the medication to last a period of no longer than thirty days without any refills. A refill may be authorized only if the individual is personally examined by the pain specialist.

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(-) *CRITERION 12:*
Medical decisions are restricted

CATEGORY D:
Undue prescription limitations

COMMENT: Seems to create a treatment disparity for any patient treated in a licensed pain management clinic, since the 30-day limit on the quantity of medication is not a requirement for all patients.

(-) *CRITERION 16:*
Provisions that are ambiguous

CATEGORY B:
Unclear intent leading to possible misinterpretation

COMMENT: Seems to apply to all prescription medications, including Schedule II controlled substances which cannot be refilled under either federal or state law.

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Madison, Wisconsin

MAINE

STATUTES

- CONTROLLED SUBSTANCES ACT (*No provisions found*)
  Title 25. Internal Security and Public Safety; Part 8. Public Safety Miscellaneous Provisions; Chapter 353. Maine Drug Enforcement Act of 1992

- MEDICAL PRACTICE ACT (*No provisions found*)
  Title 32. Professions and Occupations; Chapter 48. Board of Licensure in Medicine

- OSTEOPATHIC PRACTICE ACT (*No provisions found*)
  Title 32. Professions and Occupations; Chapter 36. Osteopathic Physicians

- PHARMACY PRACTICE ACT
  Title 32. Professions and Occupations; Chapter 117. Maine Pharmacy Act

- INTRACTABLE PAIN TREATMENT ACT
  No policy found

REGULATIONS

- CONTROLLED SUBSTANCES REGULATIONS (*No provisions found*)
  Agency 16. Department of Public Safety; Sub-Agency 230. Maine Drug Enforcement Agency; Chapter 001. Requirements for Written Prescriptions of Schedule II Drugs

- MEDICAL BOARD REGULATIONS
  Agency 02. Department of Professional and Financial Regulation; Sub-Agency 373. Board of Licensure in Medicine

- OSTEOPATHIC BOARD REGULATIONS (*No provisions found*)
  Agency 02. Department of Professional and Financial Regulation; Sub-Agency 383. Board of Osteopathic Licensure

- PHARMACY BOARD REGULATIONS (*No provisions found*)
  Agency 02. Department of Professional and Financial Regulation; Sub-Agency 392. Board of Pharmacy

OTHER GOVERNMENTAL POLICIES

No policies found

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RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY KEY WORD SEARCHES

- PRESCRIPTION PRIVACY
  Title 22. Health and Welfare; Subtitle 2. Health; Part 4. Hospitals and Medical Care; Chapter 401. General Provisions

- CONTROLLED SUBSTANCES PRESCRIPTION MONITORING
  Title 22. Health and Welfare; Subtitle 4. Human Services; Part 3. Drug Abuse; Chapter 1603. Controlled Substances Prescription Monitoring

- HOSPICE LICENSING
  Title 22. Health and Welfare; Subtitle 6. Facilities for Children and Adults; Chapter 1681. Licensing of Hospice Programs

- HOSPICE LICENSING
  Agency 10. Department of Health and Human Services; Sub-Agency 144. General; Chapter 120. Regulations Governing the Licensing and Functioning of Hospice Programs

MAINE

STATUTES

Pharmacy Practice Act

32 M.R.S. § 13702

§ 13702. Definitions

As used in this chapter, unless the context otherwise indicates, the following terms have the following meanings.

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29. PRACTITIONER. "Practitioner" means an individual who is licensed, registered or otherwise authorized in the appropriate jurisdiction to prescribe and administer drugs in the course of professional practice.

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(+) *CRITERION 3:*
Opioids are part of professional practice

Pain & Policy Studies Group
University of Wisconsin Carbone Cancer Center
Madison, Wisconsin

MAINE

REGULATIONS

Joint Board Regulations

Chapter 21: USE OF CONTROLLED SUBSTANCES FOR TREATMENT OF PAIN

Rule Index

Section I: Definitions
Section II: Joint Statement on the Treatment of Pain
Section III: Principles of Proper Pain Management
Section IV:Controlled Substances Contract

Section I: Definitions. As used by the Boards when evaluating practice and prescribing issues, the following terms are defined as follows:

1. **Acute pain** – Acute pain is the normal, predicted physiological response to a noxious chemical, thermal or mechanical stimulus and typically is associated with invasive procedures, trauma and disease. It is generally time-limited.

2. **Addiction** – Addiction is a primary, chronic, neurobiologic disease, with genetic, psychosocial and environmental factors influencing its development and manifestations. It is characterized by behaviors that include the following: impaired control over drug use, craving, compulsive use and continued use despite harm. Physical dependence and tolerance are normal physiological consequences of extended opioid therapy for pain and are not the same as addiction.

3. **Chronic Pain** – Chronic pain is a state in which pain persists beyond the usual course of an acute disease or healing of an injury that may or may not be associated with an acute or chronic pathologic process that causes continuous or intermittent pain over months or years.

4. **Clinician** – An allopathic (MD) or osteopathic (DO) physician, physician assistant (PA), nurse practitioner (NP) or certified nurse midwife (CNM), dentist (DMD or DDS), or podiatrist (DPM).

5. **Pain** – An unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage.

6. **Physical Dependence** – Physical dependence is a state of adaptation manifested by drug class-specific signs and symptoms that can be produced by abrupt cessation, rapid dose reduction, decreasing blood level of the drug, and/or administration of an antagonist. Physical dependence, by itself, does not equate with addiction.

7. **Pseudoaddiction** – the iatrogenic syndrome (medically caused) resulting from the misinterpretation of relief seeking behaviors as though they are drug-seeking behaviors that are commonly seen with addiction. The relief seeking behaviors resolve upon institution of effective analgesic therapy.

8. **Substance Abuse** – Substance abuse is the use of any substance(s) for non-therapeutic purposes of medication for purposes other than those for which it is prescribed.

9. **Tolerance** – Tolerance is a physiologic state resulting from regular use of a drug in which an increased dosage is needed to produce a specific effect or a reduced effect is observed with a constant dose over time. Tolerance may or may not be evident during opioid treatment and does not equate with addiction.

(CONTINUED ON NEXT PAGE)

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REGULATIONS

Joint Board Regulations

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Recognizes that inadequate treatment of pain is subject to disciplinary action just as other substandard practices might be.

(+) *CRITERION 4:*
Encourages pain management

(CONTINUED)

Section II: Joint Statement on the Treatment of Pain.

The Boards recognize that principles of quality medical, dental and advanced nursing practice dictate that the people of the State of Maine have access to appropriate and effective pain relief. The appropriate application of up-to-date knowledge and treatment modalities can serve to improve the quality of life for those patients who suffer from pain as well as to reduce the morbidity and costs associated with untreated or inappropriately treated pain. For the purposes of this rule, the inappropriate treatment of pain includes nontreatment, undertreatment, overtreatment and the continued use of ineffective treatments.

The diagnosis and treatment of pain is integral to the practice of medicine, dentistry and advanced nursing. The Boards encourage clinicians to view pain management as a part of quality medical practice for all patients with pain, acute or chronic, and it is especially urgent for patients who experience pain as a result of terminal illness. All clinicians should become knowledgeable about assessing patients' pain and effective methods of pain treatment, as well as statutory requirements for prescribing controlled substances. Accordingly, this rule has been developed to clarify the Boards' position on pain control, particularly as related to the use of controlled substances, to alleviate clinician uncertainty and to encourage better pain management.

Inappropriate pain treatment may result from clinicians' lack of knowledge about pain management. Fears of investigation or sanction by federal, state and local agencies may also result in inappropriate treatment of pain. Appropriate pain management is the treating clinician's responsibility. As such, the Boards will consider the inappropriate treatment of pain to be a departure from standards of practice and will investigate such allegations, recognizing that some types of pain cannot be completely relieved, and taking into account whether the treatment is appropriate for the diagnosis.

The Boards recognize controlled substances, including opioid analgesics, may be essential in the treatment of acute pain due to trauma or surgery and chronic pain, whether due to cancer or non-cancer origins. The Boards will refer to current clinical practice guidelines and expert review in approaching cases involving management of pain. The management of pain should consider current clinical knowledge and scientific research and the use of pharmacologic and non-pharmacologic modalities according to the judgment of the clinician. Pain should be assessed and treated promptly and the quantity and frequency of doses should be adjusted according to the intensity, duration of the pain and treatment outcomes. Clinicians should recognize that tolerance and physical dependence are normal consequences of sustained use of opioid analgesics and are not the same as addiction.

The Boards are obligated under the laws of the State of Maine to protect the public health and safety. The Boards recognize that the use of opioid analgesics for other than legitimate medical purposes poses a threat to the individual and society and that the inappropriate prescribing of controlled substances, including opioid analgesics, may lead to drug diversion and abuse by individuals who seek them for other than legitimate medical use. Accordingly, the Boards expect that clinicians will incorporate safeguards into their practices to minimize the potential for the abuse and diversion of controlled substances.

(CONTINUED ON NEXT PAGE)

(+) *CRITERION 2:*
Pain management is part of healthcare practice

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Identifies the potential impact of important barriers on the provision of effective pain care.

(+) *CRITERION 7:*
Physical dependence or analgesic tolerance are not confused with "addiction"

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Pain & Policy Studies Group
University of Wisconsin Carbone Cancer Center
Madison, Wisconsin

MAINE

REGULATIONS

Joint Board Regulations

(CONTINUED)

Clinicians should not fear disciplinary action from the Boards for ordering, prescribing, dispensing or administering controlled substances, including opioid analgesics, for a legitimate medical purpose and in the course of professional practice. The Boards will consider prescribing, ordering, dispensing or administering controlled substances for pain to be for a legitimate medical purpose if based on sound clinical judgment. All such prescribing must be based on clear documentation of unrelieved pain. To be within the usual course of professional practice, a clinician-patient relationship must exist and the prescribing should be based on a diagnosis and documentation of unrelieved pain. Compliance with applicable state and/or federal law is required.

The Boards will judge the validity of the clinician's treatment of the patient based on available documentation, rather than solely on the quantity and duration of medication administration. The goal is to control the patient's pain while effectively addressing other aspects of the patient's functioning, including physical, psychological, social and work-related factors.

Allegations of inappropriate pain management will be evaluated on an individual basis. The Boards will not take disciplinary action against a clinician for deviating from this rule when contemporaneous medical records document reasonable cause for deviation. The clinician's conduct will be evaluated to a great extent by the outcome of pain treatment, recognizing that some types of pain cannot be completely relieved, and by taking into account whether the drug used is appropriate for the diagnosis, as well as improvement in patient functioning and/or quality of life.

Section III: Principles of Proper Pain Management

The Boards have adopted the following criteria when evaluating the clinician's treatment of pain including the use of controlled substances. Each of these principles is essential in the treatment of patients with pain.

1. **Evaluation of the Patient** — A medical history and appropriate physical examination must be obtained, evaluated and documented in the medical record. The medical record should document the nature and intensity of the pain, current and past treatments for pain, underlying or coexisting diseases or conditions, the effect of the pain on physical and psychological function and history of substance abuse. It is recommended that the State's Controlled Substance Prescription Monitoring Program Database (PMP) be utilized. The medical record also should document the presence of one or more recognized medical indications for the use of a controlled substance.

2. **Treatment Plan** — The written treatment plan should state objectives that will be used to determine treatment success, such as pain relief and improved physical and psychosocial function, and should indicate if any further diagnostic evaluations or other treatments are planned. After treatment begins, the clinician should adjust drug therapy to the individual medical needs of each patient. Other treatment modalities or a rehabilitation program may be necessary depending on the etiology of the pain and the extent to which the pain is associated with physical and psychosocial impairment.

(CONTINUED ON NEXT PAGE)

(+) *CRITERION 5:*
Addresses fear of regulatory scrutiny

(+) *CRITERION 6:*
Prescription amount alone does not determine legitimacy

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT:
Acknowledges the need for treatment flexibility for physicians to respond to individual clinical circumstances, as long as their prescribing maintains the standards of good medical practice.

(+) *CRITERION 3:*
Opioids are part of professional practice

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Recognizes that the goal of pain treatment should include improvements in patient functioning and quality of life.

Pain & Policy Studies Group
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Madison, Wisconsin

MAINE

REGULATIONS

Joint Board Regulations

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Encourages healthcare professionals to incorporate in their practice the evaluations of, and discussions with patients about, the potential benefits and risks of treatment with opioids, which can better ensure a clinical indication of such treatment so that opioids will be used for medical purposes.

(CONTINUED)

3. **Informed Consent and Agreement for Treatment** — The clinician should discuss the risks and benefits of the use of controlled substances with the patient, persons designated by the patient or with the patient's surrogate or guardian if the patient is without medical decision-making capacity. The patient should receive prescriptions from one clinician and one pharmacy whenever possible. If the patient is at high risk for medication abuse or has a history of substance abuse or substance dependence, the clinician should use a written agreement between clinician and patient outlining patient responsibilities, including:

a. urine/serum medication levels screening when requested;
b. pill count when requested;
c. number and frequency of all prescription refills; and
d. reasons for which drug therapy may be discontinued (e.g., violation of agreement).

4. **Periodic Review of Treatment Efficacy** — The clinician should periodically review the course of pain treatment and any new information about the etiology of the pain or the patient's state of health. Continuation or modification of controlled substances for pain management therapy depends on the clinician's evaluation of progress toward treatment objectives. Satisfactory response to treatment may be indicated by the patient's decreased pain, increased level of function or improved quality of life. Objective evidence of improved or diminished function should be monitored and information from family members or other caregivers should be considered in determining the patient's response to treatment. If the patient's progress is unsatisfactory, the clinician should assess the appropriateness of continued use of the current treatment plan and consider the use of other therapeutic modalities. Likewise, the clinician should periodically review the course of treatment where psychoactive drugs are used for the treatment of components of chronic pain, e.g., emotional, psychological, or psychosocial stressors, and assess the appropriateness of continued use of the current treatment plan if the patient's progress is unsatisfactory.

5. **Consultation or Referral** — The clinician should consult or refer, as necessary, for additional evaluation and treatment in order to achieve treatment objectives. Special attention should be given to those patients with pain who are at risk for medication misuse, abuse or diversion. Chronic pain often has, as a component, emotional, psychological, or psychosocial stress. In these situations, a number of patients may benefit from psychoactive medications, as well as controlled substances for pain control. The combination of opiates with psychoactive medications, e.g., benzodiazepines, may place the patient at greater risk. The risk may be associated with drug interaction, potentiation, or abuse. In these situations, consultation with or referral to an expert in the management of such patients may be required.

6. **Medical Records** — The clinician should keep accurate and complete records to include:

a. the medical history and appropriate physical examination;
b. diagnostic, therapeutic and laboratory results;
c. evaluations and consultations;
d. treatment objectives;
e. discussion of risks and benefits;
f. informed consent;
g. treatments;
h. medications (including date, type, dosage and quantity prescribed);
i. instructions and agreements; and
j. periodic reviews.

Records should remain current and be maintained in an accessible manner, readily available for review.

(CONTINUED ON NEXT PAGE)

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY B:
Issues related to patients

COMMENT:
Acknowledges that a patient's prior history or current status of drug abuse does not necessarily contraindicate appropriate pain management.

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MAINE

REGULATIONS

Joint Board Regulations

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT*:* Encourages healthcare professionals to understand and follow federal and state laws governing their practice, which can better ensure that practitioners follow the *balanced* approach represented by federal law and the laws in many states.

(CONTINUED)

7. **Reportable Acts** — Generally, information gained as part of the clinician/patient relationship remains confidential. However, the clinician has an obligation to deal with persons who use the clinician to perpetrate illegal acts, such as illegal acquisition or selling of drugs; this may include reporting to law enforcement. Information suggesting inappropriate or drug-seeking behavior, should be addressed appropriately and documented. Use of the PMP is recommended.

8. **Compliance With Controlled Substances Laws and Regulations** — To prescribe, dispense or administer controlled substances, the clinician must be licensed or otherwise authorized and comply with applicable federal and state regulations. Clinicians are referred to the *Physicians Manual of the U.S. Drug Enforcement Administration* and any relevant documents issued by the appropriate board or agency for specific rules governing controlled substances as well as applicable state regulations.

Section IV: Controlled Substances Contract.

Suggested elements of a controlled substance contract are as follows:

1. Specifies that the clinician is the single source of controlled substances;

2. May specify the pharmacy;

3. Provides written, informed consent to release contract to local emergency departments and pharmacies;

4. If written consent is given for release to local emergency departments and/or pharmacies, consent is also being given to the other clinicians and providers such as pharmacists to report violations of the contract back to the prescribing clinician;

5. Specifies that if the clinician becomes concerned that there has been illegal activity, the clinician may notify the proper authorities;

6. Provides that if the clinician has obtained a written release, ER personnel and other providers shall report violations of the contract back to the doctor who prescribed the controlled substance(s);

7. Specifies that a violation of the contract will result in a tapering and discontinuation of the narcotics prescription;

8. Specifies that a risk of chronic narcotics treatment is physical dependence (as defined);

9. Specifies that a risk of chronic narcotics treatment is addiction (as defined);

10. Specifies that it is the responsibility of the patient to be discreet about possessing narcotics and keeping medications in an inaccessible place so that they may not be stolen;

(11. If the patient violates the terms of the contract, the violation should be documented. The clinician response to the violation should be documented, as well as the rationale of and changes in the treatment plan;

12 Clinician may consider "fill only at _____ pharmacy" on the prescription form;

13. Specifies use of urine/serum medications levels screening when

appropriate; and

14. Specifies use of a pill count when appropriate.

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MAINE

STATUTES

Prescription Privacy

22 M.R.S. § 1711-E

§ 1711-E. Confidentiality of prescription drug information

1. DEFINITIONS. As used in this section, unless the context otherwise indicates, the following terms have the following meanings.

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G-1. "Prescriber" means a person who is licensed, registered or otherwise authorized in the appropriate jurisdiction to prescribe and administer drugs in the course of professional practice.

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(+) CRITERION 3:
Opioids are part of professional practice

STATUTES

Controlled Substances Prescription Monitoring

22 M.R.S. § 7245

§ 7245. Legislative intent

It is the intent of the Legislature that the prescription monitoring program established pursuant to this chapter serve as a means to promote the public health and welfare and to detect and prevent substance abuse. This chapter is not intended to interfere with the legitimate medical use of controlled substances.

(+) CRITERION 8:
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Represents the principle of Balance, which states that the regulation of controlled substances should not interfere with legitimate medical use.

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MAINE

STATUTES

Hospice Licensing

22 M.R.S. § 8623

§ 8623. Rules

The department shall adopt rules in accordance with Title 5, chapter 375 that specify the requirements for licensure under this chapter. The rules must require, but are not limited to, the following provisions.

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7. TRAINING. A hospice program shall provide an educational program that offers a comprehensive overview of hospice philosophy and hospice care. A minimum of 18 hours of education, including 4 hours of orientation, is required for all direct service providers delivering hospice care. The educational program must include, but is not limited to, the following subjects:

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C. Pain and symptom management;

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(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT*:* Establishes a mechanism (training) for hospices to ensure that pain management is an essential part of patient care.

REGULATIONS

Hospice Licensing

CMR 10-144-120

10 144 120 Regulations Governing the Licensing and Functioning of Hospice Programs

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5.G. Training

A hospice program shall provide an educational program that offers a comprehensive overview of hospice philosophy and hospice care. A minimum of eighteen (18) hours of education, including four (4) hours of orientation, is required for all direct service providers delivering hospice care. The educational program must include, but is not limited to, the following subjects:

5.G.1. Hospice philosophy,

5.G.2. Family dynamics;

5.G.3. Pain and symptom management;

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(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT*:* Establishes a mechanism (educational program) for hospices to ensure that pain management is an essential part of patient care.

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MARYLAND

STATUTES

- CONTROLLED SUBSTANCES ACT
  Criminal Law; Title 5. Controlled Dangerous Substances, Prescriptions, and Other Substances

- MEDICAL PRACTICE ACT (*No provisions found*)
  Health Occupations; Title 14. Physicians

- PHARMACY PRACTICE ACT (*No provisions found*)
  Health Occupations; Title 12. Pharmacists and Pharmacies

- INTRACTABLE PAIN TREATMENT ACT
  No policy found

REGULATIONS

- CONTROLLED SUBSTANCES REGULATIONS
  Title 10. Department of Health and Mental Hygiene;
  Subtitle 13. Drugs; Chapter 01. Dispensing of Prescription Drugs by a Licensee
  Subtitle 19. Dangerous Devices and Substances; Chapter 03. Controlled Dangerous Substances

- MEDICAL BOARD REGULATIONS (*No provisions found*)
  Title 10. Department of Health and Mental Hygiene; Subtitle 32. Board of Physicians

- PHARMACY BOARD REGULATIONS
  Title 10. Department of Health and Mental Hygiene; Subtitle 34. Board of Pharmacy

OTHER GOVERNMENTAL POLICIES

- MEDICAL BOARD GUIDELINE
  Maryland Board of Physicians. *Prescribing Controlled Substances*. Maryland BPQA Newsletter. Vol. 4, No. 1, pp. 1-3. Adopted: March, 1996.

RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY KEY WORD SEARCHES

- ASSISTED SUICIDE
  Criminal Law; Title 3. Other Crimes Against the Person; Subtitle 1. Assisted Suicide

- RIGHTS OF INDIVIDUALS
  Health-General; Title 19. Health Care Facilities; Subtitle 3. Hospitals and Related Institutions; Part VI. Rights of Individuals

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- PRESCRIPTION DRUG MONITORING PROGRAM
  Health-General; Title 21. Food, Drugs, and Cosmetics;
  Subtitle 2A. Prescription Drug Monitoring Program

- ASSISTED LIVING PROGRAMS
  Title 10. Department of Health and Mental Hygiene; Subtitle 07. Hospitals;
  Chapter 14. Assisted Living Programs

- HOSPICE CARE PROGRAMS
  Title 10. Department of Health and Mental Hygiene; Subtitle 07. Hospitals;
  Chapter 21. Hospice Care Programs

MARYLAND

STATUTES

Controlled Substances Act

Md. CRIMINAL LAW Code Ann. § 5-101

§ 5-101. Definitions

(a) In general. -- In this title the following words have the meanings indicated.

. . .

(d) Authorized provider. --

(1) "Authorized provider" means:

(i) a person licensed, registered, or otherwise allowed to administer, distribute, dispense, or conduct research on a controlled dangerous substance in the State in the course of professional practice or research;

. . .

(o) Drug dependent person. -- "Drug dependent person" means a person who:

(1) is using a controlled dangerous substance; and

(2) is in a state of psychological or physical dependence, or both, that:

(i) arises from administration of that controlled dangerous substance on a continuous basis; and

(ii) is characterized by behavioral and other responses that include a strong compulsion to take the substance on a continuous basis in order to experience its psychological effects or to avoid the discomfort of its absence.

. . .

Md. CRIMINAL LAW Code Ann. § 5-102

§ 5-102. Legislative findings and purpose of title

(a) Findings. -- The General Assembly finds that:

(1) many of the substances listed in this title have a useful and legitimate medical purpose and are necessary to maintain the health and general welfare of the people of the State; but

(2) the illegal manufacture, distribution, possession, and administration of controlled dangerous substances have a substantial and detrimental effect on the health and general welfare of the people of the State.

(b) Purpose. --

(1) The purpose of this title is to establish a uniform law to control the manufacture, distribution, possession, and administration of controlled dangerous substances and related paraphernalia to:

(i) ensure their availability for legitimate medical and scientific purposes; but

(ii) prevent their abuse, which results in a serious health problem to the individual and represents a serious danger to the welfare of the people of the State.

(2) This title shall be liberally construed to accomplish this purpose.

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(+) *CRITERION 3:*
Opioids are part of professional practice

(-) *CRITERION 11:*
Physical dependence or analgesic tolerance confused with "addiction"

(+) *CRITERION 1:*
Controlled substances are necessary for public health

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Represents the principle of Balance, which states that the regulation of controlled substances should not interfere with legitimate medical use.

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University of Wisconsin Carbone Cancer Center
Madison, Wisconsin

MARYLAND

REGULATIONS

Controlled Substances Regulations

COMAR 10.19.03.02

.02 Definitions.

A. As used in this chapter, unless otherwise provided, those definitions appearing in *Criminal Law Article, § 5-101*, Annotated Code of Maryland, shall apply.

B. In this chapter, the following terms have the meanings indicated.

C. Terms Defined.

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(7) Individual Practitioner.

(a) "Individual practitioner" means a physician, dentist, veterinarian, or other individual licensed, registered, or otherwise permitted by the United States or the jurisdiction in which the individual practitioner practices, to dispense a controlled dangerous substance in the course of professional practice.

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(+) *CRITERION 3:*
Opioids are part of professional practice

REGULATIONS

Pharmacy Board Regulations

COMAR 10.34.33.02

.02 Definitions.

A. In this chapter, the following terms have the meanings indicated.

B. Terms Defined.

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(4) "Health care practitioner" means an individual who is licensed, certified, or otherwise authorized under the Health Occupations Article, Annotated Code of Maryland, to provide health care services in the ordinary course of business or practice of a profession and has prescribing authority in this State.

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(+) *CRITERION 3:*
Opioids are part of professional practice

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Madison, Wisconsin

MARYLAND

OTHER GOVERNMENTAL POLICY

Medical Board Guideline

PRESCRIBING CONTROLLED SUBSTANCES

In a recent AMA survey of physicians, the majority of physicians responding reported that their prescribing of controlled drugs was negatively influenced by a fear of licensing board sanctions. The issue of prescribing adequate pain medication for the terminally ill, generally patients with cancer, has received extensive attention. But what about patients with chronic noncancer pain? Little has been done to alleviate physician anxiety that regularly prescribing controlled drugs to such patients will result in the physician being accused of diverting drugs illegally or supporting addictive patients in their habits. How can a physician both meet their patients' needs and avoid coming to the attention of the licensing authorities?

BPQA, by statute, has a minimum of eleven Board members who are actively practicing physicians. We see these patients in our offices, too, and we recognize that there are many painful conditions which cannot be cured and that diagnoses may be totally based on subjective symptoms. As physicians, our role is to relieve suffering; we may have no hard evidence that "proves" the patient is in pain, yet we believe our patients and we try to help them. All the members of BPQA wish to reassure Maryland physicians that they need not under-prescribe needed medications for fear of Board action. Under-prescribing results in unnecessary suffering.

But what about all those Board actions you've read about in which the doctors are sanctioned for "inappropriate" controlled dangerous substance prescribing practices? Were these physicians just trying to alleviate suffering with the end result that the Board sanctioned them? Hardly. Most of the physicians charged under this provision of the Medical Practice Act were clearly acting in other than the best interest of their patients. Usually, obvious addicts were buying prescriptions from the physicians and the transactions were disguised as office visits. Occasionally, truly naive physicians, once they have been targeted as "easy writes," attract every addict in town. All of us in practice occasionally have been duped by a patient in this way. But some physicians simply don't recognize addiction. Usually, in addition to inappropriate prescribing, we find that the physician's practice is substandard in multiple other areas. It is rare that an otherwise well-trained and competent physician is identified as a naive prescriber.

Because the Board is concerned that fear of disciplinary action may lead to inappropriately restrictive prescribing of controlled drugs, the following guidelines are offered by Dr. Charles Hobelmann Jr., who has served on the Board since 1991. Although the primary focus of his remarks is analgesic prescribing, these guidelines can be applied to every prescribing and treatment situation. It's just good medical practice spelled out, and it's how the Board evaluates the delivery of all medical care, not just controlled drug prescribing. His comments follow.

In order to help the physicians whose patients may require long-term analgesic medications, a common sense approach coupled with experience and medical knowledge is essential. It is important to realize that habituation and tolerance to drugs are not the same as addiction. These are expected consequences of long-term analgesic therapy and do not have the characteristics of sociopathy and psychologic dependence associated with addiction. Whereas it is inappropriate to prescribe analgesics to maintain addiction, it is good medical care to provide relief from chronic pain even in the face of habituation and tolerance. Some general guidelines may be helpful both in the management of these patients and in protecting one's self from legal or Board action in prescribing for them. The following comments have been adapted from published material of the Medical Board of California and provide a useful guide in this area.

(CONTINUED ON NEXT PAGE)

(+) *CRITERION 5:*
Addresses fear of regulatory scrutiny

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Identifies the potential impact of important barriers on the provision of effective pain care.

(+) *CRITERION 7:*
Physical dependence or analgesic tolerance are not confused with "addiction"

COMMENT: However, it is preferable to substitute "physical dependence" for the archaic term "habituation."

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MARYLAND

OTHER GOVERNMENTAL POLICY

Medical Board Guideline

(CONTINUED)

History and Physical Generally speaking, it is improper to prescribe any medication for any patient without first taking the steps essential to evaluation. This is particularly true of the chronic pain patients because other treatment modalities may be beneficial and because it is important to recognize the addict who may complain of pain as a means to maintain a habit. Prescribing narcotics without a documented evaluation always represents substandard care.

Treatment Plan Just as treatment for diabetes or hypertension has a specific objective, so should treatment for chronic pain. Frequently, the pain cannot be completely relieved but the use of analgesic drugs may lead to an improved sense of well-being, better sleep or even a return to work. The goal of analgesic therapy should be documented and the patient's progress measured against this goal.

Informed Consent Since long-term narcotic use will usually result in habituation and tolerance, these risks should be discussed with the patient. Alternatives should be offered if they exist and the clinical record should refer to the discussion.

Periodic Review The course of treatment and the meeting of therapeutic goals should be periodically reviewed as is the case with any patient suffering from chronic disease. Modification of treatment or its discontinuation should be considered depending upon how well goals are being met. New information about the etiology of the pain or its treatment should be evaluated.

Consultation The complexity of chronic pain frequently requires evaluation by consultants who may suggest alternatives or additions to therapy. This may be particularly true in the patient who is at risk for drug misuse. The patient with a history of substance abuse requires special care in documentation, evaluation and consultation before long-term opiate treatment can be safely prescribed. Some pain management specialists recommend a written agreement with these and other patients before such therapy.

Records Adequate documentation is the key to management of these difficult patients and is the key to protecting the physician from legal or Board action. Documentation of the steps noted above should be recorded in a fashion that would allow another practitioner to understand and follow through with treatment.

Finally, the physician who uses scheduled drugs should be familiar with federal and local laws regulating their use. The U.S. Drug Enforcement Administration publishes a physicians' manual and Maryland laws are available through the Board. The Board hopes that physicians will use these guidelines to help them manage patients with chronic pain without fear of regulatory scrutiny. At the same time, the Board maintains its commitment to prevent the diversion and abuse of controlled substances.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY B:
Issues related to patients

COMMENT: Acknowledges that a patient's prior history or current status of drug abuse does not necessarily contraindicate appropriate pain management.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Encourages healthcare professionals to understand and follow federal and state laws governing their practice, which can better ensure that practitioners follow the *balanced* approach represented by federal law and the laws in many states.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Recognizes that the goal of pain treatment should include improvements in patient functioning and quality of life.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Recognizes the need for a multidisciplinary approach to pain management.

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MARYLAND

STATUTES

Assisted Suicide

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT*:* Clarifies for physicians the important distinction between physician-assisted suicide and prescribing controlled substances for pain relief; this language identifies a clinical misperception that is pervasive in end-of-life care and attempts to lessen its impact on patient treatment, and the practitioners who provide it.

Md. CRIMINAL LAW Code Ann. § 3-101

§ 3-103. Exceptions

(a) Palliative care -- Pain relief. -- A licensed health care professional does not violate § 3-102 of this subtitle by administering or prescribing a procedure or administering, prescribing, or dispensing a medication to relieve pain, even if the medication or procedure may hasten death or increase the risk of death, unless the licensed health care professional knowingly administers or prescribes the procedure or administers, prescribes, or dispenses the medication to cause death.

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STATUTES

Rights of Individuals

Md. HEALTH-GENERAL Code Ann. § 19-342

§ 19-342. Hospitals

(a) Patient's bill of rights. -- Each administrator of a hospital is responsible for making available to each patient in the hospital a copy of the patient's bill of rights that the hospital adopts under the Joint Commission on Accreditation of Hospitals' guidelines.

(b) Patient's bill of rights -- Statement. -- The patient's bill of rights shall include a statement that a patient has a right to expect and receive appropriate assessment, management, and treatment of pain as an integral component of the patient's care.

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(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT*:* Establishes a responsibility for hospitals to ensure that pain management is an essential part of patient care.

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MARYLAND

STATUTES

Prescription Drug Monitoring Program

Md. HEALTH-GENERAL Code Ann. § 21-2A-05

§ 21-2A-05. Advisory Board

(a) Established. -- There is an Advisory Board on Prescription Drug Monitoring in the Department.

(b) Composition. -- The Board shall consist of the following members:

(1) The Secretary, or the Secretary's designee;

(2) The President of the Maryland Board of Pharmacy, or the President's designee;

(3) The Chair of the Maryland Board of Physicians, or the Chair's designee;

(4) The President of the Maryland Board of Nursing, or the President's designee;

(5) The Chairman of the Maryland Health Care Commission, or the Chairman's designee;

(6) Four physicians and one nurse practitioner with expertise in clinical treatment using controlled dangerous substances, including pain management, substance abuse, and behavioral disorders, appointed by the Secretary after consultation with:

(i) For the physician appointments, the Medical and Chirurgical Faculty of Maryland, the Maryland Physical Medicine and Rehabilitation Society, the Maryland Society of Anesthesiologists, the Maryland-D.C. Society of Clinical Oncology, the Hospice and Palliative Care Network of Maryland, and the Maryland Chapter of the American Academy of Pediatrics; and

(ii) For the nurse practitioner appointment, the Maryland Nurses Association;

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Md. HEALTH-GENERAL Code Ann. § 21-2A-07

§ 21-2A-07. Technical Advisory Committee

(a) Established. -- There is a technical advisory committee to the Program.

(b) Purpose. -- The purpose of the technical advisory committee is to review requests for information from the Program under § 21-2A-06(b)(3), (4), (5), (7), and (8) of this subtitle.

(c) Composition. -- The technical advisory committee consists of the following members, appointed by the Secretary:

(1) A board certified anesthesiologist licensed and practicing in the State, nominated by the Maryland Society of Anesthesiologists;

(2) A certified addiction medicine specialist licensed and practicing in the State, nominated by the Maryland Society for Addiction Medicine;

(3) A pharmacist licensed and practicing in the State;

(4) A medical professional, licensed and practicing in the State, who is treating cancer patients; and

(5) A board certified physician specializing in the treatment of patients with pain, licensed and practicing in the State, nominated by the Maryland Society of Physical Medicine and Rehabilitation.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Requires an expertise in pain management on an Advisory Board that provides consultation and recommendations on PMP implementation, operation, and evaluation.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Requires an expertise in pain management on a Technical Advisory Committee that reviews requests for PMP information.

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MARYLAND

REGULATIONS

Assisted Living Programs

COMAR 10.07.14.15-2

.15-2 Assisted Living Manager Training--Basic Course.

The assisted living manager's training shall include the following courses:

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E. Clinical management, 20 hours, including:

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(18) Effective pain management;

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I. End of life care, 4 hours, including:

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(6) Pain management;

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(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (manager training) for assisted living facilities to ensure that pain management is an essential part of patient care.

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Madison, Wisconsin

MARYLAND

REGULATIONS

Hospice Care Programs

COMAR 10.07.21.08

.08 Personnel.

A. The hospice care program shall maintain sufficient health care professionals and volunteers to meet patient care needs.

B. The hospice care program shall identify an interdisciplinary care team with responsibility for ensuring continuous assessment of the patient's and family's needs and implementation of an integrated plan of care. The hospice care program shall ensure that:

(1) A qualified health care professional coordinates the activities of the interdisciplinary care team;

(2) The number of individuals who perform interdisciplinary team services is consistent with the needs of patients and their families and the type of services provided by the hospice care program; and

(3) Each interdisciplinary care team consists of at least:

(a) The patient's attending physician,

(b) A physician with training in palliative care,

(c) A registered nurse with demonstrated experience in pain and symptom management and the performance of physical assessments,

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Recognizes the need for a multidisciplinary approach to pain management.

COMAR 10.07.21.13

.13 Physician Services.

A. Medical Director. The hospice care program shall have a medical director who shall be:

(1) A physician licensed to practice medicine in this State; and

(2) Knowledgeable about the psychosocial and medical aspects of hospice care.

B. Medical Director Duties. The medical director is responsible for:

(1) Reviewing, coordinating, and managing the clinical and medical care for all patients in the hospice care program;

(2) Consulting with attending physicians regarding pain and symptom control;

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(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (consultation responsibilities) for hospices to ensure that pain management is an essential part of patient care.

COMAR 10.07.21.13

.21 Patient's Rights.

A. The hospice care program shall provide the patient or representative with a written notice of the patient's rights in advance of furnishing care. Documentation verifying receipt of and understanding of this information shall be included as part of the patient's record.

B. The patient has the right to:

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(9) Be informed of short-term inpatient care options available for pain control, management, and respite;

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(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (written notice of patient's rights) for hospices to ensure that pain management is an essential part of patient care.

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MASSACHUSETTS

STATUTES

- CONTROLLED SUBSTANCES ACT
  Part 1. Administration of the Government; Title XV. Regulation of Trade;
  Chapter 94C. Controlled Substances Act

- MEDICAL PRACTICE ACT (*No provisions found*)
  Part 1. Administration of the Government; Title XVI. Public Health;
  Chapter 112. Registration of Certain Professions and Occupations; Registration of Physicians and Surgeons

- OSTEOPATHIC PRACTICE ACT (*No provisions found*)
  Part 1. Administration of the Government; Title XVI. Public Health;
  Chapter 112. Registration of Certain Professions and Occupations; Osteopathy

- PHARMACY PRACTICE ACT (*No provisions found*)
  Part 1. Administration of the Government; Title XVI. Public Health;
  Chapter 112. Registration of Certain Professions and Occupations; Registration of Pharmacists

- INTRACTABLE PAIN TREATMENT ACT
  No policy found

REGULATIONS

- CONTROLLED SUBSTANCES REGULATIONS
  Title 105. Department of Public Health;
  Chapter 700.000. Implementation of M. G. L. c. 94C
  Chapter 701.000. Regulations Adopted Jointly by the Department of Public Health and the Board of Registration in Pharmacy for the Implementation of M. G. L. c. 94C

- MEDICAL BOARD REGULATIONS
  Title 243. Board of Registration in Medicine

- PHARMACY BOARD REGULATIONS
  Title 247. Board of Registration in Pharmacy

OTHER GOVERNMENTAL POLICIES

- MEDICAL BOARD GUIDELINE
  Massachusetts Board of Registration in Medicine. *Model Policy for the Use of Controlled Substances for the Treatment of Pain*. Adopted: December 15, 2004.

- MEDICAL BOARD GUIDELINE
  Massachusetts Board of Registration in Medicine. *Prescribing Practices Policies and Guidelines*. Adopted: August 1, 1989; Amended: November 17, 2010.

- PHARMACY BOARD POLICY STATEMENT
  Massachusetts Board of Registration in Pharmacy. *Policy on the Management of Pain*. Adopted: March 31, 2009; Revised: August 16, 2011.

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RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY KEY WORD SEARCHES

- HEALTH PLANNING COUNCIL
  Part 1. Administration of the Government; Title II. Executive and Administrative Officers of the Commonwealth; Chapter 6A. Executive Offices

- DUTIES OF THE DEPARTMENT OF PUBLIC HEALTH
  Part 1. Administration of the Government; Title XVI. Public Health; Chapter 111. Public Health

- PALLIATIVE CARE AND END-OF-LIFE OPTIONS
  Part 1. Administration of the Government; Title XVI. Public Health; Chapter 111. Public Health

- HOSPITAL LICENSURE
  Title 105. Department of Public Health; Chapter 130.000. Hospital Licensure; Subpart D. Supplementary Standards: Particular Services

- HOSPICE LICENSURE
  Title 105. Department of Public Health; Chapter 141.000. Licensure of Hospice Programs; Subpart B. General Requirement; Administration

MASSACHUSETTS

STATUTES

Controlled Substances Act

ALM GL ch. 94C, § 1

§ 1. Definitions.

As used in this chapter, the following words shall, unless the context clearly requires otherwise, have the following meanings:

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"Practitioner",

(a) A physician, dentist, veterinarian, podiatrist, scientific investigator, or other person registered to distribute, dispense, conduct research with respect to, or use in teaching or chemical analysis, a controlled substance in the course of professional practice or research in the commonwealth.

(+) *CRITERION 3:*
Opioids are part of professional practice

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ALM GL ch. 94C, § 9

§ 9. Authorized Possession, Administration and Dispensation of Controlled Substances; Records.

(a) A physician, dentist, podiatrist, optometrist as limited by sections 66 and 66B of chapter 112 and paragraph (h) of section 7, nurse practitioner and psychiatric nurse mental health clinical specialist as limited by paragraph (g) of said section 7 and section 80E of said chapter 112, physician assistant as limited by said paragraph (g) of said section 7 and section 9E of said chapter 112, a certified nurse-midwife as provided in section 80C of said chapter 112 or a veterinarian when registered pursuant to the provisions of said section 7 and acting in accordance with the provisions of applicable federal law and any provision of this chapter which is consistent with federal law, in good faith and in the course of a professional practice for the alleviation of pain and suffering or for the treatment or alleviation of disease, may possess such controlled substances as may reasonably be required for the purpose of patient treatment and may administer controlled substances or may cause the same to be administered under his direction by a nurse.

(+) *CRITERION 2:*
Pain management is part of medical practice

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ALM GL ch. 94C, § 18

§ 18. Prescriptions, Who May Issue.

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(e) Practitioners who prescribe controlled substances, except veterinarians, shall be required, as a prerequisite to obtaining or renewing their professional license, to complete appropriate training relative to: (i) effective pain management; (ii) identification of patients at high risk for substance abuse; and (iii) counseling patients about the side effects, addictive nature and proper storage and disposal of prescription medications. The boards of registration for each professional license that requires such training shall develop the standards for appropriate training programs.

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(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT*:* Establishes a mechanism (continuing education) to provide practitioners information/education about pain management.

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MASSACHUSETTS

STATUTES

Controlled Substances Act

ALM GL ch. 94C, § 21

§ 21. Filling of Prescription; Required Information on Label.

The pharmacist filling a written or oral prescription for a controlled substance shall package the controlled substance in a container, affixing to the container a label showing the date of filling, the pharmacy name and address, the filling pharmacist's initials, the serial number of the prescription, the name of the patient, unless it is a veterinary prescription, the name of the prescribing practitioner, the name of the controlled substance, directions for use and cautionary statements, if any, contained in such prescription or required by law, and if the controlled substance is dispensed as tablets or capsules the number of same in such container.

Upon the request of an elderly person, as defined in section fourteen of chapter nineteen A or a person visually impaired, directions on the label affixed by the pharmacist to a container of a prescription drug shall be typed in a print size allowing no more than ten characters per inch.

The department of public health shall produce and distribute either in written or electronic form to pharmacies, not including institutional pharmacies, pamphlets for consumers relative to narcotic drugs that includes educational information about: (i) pain management; (ii) misuse and abuse by adults and children; (iii) risk of dependency and addiction; (iv) proper storage and disposal; (v) addiction support and treatment resources; and (vi) the telephone helpline operated by the bureau of substance abuse services established in *section 18 of chapter 17*. A pharmacist shall distribute the pamphlet when dispensing a narcotic or controlled substance contained in Schedule II or III.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT*:* Establishes a mechanism (pamphlets) to provide the public information/education about pain management.

Pain & Policy Studies Group
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Madison, Wisconsin

MASSACHUSETTS

REGULATIONS

Controlled Substances Regulations

105 CMR 700.001

700.001: Definitions

For the purpose of *105 CMR 700.000*, the following definitions apply, in addition to those definitions appearing in *M.G.L. c. 94C, § 1*, unless the context or subject matter requires a different meaning.

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Practitioner means

(1) A physician, dentist, veterinarian, podiatrist, scientific investigator or other person registered to distribute, dispense, conduct research with respect to, or use in teaching or chemical analysis, a controlled substance in the course of professional practice or research in the commonwealth;

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105 CMR 700.012

700.012: Prescription Monitoring Program

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(B) **Prescription Monitoring Program Advisory Council**.

(1) The Commissioner of the Department of Public Health may establish a Prescription Monitoring Program Advisory Council to advise the Department on the implementation of *105 CMR 700.012*. The membership of the Advisory Council may include, but need not be limited to, representatives of the Department of Public Health; Executive Office of Health and Human Services; Executive Office of Public Safety; Boards of Registration responsible for licensing professionals authorized to prescribe or dispense controlled substances, including the Boards of Registration in Medicine, Pharmacy, Dentistry, Podiatry, Veterinary Medicine, Optometry, Nursing and Physician Assistants; representatives of associations or societies representing professions authorized to prescribe or dispense controlled substances, patient interests, privacy interests; and a person with expertise in the design or operation of a secure automated data system.

(2) The Prescription Monitoring Program Advisory Council may assist the Department and Boards of Registration, as appropriate, in designing education programs for the appropriate use of prescription monitoring program information.

(C) **Prescription Monitoring Program Medical Review Group**.

(1) The Commissioner may establish the Prescription Monitoring Program Medical Review Group to advise the Department on accepted medical practice standards related to the disclosure of information pursuant to subsection *105 CMR 700.012(D)(4)(b)*. The Medical Review Group shall advise the Department in the evaluation of prescription information and clinical aspects of the implementation of *105 CMR 700.012*.

(2) Members of the Medical Review Group shall be licensed health care practitioners and pharmacists and, to the extent feasible, at least one member shall be licensed in the same discipline as the practitioner whose records are under review. Practitioners serving on the Medical Review Group must have a valid Controlled Substances Registration for Schedules II through VI pursuant to *M.G.L. c. 94C, § 7*.

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(+) *CRITERION 3:*
Opioids are part of professional practice

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Requires an expertise in pain management on an Advisory Board that provides consultation and recommendations on PMP implementation, operation, and evaluation.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (review by medical review group members with the same professional license) to assist in the evaluation of prescription monitoring program information.

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MASSACHUSETTS

REGULATIONS

Medical Board Regulations

243 CMR 2.02

2.02: Initial Licensure for Graduates of Medical Schools in the US, CA, and PR

(1) Prerequisites to Initial Licensure. The Board shall determine whether an applicant is qualified to hold a full active license to practice medicine. In order to qualify for a full medical license, an applicant shall meet all of the following minimum requirements for licensure:

(a) Be age 18 or over;

(b) Possess Good Moral Character;

(c) Have Pre-medical Education as described in *243 CMR 2.02(2)(a);*

(d) Have a Medical School Education as described in either *243 CMR 2.02* or 2.03;

(e) Have Post-graduate Medical Training as described in either *243 CMR 2.02* or 2.03;

(f) Pass a Professional Examination as described in *243 CMR 2.02(3)* or (4);

(g) Complete Pain Management training, as described in *M.G.L. c. 94C, § 18.*

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(2) Procedure for Obtaining an Initial Full License for Graduates of Medical Schools in the United States, Canada and the Commonwealth of Puerto Rico. In order to qualify for a full medical license, an applicant shall meet the prerequisites to licensure in *243 CMR 2.02(1)* and the following requirements, in addition to other requirements for licensure as set forth in the Board's regulations (243 CMR) and M.G.L. c. 112.

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(e) Pain Management Training. Applicants who prescribe controlled substances shall, as a prerequisite to obtaining or renewing a medical license, complete appropriate pain management training and opioid education, according to *M.G.L. c. 94C, § 18* and *243 CMR 2.00*. Pain Management training shall consist of at least three credits of Board-approved continuing professional development and may be used toward the required ten credits of risk management training.

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243 CMR 2.06

2.06: License Renewals

(6) Continuing Professional Development.

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(d) Opioid Education and Pain Management Training. Renewing licensees who prescribe controlled substances, as defined in *M.G.L. c. 94C, § 1*, shall, as a prerequisite to renewing a medical license, complete three credits in pain management training, pursuant to St. 2010, c. 283. Pain management training shall include, but not be limited to, training in how to identify patients at high risk for substance abuse and training in how to counsel patients on the side effects, addictive nature and proper storage and disposal of prescription medicines. Three credits of opioid education and pain management training shall be required of licensees when they biennially renew their licenses. Opioid education and pain management training may be used toward a licensee's required risk management credits of continuing professional education.

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(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT*:* Establishes a mechanism (licensure requirement) to provide practitioners information/education about pain management.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT*:* Establishes a mechanism (continuing education) to provide practitioners information/education about pain management.

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Madison, Wisconsin

MASSACHUSETTS

REGULATIONS

Pharmacy Board Regulations

247 CMR 2.00

2.00: Definitions

Additional definitions pertaining to:

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Practitioner means any person with prescriptive privileges as defined in *M.G.L. c. 94C, § 1.* (by reference: A physician, dentist, veterinarian, podiatrist, scientific investigator or other person registered to distribute, dispense, conduct research with respect to, or use in teaching or chemical analysis, a controlled substance in the course of professional practice or research in the commonwealth;)

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(+) *CRITERION 3:*
Opioids are part of professional practice

Pain & Policy Studies Group
University of Wisconsin Carbone Cancer Center
Madison, Wisconsin

MASSACHUSETTS

OTHER GOVERNMENTAL POLICY

Medical Board Guideline

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT*:* Recognizes that inadequate treatment of pain is subject to disciplinary action just as other substandard practices might be.

(+) *CRITERION 4:*
Encourages pain management

Model Policy for the Use of Controlled Substances for the Treatment of Pain

Section I: Preamble
The Massachusetts Board of Registration in Medicine recognizes that principles of quality medical practice dictate that the people of the Commonwealth of Massachusetts have access to appropriate and effective pain relief. The appropriate application of up-to-date knowledge and treatment modalities can serve to improve the quality of life for those patients who suffer from pain as well as reduce the morbidity and costs associated with untreated or inappropriately treated pain. For the purposes of this policy, the inappropriate treatment of pain includes nontreatment, undertreatment, overtreatment, and the continued use of ineffective treatments.

The diagnosis and treatment of pain is integral to the practice of medicine. The Board encourages physicians to view pain management as a part of quality medical practice for all patients with pain, acute or chronic, and it is especially urgent for patients who experience pain as a result of terminal illness. All physicians should become knowledgeable about assessing patients' pain and effective methods of pain treatment, as well as statutory requirements for prescribing controlled substances. Accordingly, this policy have been developed to clarify the Board's position on pain control, particularly as related to the use of controlled substances, to alleviate physician uncertainty and to encourage better pain management.

Inappropriate pain treatment may result from physicians' lack of knowledge about pain management. Fears of investigation or sanction by federal, state and local agencies may also result in inappropriate treatment of pain. Appropriate pain management is the treating physician's responsibility. As such, the Board will consider the inappropriate treatment of pain to be a departure from standards of practice and will investigate such allegations, recognizing that some types of pain cannot be completely relieved, and taking into account whether the treatment is appropriate for the diagnosis.

The Board recognizes that controlled substances including opioid analgesics may be essential in the treatment of acute pain due to trauma or surgery and chronic pain, whether due to cancer or non-cancer origins. The Board will refer to current clinical practice guidelines and expert review in approaching cases involving management of pain. The medical management of pain should consider current clinical knowledge and scientific research and the use of pharmacologic and non-pharmacologic modalities according to the judgment of the physician. Pain should be assessed and treated promptly, and the quantity and frequency of doses should be adjusted according to the intensity, duration of the pain, and treatment outcomes. Physicians should recognize that tolerance and physical dependence are normal consequences of sustained use of opioid analgesics and are not the same as addiction.

The Massachusetts Board of Registration in Medicine is obligated under the laws of the Commonwealth to protect the public health and safety. The Board recognizes that the use of opioid analgesics for other than legitimate medical purposes pose a threat to the individual and society and that the inappropriate prescribing of controlled substances, including opioid analgesics, may lead to drug diversion and abuse by individuals who seek them for other than legitimate medical use. Accordingly, the Board expects that physicians incorporate safeguards into their practices to minimize the potential for the abuse and diversion of controlled substances.

(CONTINUED ON NEXT PAGE)

(+) *CRITERION 2:*
Pain management is part of healthcare practice

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Identifies the potential impact of important barriers on the provision of effective pain care.

(+) *CRITERION 7:*
Physical dependence or analgesic tolerance are not confused with "addiction"

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OTHER GOVERNMENTAL POLICY

Medical Board Guideline

(CONTINUED)

Physicians should not fear disciplinary action from the Board for ordering, prescribing, dispensing or administering controlled substances, including opioid analgesics, for a legitimate medical purpose and in the course of professional practice. The Board will consider prescribing, ordering, dispensing or administering controlled substances for pain to be for a legitimate medical purpose if based on sound clinical judgment. All such prescribing must be based on clear documentation of unrelieved pain. To be within the usual course of professional practice, a physician-patient relationship must exist and the prescribing should be based on a diagnosis and documentation of unrelieved pain. Compliance with applicable state or federal law is required.

The Board will judge the validity of the physician's treatment of the patient based on available documentation, rather than solely on the quantity and duration of medication administration. The goal is to control the patient's pain while effectively addressing other aspects of the patient's functioning, including physical, psychological, social and work-related factors.

Allegations of inappropriate pain management will be evaluated on an individual basis. The board will not take disciplinary action against a physician for deviating from this policy when contemporaneous medical records document reasonable cause for deviation. The physician's conduct will be evaluated to a great extent by the outcome of pain treatment, recognizing that some types of pain cannot be completely relieved, and by taking into account whether the drug used is appropriate for the diagnosis, as well as improvement in patient functioning and/or quality of life.

Section II: Guidelines
The Board has adopted the following criteria when evaluating the physician's treatment of pain, including the use of controlled substances:

Evaluation of the Patient—A medical history and physical examination must be obtained, evaluated, and documented in the medical record. The medical record should document the nature and intensity of the pain, current and past treatments for pain, underlying or coexisting diseases or conditions, the effect of the pain on physical and psychological function, and history of substance abuse. The medical record also should document the presence of one or more recognized medical indications for the use of a controlled substance.

Treatment Plan—The written treatment plan should state objectives that will be used to determine treatment success, such as pain relief and improved physical and psychosocial function, and should indicate if any further diagnostic evaluations or other treatments are planned. After treatment begins, the physician should adjust drug therapy to the individual medical needs of each patient. Other treatment modalities or a rehabilitation program may be necessary depending on the etiology of the pain and the extent to which the pain is associated with physical and psychosocial impairment.

(CONTINUED ON NEXT PAGE)

(+) *CRITERION 5:*
Addresses fear of regulatory scrutiny

(+) *CRITERION 6:*
Prescription amount alone does not determine legitimacy

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT*:*
Acknowledges need for treatment flexibility for physicians to respond to individual clinical circumstances, as long as their prescribing maintains the standards of good medical practice.

(+) *CRITERION 3:*
Opioids are part of professional practice

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Recognizes that the goal of pain treatment should include improvements in patient functioning and quality of life.

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OTHER GOVERNMENTAL POLICY

Medical Board Guideline

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Encourages healthcare professionals to incorporate in their practice the evaluations of, and discussions with patients about, the potential benefits and risks of treatment with opioids, which can better ensure a clinical indication of such treatment so that opioids will be used for medical purposes.

(CONTINUED)

Informed Consent and Agreement for Treatment—The physician should discuss the risks and benefits of the use of controlled substances with the patient, persons designated by the patient or with the patient's surrogate or guardian if the patient is without medical decision-making capacity. The patient should receive prescriptions from one physician and one pharmacy whenever possible. If the patient is at high risk for medication abuse or has a history of substance abuse, the physician should consider the use of a written agreement between physician and patient outlining patient responsibilities, including

- urine/serum medication levels screening when requested;
- number and frequency of all prescription refills; and
- reasons for which drug therapy may be discontinued (e.g., violation of agreement).

Periodic Review—The physician should periodically review the course of pain treatment and any new information about the etiology of the pain or the patient's state of health. Continuation or modification of controlled substances for pain management therapy depends on the physician's evaluation of progress toward treatment objectives. Satisfactory response to treatment may be indicated by the patient's decreased pain, increased level of function, or improved quality of life. Objective evidence of improved or diminished function should be monitored and information from family members or other caregivers should be considered in determining the patient's response to treatment. If the patient's progress is unsatisfactory, the physician should assess the appropriateness of continued use of the current treatment plan and consider the use of other therapeutic modalities.

Consultation—The physician should be willing to refer the patient as necessary for additional evaluation and treatment in order to achieve treatment objectives. Special attention should be given to those patients with pain who are at risk for medication misuse, abuse or diversion. The management of pain in patients with a history of substance abuse or with a comorbid psychiatric disorder may require extra care, monitoring, documentation and consultation with or referral to an expert in the management of such patients.

Medical Records—The physician should keep accurate and complete records to include

1. the medical history and physical examination,
2. diagnostic, therapeutic and laboratory results,
3. evaluations and consultations,
4. treatment objectives,
5. discussion of risks and benefits,
6. informed consent,
7. treatments,

(CONTINUED ON NEXT PAGE)

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY B:
Issues related to patients

COMMENT:
Acknowledges that a patient's prior history or current status of drug abuse does not necessarily contraindicate appropriate pain management.

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OTHER GOVERNMENTAL POLICY

Medical Board Guideline

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT*:* Encourages healthcare professionals to understand and follow federal and state laws governing their practice, which can better ensure that practitioners follow the *balanced* approach represented by federal law and the laws in many states.

(CONTINUED)

8. medications (including date, type, dosage and quantity prescribed),
9. instructions and agreements and
10. periodic reviews.

Records should remain current and be maintained in an accessible manner and readily available for review.

Compliance With Controlled Substances Laws and Regulations—To prescribe, dispense or administer controlled substances, the physician must be licensed in the state and comply with applicable federal and state regulations. Physicians are referred to the Physicians Manual of the U.S. Drug Enforcement Administration and (any relevant documents issued by the state medical board) for specific rules governing controlled substances as well as applicable state regulations.

Section III: Definitions
For the purposes of these guidelines, the following terms are defined as follows:

Acute Pain—Acute pain is the normal, predicted physiological response to a noxious chemical, thermal or mechanical stimulus and typically is associated with invasive procedures, trauma and disease. It is generally time-limited.

Addiction—Addiction is a primary, chronic, neurobiologic disease, with genetic, psychosocial, and environmental factors influencing its development and manifestations. It is characterized by behaviors that include the following: impaired control over drug use, craving, compulsive use, and continued use despite harm. Physical dependence and tolerance are normal physiological consequences of extended opioid therapy for pain and are not the same as addiction.

Chronic Pain—Chronic pain is a state in which pain persists beyond the usual course of an acute disease or healing of an injury, or that may or may not be associated with an acute or chronic pathologic process that causes continuous or intermittent pain over months or years.

Pain—An unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage.

Physical Dependence—Physical dependence is a state of adaptation that is manifested by drug class-specific signs and symptoms that can be produced by abrupt cessation, rapid dose reduction, decreasing blood level of the drug, and/or administration of an antagonist. Physical dependence, by itself, does not equate with addiction.

Pseudoaddiction—The iatrogenic syndrome resulting from the misinterpretation of relief seeking behaviors as though they are drug-seeking behaviors that are commonly seen with addiction. The relief seeking behaviors resolve upon institution of effective analgesic therapy.

Substance Abuse—Substance abuse is the use of any substance(s) for non-therapeutic purposes or use of medication for purposes other than those for which it is prescribed.

Tolerance—Tolerance is a physiologic state resulting from regular use of a drug in which an increased dosage is needed to produce a specific effect, or a reduced effect is observed with a constant dose over time. Tolerance may or may not be evident during opioid treatment and does not equate with addiction.

Pain & Policy Studies Group
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Madison, Wisconsin

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OTHER GOVERNMENTAL POLICY

Medical Board Guideline

Commonwealth of Massachusetts
Board of Registration in Medicine

Prescribing Practices and Policy Guidelines
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6. Treating Drug-Dependent Persons
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It should be emphasized that patients who legitimately take controlled substances for extreme pain can become tolerant to their medications. Such patients should not be considered "drug dependent."
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(+) CRITERION 7: Physical dependence or analgesic tolerance are not confused with "addiction"

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University of Wisconsin Carbone Cancer Center
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OTHER GOVERNMENTAL POLICY

Pharmacy Board Policy Statement

2009-01 POLICY ON THE MANAGEMENT OF PAIN
Title: Policy on the Management of Pain

The Board of Registration in Pharmacy (Board) recognizes that principles of quality pharmacy practice must ensure that patients have access to appropriate and effective pain relief.

This Policy expresses the Board's support for pain management practices that assure appropriate application of up-to-date knowledge and treatment modalities in the practice of pharmacy that may improve the quality of life for patients suffering from pain, as well as reduce the morbidity and costs associated with untreated or inappropriately managed pain.

For purposes of this Policy, the inappropriate management of pain includes non-treatment, under-treatment, over-treatment and the continued use of ineffective treatment.

The Board encourages pharmacists to view pain management as a part of pharmacy practice for all patients in pain, whether acute or chronic. All pharmacists are encouraged to become knowledgeable about effective methods of pain management. (1)

Policy
A pharmacist registered by the Board should provide access to pain medication to patients with legitimate needs in accordance with accepted standards of pharmacy practice.

It is the Board's position that these standards, in the context of appropriate and effective pain management, include:

- complete, accurate and legible entries in all appropriate patient or prescription records required by federal and state laws and regulations, and recognized standards of care;
- conducting a prospective drug utilization review (DUR) before each prescription is dispensed or delivered for the purpose of promoting therapeutic appropriateness;
- reconciliation of a patient's individual history, including drug allergies, drug interactions, and other considerations relevant to the patient's drug therapy;
- the use, when appropriate, of controlled substances including opioid analgesics in the management of all pain types;
- interdisciplinary consultation and collaboration as appropriate;
- understanding that tolerance and physical dependence are normal consequences of sustained use of opioids not synonymous with addiction; that tolerance is a physiologic state resulting from regular use of a drug in which (a) an increased dosage is needed to produce a specific effect, or (b) a reduced effect is observed with a constant dose over time (2); and that physical dependence is a state of adaptation that is manifested by drug class specific signs and symptoms that can be produced by abrupt cessation, rapid dose reduction, decreasing blood level of the drug, and/or administration of an antagonist (3);

(CONTINUED ON NEXT PAGE)

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Recognizes that inadequate treatment of pain is subject to disciplinary action just as other substandard practices might be.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Recognizes the need for a multidisciplinary approach to pain management.

(+) *CRITERION 2:*
Pain management is part of healthcare practice

(+) *CRITERION 4:*
Encourages pain management

(+) *CRITERION 7:*
Physical dependence or analgesic tolerance are not confused with "addiction"

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OTHER GOVERNMENTAL POLICY

Pharmacy Board Policy Statement

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT*:* Clarifies for pharmacists the important distinction between drug-seeking behaviors resulting from poorly treated pain (i.e., pseudoaddiction) and drug-seeking behaviors related to abuse or addiction; this language identifies a potential clinical situation and attempts to lessen its impact on patient treatment.

(CONTINUED)

- recognition that pseudoaddiction may develop as a direct consequence of inadequate pain management and that pseudoaddiction can be distinguished from true addiction in that inappropriate drug seeking behaviors resolve when pain is effectively treated (4);
- recognition that patients with chemical dependency may also require specialized pain management involving controlled substances (including opioids) for other conditions;
- recognition that a patient who suffers from extreme pain or disease progression may require increased doses of pain medication and that the appropriate dose is the dose required to effectively manage the patient's pain in that particular circumstance; and
- adherence to system safeguards that are designed to minimize the potential for abuse and diversion when controlled substances are used, including a corresponding responsibility to assure that controlled substance prescriptions are issued by a practitioner for a legitimate medical purpose in the usual course of the practitioner's professional practice.

Pharmacists are encouraged to acquire and maintain current knowledge, skills and abilities necessary to practice in accordance with accepted standards of care for pain management. Such competencies may be acquired through continuing education programs, as appropriate to the pharmacist's scope of practice (5), in the areas of current federal and state laws and regulations for the prescribing, dispensing, administration and destruction of controlled substances, as well as review of the current edition of the United States Pharmacopeia Drug Information, pharmacy best practice recommendations, peer reviewed medical literature, and current evidence based guidelines developed by nationally recognized professional organizations in the assessment and management of pain. Pursuant to M.G.L. Chapter 94C, Section 18(e), a Pharmacist licensed by the Board who is authorized to prescribe controlled substances (e.g. participate in collaborative drug therapy management with a supervising physician pursuant to a written collaborative practice agreement) must complete the following education mandates as a prerequisite to obtaining or renewing professional licensure: effective pain management; identification of patients at high risk for substance abuse; and counseling of patients about the side effects, addictive nature and proper storage and disposal of prescription medications.

(1) Adapted from the Preamble, Model Policy for the Use of Controlled Substances for the Treatment of Pain (2004), Federation of State Medical Boards of the United States, Inc. Available at http://www.fsmb.org/pdf/2004_grpol_Controlled_Substances.pdf.

(2) Adopted by the Federation of State Medical Boards of the United States from the Definitions Related to the Use of Opioids for the Treatment of Pain: A Consensus Document of the American Academy of Pain Medicine, the American Pain Society and the American Society of Addiction Medicine (2001). Available at http://www.painmed.org/pdf/definition.pdf.

(3) Adopted by the Federation of State Medical Boards of the United States from the Definitions Related to the Use of Opioids for the Treatment of Pain: A Consensus Document of the American Academy of Pain Medicine, the American Pain Society and the American Society of Addiction Medicine (2001). Available at http://www.painmed.org/pdf/definition.pdf.

(4) Adapted from the Defintions, Model Policy for the Use of Controlled Substances for the Treatment of Pain (2004), Federation of State Medical Boards of the United States, Inc. Available at http://www.fsmb.org/pdf/2004_grpol_Controlled_Substances.pdf.

(5) Continuing education programs developed in accordance with 247 CMR 4.05.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY B:
Issues related to patients

COMMENT*:* Acknowledges that a patient's prior history or current status of drug abuse does not necessarily contraindicate appropriate pain management.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT*:* Encourages healthcare professionals to understand and follow federal and state laws governing their practice, which can better ensure that practitioners follow the *balanced* approach represented by federal law and the laws in many states.

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STATUTES

Health Planning Council

ALM GL ch. 6A, § 16T

§ 16T. Executive Office of Health and Human Services -- Health Planning Council.

(a) There shall be a health planning council within the executive office of health and human services, consisting of the secretary of health and human services or a designee who shall serve as chair, the commissioner of public health or a designee, the director of the office of Medicaid or a designee, the commissioner of mental health or a designee, the secretary of elder affairs or a designee, the executive director of the center for health information and analysis or a designee, the executive director of the health policy commission or a designee and 3 members appointed by the governor, of whom shall be a health economist; 1 of whom shall have experience in health policy and planning and 1 of whom shall have experience in health care market planning and service line analysis.

The council shall assemble an advisory committee of not more than 13 members who shall reflect a broad distribution of diverse perspectives on the health care system, including health care providers and provider organizations, third-party payers, both public and private, consumer representatives and labor organizations representing health care workers. The advisory committee shall review drafts and provide recommendations to the council during the development of the plan.

The executive office of health and human services, with the council, shall conduct at least 5 public hearings, in geographically diverse areas, on the plan as proposed and shall give interested persons an opportunity to submit their views orally and in writing. In addition, the executive office may create and maintain a website to allow members of the public to submit comments electronically and review comments submitted by others. The state health plan shall identify needs of the commonwealth in health care services, providers, programs and facilities; the resources available to meet those needs; and the priorities for addressing those needs.

(b) The state health plan developed by the council shall include the location, distribution and nature of all health care resources in the commonwealth and shall establish and maintain on a current basis an inventory of all such resources together with all other reasonably pertinent information concerning such resources. For purposes of this section, a health care resource shall include any resource, whether personal or institutional in nature and whether owned or operated by any person, the commonwealth or political subdivision thereof, the principal purpose of which is to provide, or facilitate the provision of, services for the prevention, detection, diagnosis or treatment of those physical and mental conditions experienced by humans which usually are the result of, or result in, disease, injury, deformity or pain.

The plan shall identify certain categories of health care resources, including acute care units; non-acute care units; specialty care units, including, but not limited to, burn, coronary care, cancer care, neonatal care, post-obstetric and post operative recovery care, pulmonary care, renal dialysis and surgical, including trauma and intensive care units; skilled nursing facilities; assisted living facilities; long-term care facilities; home health, behavioral health and mental health services; treatment and prevention services for alcohol and other drug abuse; emergency care; ambulatory care services; primary care resources; pharmacy and pharmacological services; family planning services; obstetrics and gynecology services; allied health services including, but not limited to, optometric care, chiropractic services, dental care and midwifery services; federally qualified health centers and free clinics; numbers of technologies or equipment defined as innovative services or new technologies by the department under *section 25C of chapter 111*; and health screening and early intervention services.

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(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (state health plan) to ensure that pain management is an essential part of patient care.

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STATUTES

Duties of the Department of Public Health

ALM GL ch. 111, § 24K

§ 24K. Pediatric Palliative Care Program

There is hereby established the pediatric palliative care program. Said program shall be administered by the department, subject to appropriation, under this section and regulations promulgated hereunder. The program shall assist eligible children with a life-limiting illness and their families or guardians with services designed to achieve an improved quality of life and to meet the physical, emotional and spiritual needs experienced during the course of illness, death and bereavement.

Children less than 19 years of age shall be eligible for said program if they meet the requirements established by the department, which shall include:--

(a) a diagnosis of a life-limiting illness, including but not limited to, cancer, AIDS, congenital anomalies and other advanced illnesses; provided however, no requirement regarding life expectancy shall be imposed; and

(b) a requirement that the eligible child not be covered by a third-party payer for the services provided by said program.

Services provided by the program shall be determined by the department and shall include, but not be limited to, consultations for pain and symptom management, case management and assessment, social services, counseling, bereavement services, volunteer support services, and respite services, provided by professional or volunteer staff under professional supervision. Services shall be provided by hospice programs licensed under section 57D who meet such other criteria as the department may establish by regulation, including demonstrated expertise in pediatric palliative care. The department may by regulation establish limits on services provided by said program. The program established by this section shall not give rise to enforceable legal rights in any party or an enforceable entitlement to the services described in this section and nothing stated in this section shall be construed as giving rise to such enforceable legal rights or such enforceable entitlement.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (palliative care program) to ensure that pain management is an essential part of care for pediatric patients.

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STATUTES

Palliative Care and End-of-Life Options

ALM GL ch. 111, § 227

§ 227. Disclosure of Palliative Care and End-of-Life Options.

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(b) The commissioner shall adopt regulations requiring each licensed hospital, skilled nursing facility, health center or assisted living facility to distribute to appropriate patients in its care information regarding the availability of palliative care and end-of-life options.

(c) If a patient is diagnosed with a terminal illness or condition, the patient's attending health care practitioner shall offer to provide the patient with information and counseling regarding palliative care and end-of-life options appropriate for the patient, including, but not limited to: (i) the range of options appropriate for the patient; (ii) the prognosis, risks and benefits of the various options; and (iii) the patient's legal rights to comprehensive pain and symptom management at the end-of-life. The information and counseling may be provided orally or in writing. Where the patient lacks capacity to reasonably understand and make informed choices relating to palliative care, the attending health care practitioner shall provide information and counseling under this section to a person with authority to make health care decisions for that patient. The attending health care practitioner may arrange for information and counseling under this section to be provided by another professionally qualified individual.

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(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Recognizes a practitioner's responsibility to provide patients information about pain management and palliative care when considering treatment options.

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REGULATIONS

Hospital Licensure

105 CMR 130.616

130.616: Administration and Staffing

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(D) Patient Care Policies. Each maternal and newborn service shall develop and implement written patient care policies and procedures, supported by evidence based resources, which shall include provisions for the following:

(1) Triage of patents presenting to the service to establish the diagnosis of labor, need for admission, transfer and/or other care management.
(2) Communication and decision making responsibilities with specified chain of command.
(3) Pain management, including the use of non pharmacological support techniques, analgesic medication and parenteral therapy. Routine standing orders shall not be permitted.

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(12) Care of the Newborn. Such policies shall provide for the following:

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(i) Comfort measures and reduction of pain and trauma during invasive procedures.

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(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (written policies) for hospitals to ensure that pain management is an essential part of patient care.

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MASSACHUSETTS

REGULATIONS

Hospice Licensure

105 CMR 141.204

141.204: Required Patient Care Services

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(C) Physician Services.

(1) Each hospice shall designate a physician to serve as Medical Director. The Medical Director shall have overall responsibility for the medical component of patient care and for ensuring achievement and maintenance of quality standards of professional medical care.

(2) The duties of the medical director shall include but need not be limited to:

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(k) Participating in establishing written programmatic guidelines for symptom control (*e.g.*, pain, nausea, vomiting, or other symptoms.)

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(H) Inpatient Care.

(1) The hospice shall provide or arrange for short-term inpatient care for the control of pain and management of acute and severe clinical problems that cannot be managed in a home setting.

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(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (Medical Director) for hospices to ensure that pain management is an essential part of patient care.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (short-term care) for hospices to ensure that pain management is an essential part of patient care.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (written programmatic guidelines) for hospices to ensure that pain management is an essential part of patient care.

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MICHIGAN

STATUTES

- CONTROLLED SUBSTANCES ACT
  Chapter 333. Health; Act 368 of 1978. Public Health Code; Article 7. Controlled Substances

- MEDICAL PRACTICE ACT
  Chapter 333. Health; Act 368 of 1978. Public Health Code; Article 15. Occupations; Part 170. Medicine

- OSTEOPATHIC PRACTICE ACT
  Chapter 333. Health; Act 368 of 1978. Public Health Code; Article 15. Occupations; Part 175. Osteopathic Medicine and Surgery

- PHARMACY PRACTICE ACT
  Chapter 333. Health; Act 368 of 1978. Public Health Code; Article 15. Occupations; Part 177. Pharmacy Practice and Drug Control

- INTRACTABLE PAIN TREATMENT ACT
  No policy found

REGULATIONS

- CONTROLLED SUBSTANCES REGULATIONS *(Part of Pharmacy Board Regulations)*
  Department of Licensing and Regulatory Affairs; Director's Office; Pharmacy – Controlled Substances

- MEDICAL BOARD REGULATIONS (*No provisions found*)
  Department of Licensing and Regulatory Affairs; Director's Office; Medicine – General Rules

- OSTEOPATHIC BOARD REGULATIONS (*No provisions found*)
  Department of Licensing and Regulatory Affairs; Director's Office; Osteopathic Medicine and Surgery – General Rules

- PHARMACY BOARD REGULATIONS
  Department of Licensing and Regulatory Affairs; Director's Office; Pharmacy – General Rules

OTHER GOVERNMENTAL POLICIES

- PHARMACY BOARD GUIDELINE
  Michigan Board of Pharmacy. *Michigan Board of Pharmacy Guidelines for the Use of Controlled Substances for the Treatment of Pain*. Adopted: ND.

- JOINT BOARD GUIDELINE
  Michigan Boards of Medicine and Osteopathic Medicine & Surgery. *Michigan Guidelines for the Use of Controlled Substances for the Treatment of Pain*. Adopted: Late 2003.

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RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY KEY WORD SEARCHES

- END-OF-LIFE CARE
  Chapter 333. Health; Act 368 of 1978. Public Health Code;
  Article 5. Prevention and Control of Diseases and Disabilities; Part 56A. End-of-Life Care

- PROFESSIONAL PRACTICE
  Chapter 333. Health; Act 368 of 1978. Public Health Code;
  Article 15. Occupations; Part 161. General Provisions

- FACILITIES AND AGENCIES
  Chapter 333. Health; Act 368 of 1978. Public Health Code;
  Article 17. Facilities and Agencies

- HOSPICE AND HOSPICE RESIDENCES SERVICES
  Department of Consumer and Industry Services; Director's Office;
  Hospice and Hospice Residences; Part 3. Services

MICHIGAN

STATUTES

Controlled Substances Act

(+) *CRITERION 3:*
Opioids are part of professional practice

MCLS § 333.7109

§ 333.7109. Definitions; P to U.

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(3) "Practitioner" means:

(a) A prescriber or pharmacist, a scientific investigator as defined by rule of the administrator, or other person licensed, registered, or otherwise permitted to distribute, dispense, conduct research with respect to, or administer a controlled substance in the course of professional practice or research in this state, including an individual in charge of a dog pound or animal shelter licensed or registered by the department of agriculture pursuant to *1969 PA 287, MCL 287.331* to *287.340*, or a class B dealer licensed by the United States department of agriculture pursuant to the animal welfare act, Public Law 89-544, *7 U.S.C. 2131* to 2147, 2149, and 2151 to 2159 and the department of agriculture pursuant to *1969 PA 224, MCL 287.381* to *287.395*, for the limited purpose of buying, possessing, and administering a commercially prepared, premixed solution of sodium pentobarbital to practice euthanasia on animals.

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MCLS § 333.7333a

§ 333.7333a. Electronic monitoring system.

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(7) The department, in consultation with the controlled substances advisory commission, the Michigan board of pharmacy, the Michigan board of medicine, the Michigan board of osteopathic medicine and surgery, the Michigan state police, and appropriate medical professional associations, shall examine the need for and may promulgate rules for the production of a prescription form on paper that minimizes the potential for forgery. The rules shall not include any requirement that sequential numbers, bar codes, or symbols be affixed, printed, or written on a prescription form or that the prescription form be a state produced prescription form. In examining the need for rules for the production of a prescription form on paper that minimizes the potential for forgery, the department shall consider and identify the following:

(a) Cost, benefits, and barriers.

(b) Overall cost-benefit analysis.

(c) Compatibility with the electronic monitoring system required under this section.

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(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT*:* Recognizes characteristics of prescription monitoring programs that are believed to impede the appropriate medical use of Schedule II controlled substances.

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STATUTES

Medical Practice Act

MCLS § 333.17033

§ 333.17033. Renewal of license; continuing education requirements.

Sec. 17033. (1) Notwithstanding the requirements of part 161, the board may require a licensee seeking renewal of a license to furnish the board with satisfactory evidence that during the 3 years immediately preceding application for renewal the licensee has attended continuing education courses or programs approved by the board totaling not less than 150 hours in subjects related to the practice of medicine including, but not limited to, medical ethics and designed to further educate licensees.

(2) As required under section 16204, the board shall promulgate rules requiring each applicant for license renewal to complete as part of the continuing education requirement of subsection (1) an appropriate number of hours or courses in pain and symptom management.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (mandatory continuing education) to provide practitioners information/education about pain management.

STATUTES

Osteopathic Practice Act

MCLS § 333.17533

§ 333.17533. Renewal of license; continuing education requirements.

Sec. 17533. (1) Notwithstanding the requirements of part 161, the board may require a licensee seeking renewal of a license to furnish the board with satisfactory evidence that during the 3 years immediately preceding an application for renewal the licensee has attended continuing education courses or programs approved by the board and totaling not less than 150 hours in subjects related to the practice of osteopathic medicine and surgery and designed to further educate licensees.

(2) As required under section 16204, the board shall promulgate rules requiring each applicant for license renewal to complete as part of the continuing education requirement of subsection (1) an appropriate number of hours or courses in pain and symptom management.

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(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (mandatory continuing education) to provide practitioners information/education about pain management.

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STATUTES

Pharmacy Practice Act

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (mandatory continuing education) to provide practitioners information/education about pain management.

MCLS § 333.17731

§ 333.17731. Renewal of license; continuing education requirements.

Sec. 17731. (1) Notwithstanding the requirements of part 161, the board may require a licensee seeking renewal of a pharmacist's license to furnish the board with satisfactory evidence that during the 2 years immediately preceding application for renewal the applicant has attended continuing education courses or programs, approved by the board, totaling not less than 30 hours or the satisfactory completion of a proficiency examination according to rules promulgated by the board.

(2) As required under section 16204, the board shall promulgate rules requiring each applicant for license renewal to complete as part of the continuing education or proficiency examination requirement of subsection (1) an appropriate number of hours or courses in pain and symptom management.

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REGULATIONS

Controlled Substances Regulations

Mich. Admin. Code R 338.3170

R 338.3170 Dispensing and administering controlled substances by prescribers.

Rule 70. (1) A prescriber in the course of his or her professional practice only, may dispense or administer, or both, a controlled substance listed in schedules 2 to 5 or he or she may cause them to be administered by an assistant under personal charge supervision.

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(+) CRITERION 3:
Opioids are part of professional practice

REGULATIONS

Pharmacy Board Regulations

MICH. ADMIN. CODE R 338.3041

R 338.3041 Continuing education requirements; applicability.

Rule 1. (1) These rules apply to applications for renewal of a pharmacist's license. A renewal shall not be granted unless the applicant has fulfilled the requirements of these rules.

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(6) An applicant for license renewal shall complete in each renewal period at least 1 continuing education hour in pain management, as required under section 16204 of the code. This subrule takes effect July 1, 2007.

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(+) CRITERION 8:
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (continuing education) to provide practitioners information/education about pain management.

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OTHER GOVERNMENTAL POLICY

Pharmacy Board Guideline

Michigan Board of Pharmacy Guidelines for the Use of Controlled Substances for the Treatment of Pain

Section I: Preamble

The Michigan Board of Pharmacy recognizes that principles of quality pharmacy practice dictate that the people of the State of Michigan have access to appropriate and effective pain relief. The appropriate application of up-to-date knowledge and treatment modalities can serve to improve the quality of life for those patients who suffer from pain as well as reduce the morbidity and costs associated with untreated or inappropriately treated pain. The Board encourages pharmacists to view effective pain management as a part of quality health care for all patients with pain, acute or chronic, and it is especially important for patients who experience pain as a result of terminal illness. All pharmacists should become knowledgeable about effective methods of pain treatment as well as statutory requirements for prescribing and dispensing controlled substances.

Inadequate pain control may result from a health care provider's lack of knowledge about pain management or from an inadequate understanding of addiction. Fears of investigation or sanction by federal, state and local regulatory agencies may also result in inappropriate or inadequate treatment of chronic pain patients. Accordingly, these guidelines have been developed to clarify the position of the Board on pain control, specifically as related to the use of controlled substances, in order to alleviate uncertainty of pharmacists and to encourage better pain management.

The Board recognizes that controlled substances, including opioid analgesics, may be essential in the treatment of acute pain due to trauma or surgery and chronic pain, whether due to cancer or non-cancer origins. The medical management of pain should be based on current knowledge and research and include the use of both pharmacologic and non-pharmacologic modalities. Pain should be assessed and treated promptly, and the quantity and frequency of doses should be adjusted according to the intensity and duration of the pain. Pharmacists should recognize that tolerance and physical dependence are normal consequences of sustained use of opioid analgesics and are not synonymous with addiction. Pharmacists should also be aware that pseudoaddiction may develop as a direct consequence of inadequate pain management.

The Board is obligated under the laws of the State of Michigan to protect the public health and safety. The Board recognizes that inappropriate prescribing and dispensing of controlled substances, including opioid analgesics, may lead to drug diversion and abuse by individuals who seek them for other than legitimate medical use. Pharmacists should be diligent in preventing the diversion of drugs for illegitimate purposes.

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(+) *CRITERION 2:*
Pain management is part of healthcare practice

(+) *CRITERION 4:*
Pain management is encouraged

(+) CRITERION 7:
Physical dependence or analgesic tolerance are not confused with "addiction"

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Identifies the potential impact of important barriers on the provision of effective pain care.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT*:* Clarifies for pharmacists the important distinction between drug-seeking behaviors resulting from poorly treated pain (i.e., pseudoaddiction) and drug-seeking behaviors related to abuse or addiction; this language identifies a potential clinical situation and attempts to lessen its impact on patient treatment.

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OTHER GOVERNMENTAL POLICY

Pharmacy Board Guideline

(CONTINUED)

The following are reference sources that provide sound approaches to the management of pain:

1. Acute Pain Management Guideline Panel. Acute Pain Management: Operative or Medical Procedures and Trauma. *Clinical Practice Guideline.* AHCPR Publication No. 92-0032. Rockville, Md. Agency for Health Care Policy and Research. U.S. Department of Health and Human Resources, Public Health Service. February 1992.

2. Jacox A, Carr DB, Payne R, et al. Management of Cancer Pain. *Clinical Practice Guideline No. 9.* AHCPR Publication No. 94-0592. Rockville, Md. Agency for Health Care Policy and Research. U.S. Department of Health and Human Resources, Public Health Service. March 1994.

3. Lipman AG, *Pain Management for Primary Care Clinicians* . 1st ed. American Society of Health System Pharmacists: Bethesda. 2004.

(+) *CRITERION 5:*
Addresses fear of regulatory scrutiny

Pharmacists should not fear disciplinary action from the Board or other state regulatory or enforcement agency for dispensing controlled substances, including opioid analgesics, for a legitimate medical purpose and in the usual course of professional practice. The Board will consider control of patients' pain to constitute a legitimate medical purpose when the prescribing and dispensing of controlled substances is based on accepted scientific knowledge of the treatment of pain and/or when based on sound clinical grounds.

(+) *CRITERION 3:*
Opioids are part of professional practice

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT*:*
Acknowledges need for treatment flexibility for physicians to respond to individual clinical circumstances, as long as their prescribing maintains the standards of good medical practice.

The Board will not take disciplinary action against a pharmacist for failing to adhere strictly to the provisions of these guidelines, if good cause is shown for such deviation. In each case, the conduct of the pharmacist will be evaluated to a great extent by patient outcome, taking into account whether the drug used is medically and/or pharmacologically recognized to be appropriate for the patient's condition**.** In addition, the pharmacist will have taken steps in good faith to assure safe and effective medication use and to prevent possible drug diversion.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT*:* Represents the principle of Balance, which states that efforts to reduce the abuse and diversion of controlled substances should not interfere with legitimate medical use.

Section II: Guidelines

The following guidelines are not intended to define complete or best practices, but rather to communicate what the Board considers to be minimum standards of practice for pharmacists caring for patients requiring pain control and presenting with prescriptions for controlled substances.

Review of the Prescription

The pharmacist should exercise due diligence to verify that each prescription for a controlled substance has been issued for a legitimate medical purpose. The review should include, but not necessarily be limited to, a careful review of the prescription document for evidence of forgery or alteration, a discussion with the patient regarding the signs and symptoms of the disorder or disease and the diagnosis, a review of the patient's prescription records, and/or a discussion with the prescriber. The pharmacist may also determine that a query to the Michigan Automated Prescription System (MAPS) is warranted if fraud is suspected. Each of these and/or other steps taken to assure the validity of a prescription should be documented and filed in a readily retrievable manner.

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MICHIGAN

OTHER GOVERNMENTAL POLICY

Pharmacy Board Guideline

(CONTINUED)

Fictitious or Possibly Fictitious Prescriptions

When a pharmacist is reasonably certain that a prescription is fictitious, he/she should contact the appropriate law enforcement agency. In cases where the pharmacist suspects, but cannot be certain, that a prescription is fictitious, he/she should take necessary steps to help assure that a patient's symptoms are managed during the time it takes to confirm the validity of the prescription. In these cases, the pharmacist should also be certain to obtain positive patient identification in case the event must later be reported to enforcement agencies. The pharmacist may also determine that a query to the Michigan Automated Prescription System (MAPS) is warranted.

Prescription Refills

The pharmacist should evaluate the patient at each refill of a controlled substance to help assure that positive, intended outcomes are achieved and that the patient is not experiencing untoward effects. This evaluation should include but not necessarily be limited to, a discussion with the patient regarding signs and symptoms of the condition being treated, a review of signs and symptoms of untoward effects, a review of the patient's prescription records, and/or a discussion with the prescriber regarding the need for continuation or modification of therapy.

Special attention should be given to those pain patients who are at risk for misusing their medications. The management of pain in patients with a history of substance abuse or with a co-morbid psychiatric disorder may require extra care, monitoring, documentation and consultation with or referral to an expert in the management of such patients.

The steps undertaken in the process of evaluation should be documented and filed in a readily retrievable manner.

Patient Referral

When a patient presents with a prescription for a controlled substance that is not stocked in the pharmacy, the pharmacist should make every effort to refer the patient to another proper source of care to help assure the patient finds access to medication required for symptom relief.

Section III: Definitions

For the purposes of these guidelines, the following terms are defined as follows:

Acute Pain
Acute pain is the normal, predicted physiological response to an adverse chemical, thermal or mechanical stimulus and is associated with surgery, trauma and acute illness. It is generally time-limited and is responsive to opioid therapy, among other therapies.

Addiction
Addiction is a neurobehavioral syndrome with genetic and environmental influences that results in psychological dependence on the use of substances for their psychic effects and is characterized by compulsive use despite harm. Addiction may also be referred to by terms such as "drug dependence" and "psychological dependence." Physical dependence and tolerance are normal physiological consequences of extended opioid therapy for pain and should not be considered addiction.

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(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY B:
Issues related to patients

COMMENT:
Acknowledges that a patient's prior history or current status of drug abuse does not necessarily contraindicate appropriate pain management.

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MICHIGAN

OTHER GOVERNMENTAL POLICY

Pharmacy Board Guideline

(CONTINUED)

Analgesic Tolerance
Analgesic tolerance is the need to increase the dose of opioid to achieve the same level of analgesia. Analgesic tolerance may or may not be evident during opioid treatment and does not equate with addiction.

Chronic Pain
A state of pain which is persistent and in which the cause of the pain cannot be removed or otherwise treated. Chronic pain may be associated with a long-term incurable or intractable medical condition or disease.

Controlled Substance
A controlled substance is a drug, substance, or immediate precursor included in schedules 1 to 5 of Article 7, part 72, of Public Act 368 of 1978 as amended (the Michigan Public Health Code).

Dispense
Dispense means to deliver or issue a controlled substance to an ultimate user or research subject by or pursuant to the lawful order of a practitioner, including prescribing, administering, or compounding necessary to prepare the substance for the delivery or issuance.

Dispenser
Dispenser means a practitioner that dispenses.

Good Faith
The prescribing or dispensing of a controlled substance by a practitioner licensed under section 333.7303 of the Michigan Public Health Code, in the regular course of professional treatment to, or for, an individual who is under treatment by a practitioner for a pathology or condition other than that individual's physical or psychological dependence upon or addiction to a controlled substance, except as provided in this article. Application of good faith to a pharmacist is the dispensing of a controlled substance pursuant to a prescriber's order that, in the professional judgment of the pharmacist, is lawful. The pharmacist shall be guided by nationally accepted professional standards including, but not limited to, all of the following, in making the judgment:

(a) Lack of consistency in the doctor-patient relationship
(b) Frequency of prescriptions for the same drug by one prescriber for larger numbers of patients
(c) Quantities beyond those normally prescribed for the same drug
(d) Unusual dosages
(e) Unusual geographic distances between patient, pharmacist, and prescriber.

Pain
An unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage.

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Pharmacy Board Guideline

(CONTINUED)

Pharmacy Practice
Pharmacy practice means a health service, the clinical application of which includes the encouragement of safety and efficacy in the prescribing, dispensing, administering, and use of drugs and related articles for the prevention of illness, and the maintenance and management of health. Professional functions associated with the practice of pharmacy include:

(a) The interpretation and evaluation of the prescription
(b) Drug product selection
(c) The compounding, dispensing, safe storage, and distribution of drugs and devices.

Physical Dependence
Physical dependence on a controlled substance is a physiologic state of neuro-adaptation which is characterized by the emergence of a withdrawal syndrome if drug use is stopped or decreased abruptly, or if an antagonist is administered. Physical dependence is an expected result of opioid use. Physical dependence, by itself, does not equate with addiction.

Positive Identification
Positive identification means identification that includes a photograph of an individual in addition to his or her date of birth. Positive identification shall include an identification card issued by a governmental agency provided the ID card meets these requirements.

Practitioner
A prescriber or pharmacist, a scientific investigator as defined by rule or the administrator, or other person, licensed, registered, or otherwise permitted to distribute, dispense, conduct research with respect to or administer a controlled substance in the course of the professional practice or research in this state.

A pharmacy, hospital, or other institution or place of professional practice licensed, registered, or otherwise permitted to distribute, prescribe, dispense, conduct research with respect to, administer a controlled substance in the course of professional practice or research in this state.

Pseudoaddiction
Pseudoaddiction is the term that describes patient drug-seeking behaviors that may develop as a direct consequence of inadequate pain management. Pseudoaddiction can be distinguished from true addiction in that the behaviors resolve when the pain is effectively treated.

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MICHIGAN

OTHER GOVERNMENTAL POLICY

Joint Board Guideline

Michigan Guidelines for the Use of Controlled Substances for the Treatment of Pain

Section I: Preamble

The Michigan Boards of Medicine and Osteopathic Medicine & Surgery recognize that principles of quality medical practice dictate that the people of the State of Michigan have access to appropriate and effective pain relief. The appropriate application of up-to-date knowledge and treatment modalities can serve to improve the quality of life for those patients who suffer from pain as well as reduce the morbidity and costs associated with untreated or inappropriately treated pain. The Board encourages physicians to view effective pain management as a part of quality medical practice for all patients with pain, acute or chronic, and it is especially important for patients who experience pain as a result of terminal illness. All physicians should become knowledgeable about effective methods of pain treatment as well as statutory requirements for prescribing controlled substances.

Inadequate pain control may result from physicians' lack of knowledge about pain management or an inadequate understanding of addiction. Fears of investigation or sanction by federal, state and local regulatory agencies may also result in inappropriate or inadequate treatment of chronic pain patients. Accordingly, these guidelines have been developed to clarify the Boards' position on pain control, specifically as related to the use of controlled substances, to alleviate physician uncertainty and to encourage better pain management.

The Boards recognize that controlled substances, including opioid analgesics, may be essential in the treatment of acute pain due to trauma or surgery and chronic pain, whether due to cancer or non-cancer origins. Physicians are referred to the U.S. Agency for Health Care and Research Clinical Practice Guidelines for a sound approach to the management of acute (1) and cancer-related pain (2). The medical management of pain should be based on current knowledge and research and include the use of both pharmacologic and non-pharmacologic modalities. Pain should be assessed and treated promptly, and the quantity and frequency of doses should be adjusted according to the intensity and duration of the pain. Physicians should recognize that tolerance and physical dependence are normal consequences of sustained use of opioid analgesics and are not synonymous with addiction.

The Boards are obligated under the laws of the State of Michigan to protect the public health and safety. The Boards recognize that inappropriate prescribing of controlled substances, including opioid analgesics, may lead to drug diversion and abuse by individuals who seek them for other than legitimate medical use. Physicians should be diligent in preventing the diversion of drugs for illegitimate purposes.

1. Acute Pain Management Guideline Panel. Acute Pain Management: Operative or Medical Procedures and Trauma. Clinical Practice Guideline. AHCPR Publication No. 92-0032. Rockville, Md. Agency for Health Care Policy and Research. U.S. Department of Health and Human Resources, Public Health Service. February 1992.

2. Jacox A, Carr DB, Payne R, et al. Management of Cancer Pain. Clinical Practice Guideline No. 9. AHCPR Publication No. 94-0592. Rockville, Md. Agency for Health Care Policy and Research. U.S. Department of Health and Human Resources, Public Health Service. March 1994.

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(+) CRITERION 8:
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Identifies the potential impact of important barriers on the provision of effective pain care.

(+) CRITERION 7:
Physical dependence or analgesic tolerance are not confused with "addiction"

(+) CRITERION 2:
Pain management is part of healthcare practice

(+) CRITERION 4:
Encourages pain management

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University of Wisconsin Carbone Cancer Center
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OTHER GOVERNMENTAL POLICY

Joint Board Guideline

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Physicians should not fear disciplinary action from the Board or other state regulatory or enforcement agency for prescribing, dispensing or administering controlled substances, including opioid analgesics, for a legitimate medical purpose and in the usual course of professional practice. The Board will consider prescribing, ordering, administering or dispensing controlled substances for pain to be for a legitimate medical purpose if based on accepted scientific knowledge of the treatment of pain or if based on sound clinical grounds. All such prescribing must be based on clear documentation of unrelieved pain and in compliance with applicable state or federal law.

Each case of prescribing for pain will be evaluated on an individual basis. The board will not take disciplinary action against a physician for failing to adhere strictly to the provisions of these guidelines, if good cause is shown for such deviation. The physician's conduct will be evaluated to a great extent by the treatment outcome, taking into account whether the drug used is medically and/or pharmacologically recognized to be appropriate for the diagnosis, the patient's individual needs—including any improvement in functioning—and recognizing that some types of pain cannot be completely relieved.

The Boards will judge the validity of prescribing based on the physician's treatment of the patient and on available documentation, rather than on the quantity and chronicity of prescribing. The goal is to control the patient's pain for its duration while effectively addressing other aspects of the patient's functioning, including physical, psychological, social and work-related factors. The following guidelines are not intended to define complete or best practice, but rather to communicate what the Boards consider to be within the boundaries of professional practice.

Section II: Guidelines

The Boards have adopted the following guidelines when evaluating the use of controlled substances for pain control:

1. Evaluation of the Patient

A complete medical history and physical examination must be conducted and documented in the medical record. The medical record should document the nature and intensity of the pain, current and past treatments for pain, underlying or coexisting diseases or conditions, the effect of the pain on physical and psychological function, and history of substance abuse. The medical record also should document the presence of one or more recognized medical indications for the use of a controlled substance.

2. Treatment Plan

The written treatment plan should state objectives that will be used to determine treatment success, such as pain relief and improved physical and psychosocial function, and should indicate if any further diagnostic evaluations or other treatments are planned. After treatment begins, the physician should adjust drug therapy to the individual medical needs of each patient. Other treatment modalities or a rehabilitation program may be necessary depending on the etiology of the pain and the extent to which the pain is associated with physical and psychosocial impairment.

(CONTINUED ON NEXT PAGE)

(+) CRITERION 5:
Addresses fear of regulatory scrutiny

(+) CRITERION 8:
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT*:*
Acknowledges need for treatment flexibility for physicians to respond to individual clinical circumstances, as long as their prescribing maintains the standards of good medical practice.

(+) CRITERION 3:
Opioids are part of professional practice

(+) CRITERION 6:
Prescription amount alone does not determine legitimacy

(+) CRITERION 8:
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Recognizes that the goal of pain treatment should include improvements in patient functioning and quality of life.

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Joint Board Guideline

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Encourages healthcare professionals to incorporate in their practice the evaluations of, and discussions with patients about, the potential benefits and risks of treatment with opioids, which can better ensure a clinical indication of such treatment so that opioids will be used for medical purposes.

(CONTINUED)

3. Informed Consent and Agreement for Treatment

The physician should discuss the risks and benefits of the use of controlled substances with the patient, persons designated by the patient or with the patient's surrogate or guardian if the patient is incompetent. The patient should receive prescriptions from one physician and one pharmacy where possible. If the patient is determined to be at high risk for medication abuse or have a history of substance abuse, the physician may employ the use of a written agreement between physician and patient outlining patient responsibilities, including

- o urine/serum medication levels screening when requested;
- o number and frequency of all prescription refills; and
- o reasons for which drug therapy may be discontinued (i.e., violation of agreement).

4. Periodic Review

At reasonable intervals based on the individual circumstances of the patient, the physician should review the course of treatment and any new information about the etiology of the pain. Continuation or modification of therapy should depend on the physician's evaluation of progress toward stated treatment objectives, such as improvement in patient's pain intensity and improved physical and/or psychosocial function, i.e., ability to work, need of health care resources, activities of daily living and quality of social life. If treatment goals are not being achieved, despite medication adjustments, the physician should reevaluate the appropriateness of continued treatment. The physician should monitor patient compliance in medication usage and related treatment plans.

5. Consultation

The physician should be willing to refer the patient as necessary for additional evaluation and treatment in order to achieve treatment objectives. Special attention should be given to those pain patients who are at risk for misusing their medications and those whose living arrangement pose a risk for medication misuse or diversion. The management of pain in patients with a history of substance abuse or with a comorbid psychiatric disorder may require extra care, monitoring, documentation and consultation with or referral to an expert in the management of such patients.

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(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY B:
Issues related to patients

COMMENT:
Acknowledges that a patient's prior history or current status of drug abuse does not necessarily contraindicate appropriate pain management.

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MICHIGAN

OTHER GOVERNMENTAL POLICY

Joint Board Guideline

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6. Medical Records

The physician should keep accurate and complete records to include

- o the medical history and physical examination;
- o diagnostic, therapeutic and laboratory results;
- o evaluations and consultations;
- o treatment objectives;
- o discussion of risks and benefits;
- o treatments;
- o medications (including date, type, dosage and quantity prescribed);
- o instructions and agreements; and
- o periodic reviews.

Records should remain current and be maintained in an accessible manner and readily available for review.

7. Compliance With Controlled Substances Laws and Regulations

To prescribe, dispense or administer controlled substances, the physician must be licensed in the state and comply with applicable federal and state regulations. Physicians are referred to the Physicians Manual of the U.S. Drug Enforcement Administration and (any relevant documents issued by the state medical board) for specific rules governing controlled substances as well as applicable state regulations.

Section III: Definitions

For the purposes of these guidelines, the following terms are defined as follows:

Acute Pain
Acute pain is the normal, predicted physiological response to an adverse chemical, thermal or mechanical stimulus and is associated with surgery, trauma and acute illness. It is generally time-limited and is responsive to opioid therapy, among other therapies.

Addiction
Addiction is a neurobehavioral syndrome with genetic and environmental influences that results in psychological dependence on the use of substances for their psychic effects and is characterized by compulsive use despite harm. Addiction may also be referred to by terms such as "drug dependence" and "psychological dependence." Physical dependence and tolerance are normal physiological consequences of extended opioid therapy for pain and should not be considered addiction.

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(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT*:* Encourages healthcare professionals to understand and follow federal and state laws governing their practice, which can better ensure that practitioners follow the *balanced* approach represented by federal law and the laws in many states.

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Joint Board Guideline

(CONTINUED)

Analgesic Tolerance
Analgesic tolerance is the need to increase the dose of opioid to achieve the same level of analgesia. Analgesic tolerance may or may not be evident during opioid treatment and does not equate with addiction.

Chronic Pain
A pain state which is persistent and in which the cause of the pain cannot be removed or otherwise treated. Chronic pain may be associated with a long-term incurable or intractable medical condition or disease.

Pain
An unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage.

Physical Dependence
Physical dependence on a controlled substance is a physiologic state of neuro-adaptation which is characterized by the emergence of a withdrawal syndrome if drug use is stopped or decreased abruptly, or if an antagonist is administered. Physical dependence is an expected result of opioid use. Physical dependence, by itself, does not equate with addiction

Pseudoaddiction
Pattern of drug-seeking behavior of pain patients who are receiving inadequate pain management that can be mistaken for addiction.

Substance Abuse
Substance abuse is the use of any substance(s) for non-therapeutic purposes or use of medication for purposes other than those for which it is prescribed.

Tolerance
Tolerance is a physiologic state resulting from regular use of a drug in which an increased dosage is needed to produce the same effect, or a reduced effect is observed with a constant dose.

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MICHIGAN

STATUTES

End-of-Life Care

MCLS § 333.5655

§ 333.5655. Recommended medical treatment for advanced illness; duty of physician to inform orally and in writing; requirements.

Sec. 5655. In addition to the requirements of section 5654, a physician who has diagnosed a patient as having a reduced life expectancy due to an advanced illness and is recommending medical treatment for the patient shall, both orally and in writing, inform the patient, the patient's patient surrogate, or, if the patient has designated a patient advocate and is unable to participate in medical treatment decisions, the patient advocate, of all of the following:

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(d) That the patient or the patient's surrogate or patient advocate acting on behalf of the patient may choose adequate and appropriate pain and symptom management as a basic and essential element of medical treatment.

MCL § 333.5658

§ 333.5658. Prescription of controlled substance; immunity from administrative and civil liability.

Sec. 5658. A physician who, as part of a medical treatment plan for a terminally ill patient, prescribes for the terminally ill patient a controlled substance that is included in schedules 2 to 5 under part 72 and that is a narcotic drug is immune from administrative and civil liability based on prescribing the controlled substance if the prescription is given in good faith and with the intention to treat a patient with a terminal illness or alleviate the patient's pain, or both, and all of the following are met:

(a) The prescription is for a legitimate legal and professionally recognized therapeutic purpose.

(b) Prescribing the controlled substance is within the scope of practice of the physician.

(c) The physician holds a valid license under article 7 to prescribe controlled substances.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY B:
Issues related to patients

COMMENT: Recognizes the patient's right to request or reject different types of treatments.

(+) CRITERION 5:
Addresses fear of regulatory scrutiny

COMMENT: The immunity provision is valid only for physicians who prescribe for pain patients according to prognosis.

(+) *CRITERION 2:*
Pain management is part of healthcare practice

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Madison, Wisconsin

MICHIGAN

STATUTES

Professional Practice

MCLS § 333.16204

§ 333.16204. Completion of courses in pain and symptom management as condition for license renewal; applicability.

Sec. 16204. (1) Effective for the renewal of licenses or registrations issued under this article and expiring after January 1, 1997 if the completion of continuing education is a condition for renewal, the appropriate board shall by rule require an applicant for renewal to complete an appropriate number of hours or courses in pain and symptom management. Rules promulgated by a board under section 16205(2) for continuing education in pain and symptom management shall cover both course length and content and shall take into consideration the recommendation for that health care profession by the interdisciplinary advisory committee created in section 16204a. A board shall submit the notice of public hearing for the rules as required under section 42 of the administrative procedures act of 1969, being *section 24.242 of the Michigan Compiled Laws*, not later than 90 days after the first interdisciplinary advisory committee makes its initial recommendations and shall promulgate the rules as expeditiously as possible.

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MCLS § 333.16204a

§ 333.16204a. Advisory committee on pain and symptom management; creation; members; compensation; expenses; terms; duties; review of guidelines.

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(4) The advisory committee shall do all of the following, as necessary:

(a) At least once annually consult with all of the following boards to develop an integrated approach to understanding and applying pain and symptom management techniques:

(i) All licensure boards created under this article, except the Michigan board of veterinary medicine.

(ii) The Michigan board of social work created in section 18505 .

(b) Hold a public hearing in the same manner as provided for a public hearing held under the administrative procedures act of 1969, within 90 days after the members of the advisory committee are appointed under subsection (1) to gather information from the general public on issues pertaining to pain and symptom management.

(c) Develop and encourage the implementation of model core curricula on pain and symptom management.

(d) Develop recommendations to the licensing and registration boards and the task force created under this article on integrating pain and symptom management into the customary practice of health care professionals and identifying the role and responsibilities of the various health care professionals in pain and symptom management.

(e) Advise the licensing and registration boards created under this article on the duration and content of continuing education requirements for pain and symptom management.

(f) Annually report on the activities of the advisory committee and make recommendations on the following issues to the director of the department of consumer and industry services and to the director of the department of community health:

(i) Pain management educational curricula and continuing educational requirements of institutions providing health care education.

(ii) Information about the impact and effectiveness of previous recommendations, if any, that have been implemented, including, but not limited to, recommendations made under subdivision (d).

(iii) Activities undertaken by the advisory committee in complying with the duties imposed under subdivisions (c) and (d).

(g) Beginning in January of 2000, annually review any changes occurring in pain and symptom management.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (mandatory continuing education) to provide practitioners information/education about pain management.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (advisory committee) to improve pain management.

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MICHIGAN

STATUTES

Professional Practice

MCLS § 333.16204b

§ 333.16204b. Treatment of pain; enactment of legislation.

Sec. 16204b. The legislature finds that the treatment of pain is an appropriate issue for the legislature to consider, and that the citizens of this state would be well served by the enactment of legislation that accomplishes all of the following:

(a) Provides more and better information to health care consumers regarding the medical treatment of pain, health care coverage and benefits for the treatment of pain, and the education of health professionals in pain and symptom management.

(b) Provides for the appointment of an advisory body to study and make recommendations on model core curricula on pain and symptom management for the institutions in this state providing health care education, continuing education for health professionals on pain and symptom management, and the integration of pain and symptom management into the customary practice of health care.

(c) Educates health professionals about the disciplinary process for state licensees and registrants, including, but not limited to, how the department of consumer and industry services processes allegations of wrongdoing against licensees and registrants.

(+) *CRITERION 2:*
Pain management is part of healthcare practice

MCLS § 333.16204c

§ 333.16204c. Medical treatment of pain; use of controlled substances; legislative findings; treatment by licensed health professionals; electronic monitoring system; "controlled substance" defined.

(+) *CRITERION 3:*
Opioids are part of professional practice

Sec. 16204c. (1) The legislature finds that the use of controlled substances is appropriate in the medical treatment of certain forms of pain, and that efforts to control diversion or improper administration of controlled substances should not interfere with the legitimate, medically recognized use of those controlled substances to relieve pain and suffering.

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(+) *CRITERION 4:*
Encourages pain management

(3) It is the intent of the legislature to permit and facilitate adequate treatment for pain by licensed health professionals, including, but not limited to, the prescription or dispensing of controlled substances included in schedule 2 under section 7214, when medically appropriate , and to enable regulatory and law enforcement agencies to prevent the abuse and diversion of controlled substances by creating an electronic monitoring system.

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(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Represents the principle of Balance, which states that the regulation of controlled substances should not interfere with legitimate medical use.

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MICHIGAN

STATUTES

Professional Practice

MCL § 333.16204d

§ 333.16204d. Information booklet on pain; development by department of consumer and industry services; educational program for health professionals.

Sec. 16204d. (1) The department of consumer and industry services, in consultation with the department of community health, shall develop, publish, and distribute an informational booklet on pain. The department of consumer and industry services shall include at least all of the following in the informational booklet:

(a) Pain management educational curricula and continuing educational requirements of institutions providing health care education recommended by the advisory committee on pain and symptom management under section 16204a.

(b) Other information considered relevant or useful by the department of consumer and industry services.

(2) The department of consumer and industry services, in conjunction with the controlled substances advisory commission created in article 7, shall develop and conduct an educational program for health professionals who are licensed under part 73 to prescribe or dispense, or both, controlled substances. The department of consumer and industry services shall include, at a minimum, all of the following in the educational program:

(a) Information on how the department of consumer and industry services processes allegations of wrongdoing against licensees under this article and article 17, including, but not limited to, how the permanent historical record is maintained for each licensee, how and why a review of the permanent historical record is done, and how the decision is made to issue a formal complaint against a licensee.

(b) Information on the disciplinary process, including a licensee's rights and duties if an allegation of wrongdoing is filed against the licensee or if some other circumstance occurs that causes or requires the department of consumer and industry services to review a licensee's permanent historical record.

(c) Other information considered relevant or useful by the department of consumer and industry services or the controlled substances advisory commission, especially information that would address the findings and statements of intent contained in section 16204c.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (information booklet) to provide practitioners information/education about pain management.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (educational program) to provide practitioners information/education about the disciplinary process regarding the treatment of pain.

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MICHIGAN

STATUTES

Facilities and Agencies

MCL § 333.20155

§ 333.20155. Visits to health facilities and agencies, clinical laboratories, nursing homes, hospices, and hospitals; purposes; waiver; confidentiality of accreditation information; limitation and effect; consultation engineering survey; summary of substantial noncompliance or deficiencies and hospital response; investigations or inspections; prior notice; misdemeanor; consultation visits; record; periodic reports; access to documents; confidentiality; disclosure; delegation of functions; voluntary inspections; forwarding evidence of violation to licensing agency; reports; clarification of terms; clinical process guidelines; clinical advisory committee; definitions.

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(25) Subject to subsection (27), the department, in consultation with the clarification work group appointed under subsection (16), shall develop and adopt clinical process guidelines. The department shall establish and adopt clinical process guidelines and compliance protocols with outcome measures for all of the following areas and for other topics where the department determines that clarification will benefit providers and consumers of long-term care:

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(f) Pain management.

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MCL § 333.20201

§ 333.20201. Policy describing rights and responsibilities of patients or residents; adoption; posting and distribution; contents; additional requirements; discharging, harassing, retaliating, or discriminating against patient exercising protected right; exercise of rights by patient's representative; informing patient or resident of policy; designation of person to exercise rights and responsibilities; additional patients' rights; definitions.

Sec. 20201. (1) A health facility or agency that provides services directly to patients or residents and is licensed under this article shall adopt a policy describing the rights and responsibilities of patients or residents admitted to the health facility or agency. Except for a licensed health maintenance organization which shall comply with chapter 35 of the insurance code of 1956, *1956 PA 218, MCL 500.3501* to *500.3580* , the policy shall be posted at a public place in the health facility or agency and shall be provided to each member of the health facility or agency staff. Patients or residents shall be treated in accordance with the policy.

(2) The policy describing the rights and responsibilities of patients or residents required under subsection (1) shall include , as a minimum , all of the following :

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(o) A patient or resident is entitled to adequate and appropriate pain and symptom management as a basic and essential element of his or her medical treatment.

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MCL § 333.21521

§ 333.21521. Hospital to meet minimum standards and rules; protection of health and safety; preventive function.

Sec. 21521. A hospital shall meet the minimum standards and rules authorized by this article and shall endeavor to carry out practices that will further protect the public health and safety, prevent the spread of disease, alleviate pain and disability, and prevent premature death.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (clinical process guidelines) for health facilities or agencies to ensure that pain management is an essential part of patient care.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (patient rights policy) for health facilities or agencies to ensure that pain management is an essential part of patient care.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a responsibility for hospitals to ensure that pain management is an essential part of patient care.

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MICHIGAN

REGULATIONS

Hospice and Hospice Residences Services

MICH. ADMIN. CODE R 325.13302

R 325.13302 Medical services.

Rule 302. (1) At the time of admission to the hospice program and its hospice residence, if applicable, and thereafter, a patient shall be under the care of a physician who shall be responsible for providing or arranging for medical care. This physician may be the attending physician.

(2) The physician providing the medical care to a patient shall be responsible for the direction and quality of medical care rendered to that patient.

(3) The physician shall review the patient's medical history and physical assessment within 48 hours before or following the patient's admission to the program.

(4) The physician shall do both of the following:

(a) Validate the prognosis and life expectancy of the patient.

(b) Assist in developing the care plan of the patient.

(5) Medical care shall emphasize prevention and control of pain and other distressing symptoms.

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MICH. ADMIN. CODE R 325.13304

R 325.13304 Nursing services.

Rule 304. (1) Nursing services in a hospice and its hospice residence, if applicable, shall be available directly or by written agreement 7 days a week, 24 hours per day and shall be under the supervision of a director of nursing who is registered and licensed in the state of Michigan.

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(6) The patient care plan shall give direction to the care given in meeting the physiological, psychological, sociological, and spiritual needs of the patient/family unit. The plan shall specifically address maintenance of patient independence and pain control.

(7) Resource materials relating to the administration and untoward effects of medications and treatments used in pain and symptom control shall be readily available to hospice and hospice residence personnel.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT*:* Establishes a responsibility for hospices to ensure that pain management is an essential part of patient care.

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MINNESOTA

STATUTES

- CONTROLLED SUBSTANCES ACT
  Health; Chapter 152. Drugs; Controlled Substances

- INTRACTABLE PAIN TREATMENT ACT (*Part of Controlled Substances Act*)
  Health; Chapter 152. Drugs; Controlled Substances; Prescriptions; Section 125

- MEDICAL PRACTICE ACT
  Health; Chapter 147. Board of Medical Practice

- PHARMACY PRACTICE ACT
  Health; Chapter 151. Pharmacy

REGULATIONS

- CONTROLLED SUBSTANCES REGULATIONS (*Part of Pharmacy Board Regulations*) (*No provisions found*)
  Board of Pharmacy; Chapter 6800. Pharmacies and Pharmacists

- MEDICAL BOARD REGULATIONS (*No provisions found*)
  Board of Medical Practice; Chapter 5600. Licensure and Registration

- PHARMACY BOARD REGULATIONS (*No provisions found*)
  Board of Pharmacy; Chapter 6800. Pharmacies and Pharmacists

OTHER GOVERNMENTAL POLICIES

- MEDICAL BOARD POLICY
  Minnesota Board of Medical Practice. *Model Policy for the Use of Controlled Substances for the Treatment of Pain*. Adopted: November 10, 2007.

- JOINT BOARD POLICY STATEMENT
  Minnesota Boards of Medical Practice, Nursing, and Pharmacy. *Joint Statement on Pain Management. Minnesota Board of Medical Practice Update*. Fall 2004, p. 3. Adopted: August, 2004; Reaffirmed: December, 2009.

RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY KEY WORD SEARCHES

- HOSPICE LICENSING
  Health; Chapter 144A. Nursing Homes and Home Care; Hospice Care Licensing

- HOMICIDE AND SUICIDE
  Crimes, Criminals; Chapter 609. Criminal Code; Homicide and Suicide

- HOSPICE SERVICES
  Department of Health; Chapter 4664. Hospice Services

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MINNESOTA

STATUTES

Controlled Substances Act

Minn. Stat. § 152.126

152.126 SCHEDULE II AND III CONTROLLED SUBSTANCES PRESCRIPTION ELECTRONIC REPORTING SYSTEM

Subdivision 1. *Definitions.* --For purposes of this section, the terms defined in this subdivision have the meanings given.

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Subd. 1a. *Treatment of intractable pain.* --This section is not intended to limit or interfere with the legitimate prescribing of controlled substances for pain. No prescriber shall be subject to disciplinary action by a health-related licensing board for prescribing a controlled substance according to the provisions of section 152.125.

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Subd. 3. *Prescription Electronic Reporting Advisory Committee.*

(a) The board shall convene an advisory committee. The committee must include at least one representative of:

(1) the Department of Health;

(2) the Department of Human Services;

(3) each health-related licensing board that licenses prescribers;

(4) a professional medical association, which may include an association of pain management and chemical dependency specialists;

(5) a professional pharmacy association;

(6) a professional nursing association;

(7) a professional dental association;

(8) a consumer privacy or security advocate; and

(9) a consumer or patient rights organization.

(b) The advisory committee shall advise the board on the development and operation of the electronic reporting system, including, but not limited to:

(1) technical standards for electronic prescription drug reporting;

(2) proper analysis and interpretation of prescription monitoring data; and

(3) an evaluation process for the program.

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Subd. 8. Evaluation and reporting.

(a) The board shall evaluate the prescription electronic reporting system to determine if the system is cost-effective and whether it is negatively impacting appropriate prescribing practices of controlled substances. The board may contract with a vendor to design and conduct the evaluation.

(b) The board shall submit the evaluation of the system to the legislature by July 15, 2011.

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(+) *CRITERION 8:*
OTHER PROVISIONS THAT MAY ENHANCE PAIN MANAGEMENT

CATEGORY C:
REGULATORY OR POLICY ISSUES

COMMENT: Recognizes that a PMP Advisory Committee's objective to review practitioner prescribing profiles could benefit from the involvement of a pain management expert.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Represents the principle of Balance, which states that the regulation of controlled substances should not interfere with legitimate medical use.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Identifies the prescription monitoring program as a potential barrier to the appropriate use of opioid analgesics.

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MINNESOTA

STATUTES

Intractable Pain Treatment Act

(-) *CRITERION 10:*
Implies opioids are not part of professional practice

Minn. Stat. § 152.125

152.125 Intractable pain

Subdivision 1. Definition. For purposes of this section, "intractable pain" means a pain state in which the cause of the pain cannot be removed or otherwise treated with the consent of the patient and in which, in the generally accepted course of medical practice, no relief or cure of the cause of the pain is possible, or none has been found after reasonable efforts. Reasonable efforts for relieving or curing the cause of the pain may be determined on the basis of, but are not limited to, the following:

(1) when treating a nonterminally ill patient for intractable pain, evaluation by the attending physician and one or more physicians specializing in pain medicine or the treatment of the area, system, or organ of the body perceived as the source of the pain; or

(2) when treating a terminally ill patient, evaluation by the attending physician who does so in accordance with the level of care, skill, and treatment that would be recognized by a reasonably prudent physician under similar conditions and circumstances.

(+) *CRITERION 2:*
Pain management is part of healthcare practice

Subd. 2. Prescription and administration of controlled substances for intractable pain. Notwithstanding any other provision of this chapter, a physician may prescribe or administer a controlled substance in schedules II to V of section 152.02 to an individual in the course of the physician's treatment of the individual for a diagnosed condition causing intractable pain. No physician shall be subject to disciplinary action by the board of medical practice for appropriately prescribing or administering a controlled substance in schedules II to V of section 152.02 in the course of treatment of an individual for intractable pain, provided the physician keeps accurate records of the purpose, use, prescription, and disposal of controlled substances, writes accurate prescriptions, and prescribes medications in conformance with chapter 147.

Subd. 3. Limits on applicability. This section does not apply to:

(1) a physician's treatment of an individual for chemical dependency resulting from the use of controlled substances in schedules II to V of section 152.02;

(2) the prescription or administration of controlled substances in schedules II to V of section 152.02 to an individual whom the physician knows to be using the controlled substances for nontherapeutic purposes;

(3) the prescription or administration of controlled substances in schedules II to V of section 152.02 for the purpose of terminating the life of an individual having intractable pain; or

(4) the prescription or administration of a controlled substance in schedules II to V of section 152.02 that is not a controlled substance approved by the United States Food and Drug Administration for pain relief.

Subd. 4. Notice of risks. Prior to treating an individual for intractable pain in accordance with subdivision 2, a physician shall discuss with the individual the risks associated with the controlled substances in schedules II to V of section 152.02 to be prescribed or administered in the course of the physician's treatment of an individual, and document the discussion in the individual's record.

(-) *CRITERION 16:*
Provisions that are ambiguous

CATEGORY B:
Unclear intent leading to possible misinterpretation

COMMENT: Although similar language is used in Federal regulation, in the context of this statute this definition suggests that physicians would qualify for the immunity and, thus, relief from concerns about regulatory scrutiny provided by this statute only if they prescribe opioids after other treatments have been tried and failed, regardless of other clinical considerations.

(+) *CRITERION 3:*
Opioids are part of professional practice

(+) *CRITERION 5:*
Addresses fear of regulatory scrutiny

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MINNESOTA

STATUTES

Medical Practice Act

Minn. Stat. § 147.081

147.081 Practicing without license; penalty

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Subd. 3. Practice of medicine defined. For purposes of this chapter, a person not exempted under section 147.09 is "practicing medicine" or engaged in the "practice of medicine" if the person does any of the following:

(1) advertises, holds out to the public, or represents in any manner that the person is authorized to practice medicine in this state;

(2) offers or undertakes to prescribe, give, or administer any drug or medicine for the use of another;

(3) offers or undertakes to prevent or to diagnose, correct, or treat in any manner or by any means, methods, devices, or instrumentalities, any disease, illness, pain, wound, fracture, infirmity, deformity or defect of any person;

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(+) *CRITERION 2:*
Pain management is part of healthcare practice

STATUTES

Pharmacy Practice Act

Minn. Stat. § 151.37

151.37 Legend drugs, who may prescribe, possess

Subdivision 1. Prohibition. Except as otherwise provided in this chapter, it shall be unlawful for any person to have in possession, or to sell, give away, barter, exchange, or distribute a legend drug.

Subd. 2. Prescribing and filing. (a) A licensed practitioner in the course of professional practice only, may prescribe, administer, and dispense a legend drug, and may cause the same to be administered by a nurse, a physician assistant, or medical student or resident under the practitioner's direction and supervision, and may cause a person who is an appropriately certified, registered, or licensed health care professional to prescribe, dispense, and administer the same within the expressed legal scope of the person's practice as defined in Minnesota Statutes. A licensed practitioner may prescribe a legend drug, without reference to a specific patient, by directing a nurse, pursuant to section 148.235, subdivisions 8 and 9, physician assistant, or medical student or resident to adhere to a particular practice guideline or protocol when treating patients whose condition falls within such guideline or protocol, and when such guideline or protocol specifies the circumstances under which the legend drug is to be prescribed and administered. An individual who verbally, electronically, or otherwise transmits a written, oral, or electronic order, as an agent of a prescriber, shall not be deemed to have prescribed the legend drug. This paragraph applies to a physician assistant only if the physician assistant meets the requirements of section 147A.18.

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(+) *CRITERION 3:*
Opioids are part of professional practice

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MINNESOTA

OTHER GOVERNMENTAL POLICY

Medical Board Guideline

MINNESOTA BOARD OF MEDICAL PRACTICE
POLICY FOR THE USE OF CONTROLLED SUBSTANCES
FOR THE TREATMENT OF PAIN

Section I: Preamble

The Minnesota Board of Medical Practice ("Board") recognizes that principles of quality medical practice dictate that the people of the State of Minnesota have access to appropriate and effective pain relief. The appropriate application of up-to-date knowledge and treatment modalities can serve to improve the quality of life for those patients who suffer from pain as well as reduce the morbidity and costs associated with untreated or inappropriately treated pain. For the purposes of this policy, the inappropriate treatment of pain includes nontreatment, undertreatment, overtreatment, and the continued use of ineffective treatments.

The diagnosis and treatment of pain is integral to the practice of medicine. The Board encourages physicians to view pain management as a part of quality medical practice for all patients with pain, acute or chronic, and it is especially urgent for patients who experience pain as a result of terminal illness. All physicians should become knowledgeable about assessing patients' pain and effective methods of pain treatment, as well as statutory requirements for prescribing controlled substances. Accordingly, these guidelines have been developed to clarify the Board's position on pain control, particularly as related to the use of controlled substances, to alleviate physician uncertainty and to encourage better pain management.

Inappropriate pain treatment may result from physicians' lack of knowledge about pain management. Fears of investigation or sanction by federal, state and local agencies may also result in inappropriate treatment of pain. Appropriate pain management is the treating physician's responsibility. As such, the Board will consider the inappropriate treatment of pain to be a departure from standards of practice and will investigate such allegations just as diligently as it would allegations of other misconduct relating to prescribing practices, recognizing that some types of pain cannot be completely relieved, and taking into account whether the treatment is appropriate for the diagnosis.

The Board recognizes that controlled substances including opioid analgesics may be essential in the treatment of acute pain due to trauma or surgery and chronic pain, whether due to cancer or non-cancer origins. The Board will refer to current clinical practice guidelines and expert review in approaching cases involving management of pain. The medical management of pain should consider current clinical knowledge and scientific research and the use of pharmacologic and non-pharmacologic modalities according to the judgment of the physician. Pain should be assessed and treated promptly, and the quantity and frequency of doses should be adjusted according to the intensity, duration of the pain, and treatment outcomes. Physicians should recognize that tolerance and physical dependence are normal consequences of sustained use of opioid analgesics and are not the same as addiction.

The Board is obligated under the laws of the State of Minnesota to protect the public health and safety. The Board recognizes that the use of opioid analgesics for other than legitimate medical purposes pose a threat to the individual and society and that the inappropriate prescribing of controlled substances, including opioid analgesics, may lead to drug diversion and abuse by individuals who seek them for other than legitimate medical use. Accordingly, the Board expects that physicians incorporate safeguards into their practices to minimize the potential for the abuse and diversion of controlled substances.

(CONTINUED ON NEXT PAGE)

(+) *CRITERION 2:*
Pain management is part of healthcare practice

(+) *CRITERION 4:*
Encourages pain management

(+) *CRITERION 8:*
Other provisions that may enhance pain treatment

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Recognizes that inadequate treatment of pain is subject to disciplinary action just as other substandard practices might be.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Identifies the potential impact of important barriers on the provision of effective pain care.

(+) *CRITERION 7:*
Physical dependence or analgesic tolerance are not confused with "addiction"

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MINNESOTA

OTHER GOVERNMENTAL POLICY

Medical Board Guideline

(+) ***CRITERION 5:***
Addresses fear of regulatory scrutiny

(+) ***CRITERION 6:***
Prescription amount alone does not determine legitimacy

(+) ***CRITERION 8:***
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT:
Acknowledges need for treatment flexibility for physicians to respond to individual clinical circumstances, as long as their prescribing maintains the standards of good medical practice.

(CONTINUED)

Physicians should not fear disciplinary action from the Board for prescribing, dispensing or administering controlled substances, including opioid analgesics, for a legitimate medical purpose and in the course of professional practice. The Board will consider prescribing, ordering, dispensing or administering controlled substances for pain to be for a legitimate medical purpose if based on sound clinical judgment. All such prescribing must be based on clear documentation of unrelieved pain. If such prescribing meets these criteria, the Board will support physicians whose use of controlled substances has been questioned by another regulatory or enforcement agency. To be within the usual course of professional practice, a physician-patient relationship must exist and the prescribing should be based on a diagnosis and documentation of unrelieved pain. Compliance with applicable state or federal law is required.

The Board will judge the validity of the physician's treatment of the patient based on available documentation, rather than solely on the quantity and duration of medication administration. The goal is to control the patient's pain while effectively addressing other aspects of the patient's functioning, including physical, psychological, social and work-related factors.

Allegations of inappropriate pain management will be evaluated on an individual basis. The board will not take disciplinary action against a physician for not adhering strictly to this policy when contemporaneous medical records document reasonable cause for deviation. The physician's conduct will be evaluated to a great extent by the outcome of pain treatment, recognizing that some types of pain cannot be completely relieved, and by taking into account whether the drug used is appropriate for the diagnosis, as well as improvement in patient functioning.

Section II: Guidelines

The Board has adopted the following criteria when evaluating the physician's treatment of pain, including the use of controlled substances:

1. Evaluation of the Patient
A medical history and physical examination must be obtained, evaluated, and documented in the medical record. The medical record should document the nature and intensity of the pain, current and past treatments for pain, underlying or coexisting diseases or conditions, the effect of the pain on physical and psychological function, and history of substance abuse. The medical record also should document the presence of one or more recognized medical indications for the use of a controlled substance.

2. Treatment Plan
The written treatment plan should state objectives that will be used to determine treatment success, such as pain relief and improved physical and psychosocial function, and should indicate if any further diagnostic evaluations or other treatments are planned. After treatment begins, the physician should adjust drug therapy to the individual medical needs of each patient. Other treatment modalities or a rehabilitation program may be necessary depending on the etiology of the pain and the extent to which the pain is associated with physical and psychosocial impairment.

3. Informed Consent and Agreement for Treatment
The physician should discuss the risks and benefits of the use of controlled substances with the patient, persons designated by the patient or with the patient's surrogate or guardian if the patient is without medical decision-making capacity. The patient should receive prescriptions from one physician and one pharmacy whenever possible. If the patient is at high risk for medication abuse or has a history of substance abuse, the physician should consider the use of a written agreement between physician and patient outlining patient responsibilities, including

(CONTINUED ON NEXT PAGE)

(+) ***CRITERION 3:***
Opioids are part of professional practice

(+) ***CRITERION 8:***
Other provisions that may enhance pain treatment

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Recognizes that the goal of pain treatment should include improvements in patient functioning and quality of life.

(+) ***CRITERION 8:***
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Encourages healthcare professionals to incorporate in their practice the evaluations of, and discussions with patients about, the potential benefits and risks of treatment with opioids, which can better ensure a clinical indication of such treatment so that opioids will be used for medical purposes.

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MINNESOTA

OTHER GOVERNMENTAL POLICY

Medical Board Guideline

(CONTINUED)

- urine/serum medication levels screening when requested;
- number and frequency of all prescription refills; and
- reasons for which drug therapy may be discontinued (e.g., violation of agreement).

4. Periodic Review
The physician should periodically review the course of pain treatment and any new information about the etiology of the pain or the patient's state of health. Continuation or modification of controlled substances for pain management therapy depends on the physician's evaluation of progress toward treatment objectives. Satisfactory response to treatment may be indicated by the patient's decreased pain, increased level of function, or improved quality of life. Objective evidence of improved or diminished function should be monitored and information from family members or other caregivers should be considered in determining the patient's response to treatment. If the patient's progress is unsatisfactory, the physician should assess the appropriateness of continued use of the current treatment plan and consider the use of other therapeutic modalities.

5. Consultation
The physician should be willing to refer the patient as necessary for additional evaluation and treatment in order to achieve treatment objectives. Special attention should be given to those patients with pain who are at risk for medication misuse or diversion. The management of pain in patients with a history of substance abuse or with a comorbid psychiatric disorder may require extra care, monitoring, documentation and consultation with or referral to an expert in the management of such patients.

6. Medical Records
The physician should keep accurate and complete records to include

- the medical history and physical examination;
- diagnostic, therapeutic and laboratory results;
- evaluations and consultations;
- treatment objectives;
- discussion of risks and benefits;
- informed consent;
- treatments;
- medications (including date, type, dosage and quantity prescribed);
- instructions and agreements; and
- periodic reviews.

(CONTINUED ON NEXT PAGE)

(+) *CRITERION 8:*
Other provisions that may enhance pain treatment

CATEGORY B:
Issues related to patients

COMMENT:
Acknowledges that a patient's prior history or current status of drug abuse does not necessarily contraindicate appropriate pain management.

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OTHER GOVERNMENTAL POLICY

Medical Board Guideline

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Encourages healthcare professionals to understand and follow federal and state laws governing their practice, which can better ensure that practitioners follow the *balanced* approach represented by federal law and the laws in many states.

(CONTINUED)

Records should remain current and be maintained in an accessible manner and readily available for review.

7. Compliance With Controlled Substances Laws and Regulations
To prescribe, dispense or administer controlled substances, the physician must be licensed in the state and comply with applicable federal and state regulations. Physicians are referred to the Physicians Manual of the U.S. Drug Enforcement Administration for specific rules governing controlled substances as well as applicable state regulations.

Section III: Definitions

For the purposes of these guidelines, the following terms are defined as follows:

Acute Pain
Acute pain is the normal, predicted physiological response to a noxious chemical, thermal or mechanical stimulus and typically is associated with invasive procedures, trauma and disease. It is generally time-limited.

Addiction
Addiction is a primary, chronic, neurobiologic disease, with genetic, psychosocial, and environmental factors influencing its development and manifestations. It is characterized by behaviors that include the following: impaired control over drug use, craving, compulsive use, and continued use despite harm. Physical dependence and tolerance are normal physiological consequences of extended opioid therapy for pain and are not the same as addiction.

Chronic Pain
Chronic pain is a state in which pain persists beyond the usual course of an acute disease or healing of an injury, or that may or may not be associated with an acute or chronic pathologic process that causes continuous or intermittent pain over months or years.

Pain
An unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage.

Physical Dependence
Physical dependence is a state of adaptation that is manifested by drug class-specific signs and symptoms that can be produced by abrupt cessation, rapid dose reduction, decreasing blood level of the drug, and/or administration of an antagonist. Physical dependence, by itself, does not equate with addiction.

Pseudoaddiction
The iatrogenic syndrome resulting from the misinterpretation of relief seeking behaviors as though they are drug seeking behaviors that are commonly seen with addiction. The relief seeking behaviors resolve upon institution of effective analgesic therapy.

Substance Abuse
Substance abuse is the use of any substance(s) for non-therapeutic purposes or use of medication for purposes other than those for which it is prescribed.

Tolerance
Tolerance is a physiologic state resulting from regular use of a drug in which an increased dosage is needed to produce a specific effect, or a reduced effect is observed with a constant dose over time. Tolerance may or may not be evident during opioid treatment and does not equate with addiction.

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OTHER GOVERNMENTAL POLICY

Joint Board Policy Statement

Joint Statement on Pain Management
Minnesota Boards of Medical Practice, Nursing, and Pharmacy

Pain management is a significant issue in health care today. In 2009, it was estimated that more than 33 million Americans-men, women, and children-were living with serious pain that lasted one year or more. Thirty to fifty percent of patients undergoing cancer treatment experience pain. Common pain conditions among workers result in over $60 billion in lost productivity. The effects of unmanaged pain are serious and wide-ranging and yet, pain is widely under-treated. Untreated or inadequately treated pain impacts patients' quality of life and increases health care costs. Factors cited in the under-treatment of pain include: concerns about causing addiction or tolerance; inadequate knowledge of controlled substances and pain management; fear of scrutiny and discipline by regulatory agencies; inadequate assessment; and patient reluctance to report pain or to take pain medications.

The Joint Commission standards indicate patients have a right to effective pain management and require that pain be routinely assessed for all patients. It is, therefore, incumbent upon Minnesota physicians, nurses and pharmacists to work cooperatively and effectively to address the dimensions of pain and to provide maximum pain relief with minimal side effects. Towards that end and in the interest of public protection, the Minnesota Boards of Medical Practice, Nursing and Pharmacy issue the following joint statement.

To effectively assist patients in the management of pain, health care professionals should, within their scope of practice:

• Consistently and thoroughly assess all patients for pain. If pain is reported, the pain should be evaluated with a complete history and physical with laboratory and diagnostic testing, if indicated. The assessment of pain should be individualized, on-going and clearly documented;

• Work collaboratively in a multi-disciplinary approach to develop and implement an individualized, written treatment plan utilizing pharmacologic and non-pharmacologic interventions with specific objectives for the patient;

• Regularly evaluate the effectiveness of the treatment plan, using a consistent, developmentally appropriate, standardized pain scale, and make adjustments as needed;

• Document all aspects of pain assessment and care in a timely, clear, consistent, complete and accurate manner;

• Anticipate and effectively manage side effects of pain medications;

• Provide adequate and culturally appropriate information to patients and family members or caregivers to support patients in making informed decisions and participating in the management of their pain;

• Be aware of the risks of diversion and abuse of controlled substances and take appropriate steps to minimize these risks.

• Recognize individuals with chemical dependency may experience pain requiring medications, including opioids, and may require specialized management;

• Consult with, and refer patients to, other providers when appropriate;

• Develop organization-appropriate and evidence-based policies and protocols for pain management;

• Become and remain knowledgeable regarding effective pain management; and

• Comply with all state and federal laws and regulations regarding prescribing dispensing, and administering legend drugs, including controlled substances.

(CONTINUED ON NEXT PAGE)

(+) *CRITERION 4:*
Pain management is encouraged

(+) *CRITERION 2:*
Pain management is part of healthcare practice

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Recognizes a practitioner's responsibility to provide patients information about pain management and palliative care when considering treatment options.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Encourages healthcare professionals to understand and follow federal and state laws governing their practice, which can better ensure that practitioners follow the *balanced* approach represented by federal law and the laws in many states.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Identifies the potential impact of important barriers on the provision of effective pain care.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Recognizes the need for a multidisciplinary approach to pain management.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY B:
Issues related to patients

COMMENT: Acknowledges that a patient's prior history or current status of drug abuse does not necessarily contraindicate appropriate pain management.

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OTHER GOVERNMENTAL POLICY

Joint Board Policy Statement

(CONTINUED)

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MINNESOTA

STATUTES

Hospice Licensing

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT*:* Establishes a responsibility for hospices to ensure that pain management is an essential part of patient care.

Minn. Stat. § 144A.751

144A.751 Hospice bill of rights

Subdivision 1. Statement of rights. An individual who receives hospice care has the right to:

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(22) have pain and symptoms managed to the patient's desired level of comfort.

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STATUTES

Homicide and Suicide

Minn. Stat. § 609.215

609.215 Suicide

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Subd. 3. Acts or omissions not considered aiding suicide or aiding attempted suicide. (a) A health care provider, as defined in section 145B.02, subdivision 6, who administers, prescribes, or dispenses medications or procedures to relieve another person's pain or discomfort, even if the medication or procedure may hasten or increase the risk of death, does not violate this section unless the medications or procedures are knowingly administered, prescribed, or dispensed to cause death.

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(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT*:* Clarifies for physicians the important distinction between physician-assisted suicide and prescribing controlled substances for pain relief; this language identifies a clinical misperception that is pervasive in end-of-life care and attempts to lessen its impact on patient treatment, and the practitioners who provide it.

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MINNESOTA

REGULATIONS

Hospice Services

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT*:* Recognizes the need for a multidisciplinary approach to pain management.

Minn. R. 4664.0100

4664.0100 ASSESSMENT

Subpart 1. Requirement. A hospice provider must ensure that each hospice patient and hospice patient family has a current assessment. An interdisciplinary team must complete an individualized, comprehensive assessment of each hospice patient and hospice patient family's needs. The assessment must address, but is not limited to, the physical, nutritional, emotional, social, spiritual, pain, symptom management, medication, and special needs of the hospice patient and hospice patient's family during the final stages of illness, dying, and bereavement, and any other areas necessary to the provision of hospice care.

Subp. 2. Fines. A fine of $ 350 shall be assessed for each violation of this part.

Minn. R. 4664.0330

4664.0330 INPATIENT CARE

Subpart 1. Short-term inpatient care. A hospice provider must ensure that inpatient care is available for pain control, symptom management, and respite purposes and is provided in a licensed hospital, a nursing home, or a residential hospice facility. Inpatient care must be provided directly or under arrangement with one or more hospitals, nursing homes, or residential hospice facilities.

Subp. 2. Fines. A fine of $ 300 shall be assessed for each violation of this part.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT*:* Establishes a responsibility for hospices to ensure that pain management is an essential part of patient care.

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MISSISSIPPI

STATUTES

- CONTROLLED SUBSTANCES ACT
  Title 41. Public Health; Chapter 29. Poisons, Drugs and Other Controlled Substances; Article 3. Uniform Controlled Substances Law

- MEDICAL PRACTICE ACT (*No provisions found*)
  Title 73. Professions and Vocations; Chapter 25. Physicians

- PHARMACY PRACTICE ACT
  Title 73. Professions and Vocations; Chapter 21. Pharmacists

- INTRACTABLE PAIN TREATMENT ACT
  No policy found

REGULATIONS

- CONTROLLED SUBSTANCES REGULATIONS (*Part of Pharmacy Board Regulations*) (*No provisions found*)
  Agency 50. Regulatory Agencies; Sub-Agency 018. Pharmacy Board

- MEDICAL BOARD REGULATIONS
  Agency 50. Regulatory Agencies; Sub-Agency 013. Board of Medical Licensure

- PHARMACY BOARD REGULATIONS
  Agency 50. Regulatory Agencies; Sub-Agency 018. State Board of Pharmacy

OTHER GOVERNMENTAL POLICIES

No policies found

RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY KEY WORD SEARCHES

- HOSPICE STANDARDS
  Agency 15. Department of Health; Sub-Agency 016. Part 16. Health Facilities; Subpart 1. Health Facilities Licensure and Certification; Chapter 001. Minimum Standards of Operation for Hospice

- HOSPITAL STANDARDS
  Agency 15. Department of Health; Sub-Agency 016. Part 16. Health Facilities; Subpart 1. Health Facilities Licensure and Certification; Chapter 040. Minimum Standards of Operation for Mississippi Hospitals

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STATUTES

Controlled Substances Act

Miss. Code Ann. § 41-29-105

§ 41-29-105. Definitions

The following words and phrases, as used in this article, shall have the following meanings, unless the context otherwise requires:

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(y) "Practitioner" means:

(1) A physician, dentist, veterinarian, scientific investigator, optometrist certified to prescribe and use therapeutic pharmaceutical agents under Sections 73-19-153 through 73-19-165, or other person licensed, registered or otherwise permitted to distribute, dispense, conduct research with respect to or to administer a controlled substance in the course of professional practice or research in this state; and

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(+) *CRITERION 3:*
Opioids are part of professional practice

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MISSISSIPPI

STATUTES

Pharmacy Practice Act

Miss. Code Ann. § 73-21-83

§ 73-21-83. Board to regulate practice of pharmacy; licensing of pharmacists; fees; persons holding license on July 1, 1991

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(2) A license for the practice of pharmacy shall be obtained by all persons prior to their engaging in the practice of pharmacy. However, the provisions of this chapter shall not apply to physicians, dentists, veterinarians, osteopaths or other practitioners of the healing arts who are licensed under the laws of the State of Mississippi and are authorized to dispense and administer prescription drugs in the course of their professional practice.

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Miss. Code Ann. § 73-21-127

§ 73-21-127. Board of Pharmacy to develop and implement computerized program to track certain prescriptions; report of suspected abuse and misuse of controlled substances; access to collected data; confidentiality; penalties for knowingly failing to submit or submitting incorrect dispensing information

The Board of Pharmacy shall develop and implement a computerized program to track prescriptions for controlled substances and to report suspected abuse and misuse of controlled substances in compliance with the federal regulations promulgated under authority of the National All Schedules Prescription Electronic Reporting Act of 2005 and in compliance with the federal HIPAA law, under the following conditions:

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(d) The program shall provide information regarding the potential inappropriate use of controlled substances and the specified noncontrolled substances to practitioners, pharmacists-in-charge and appropriate state agencies in order to prevent the inappropriate or illegal use of these controlled substances. The specific purposes of the program shall be to: be proactive in safeguarding public health and safety; support the legitimate use of controlled substances; facilitate and encourage the identification, intervention with and treatment of individuals addicted to controlled substances and specified noncontrolled drugs; identify and prevent drug diversion; provide assistance to those state and federal law enforcement and regulatory agencies investigating cases of drug diversion or other misuse; and inform the public and health care professionals of the use and abuse trends related to controlled substance and specified noncontrolled drugs.

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(+) *CRITERION 3:*
Opioids are part of professional practice

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT*:* Represents the principle of Balance, which states that the regulation of controlled substances should not interfere with legitimate medical use.

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REGULATIONS

Medical Board Regulation

CMSR 50-013-2640

Rule 1.7 Use of Controlled Substances for Chronic (Non-Terminal) Pain

A. Definitions

For the purpose of Section 600 only, the following terms have the meanings indicated:

1. "Chronic Pain" is a pain state in which the cause of the pain cannot be removed or otherwise treated and which in the generally accepted course of medical practice, no relief or cure of the cause of the pain is possible or none has been found after reasonable efforts including, but not limited to, evaluation by the attending physician and one or more physicians specializing in the treatment of the area, system, or organ of the body perceived as the source of the pain. Further, if a patient is receiving controlled substances for the treatment of pain for a prolonged period of time (more than six months), then they will be considered for the purposes of this regulation to have "de facto" chronic pain and subject to the same requirements of this regulation. "Terminal Disease Pain" should not be confused with "Chronic Pain." For the purpose of this section, "Terminal Disease Pain" is pain arising from a medical condition for which there is no possible cure and the patient is expected to live no more than six (6) months.

2. "Acute Pain" is the normal, predicted physiological response to an adverse chemical, thermal, or mechanical stimulus and is associated with surgery, trauma and acute illness. It is generally time limited and is responsive to therapies, including controlled substances as defined by the U.S. Drug Enforcement Administration. Title 21 CFR Part 1301 Food and Drugs.

3. "Addiction" is a neurobehavorial syndrome with genetic and environmental influences that results in psychological dependence on the use of substances for their psychic effects and is characterized by compulsive use despite harm. Physical dependence and tolerance are normal physiological consequences of extended opioid therapy for pain and should not be considered addiction.

4. "Physical Dependence" is a physiological state of neuroadaptation to a substance which is characterized by the emergence of a withdrawal syndrome if the use of the substance is stopped or decreased abruptly, or if an antagonist is administered. Withdrawal may be relieved by re-administration of the substance. Physical dependence is a normal physiological consequence of extended opioid therapy for pain and should not be considered addiction.

5. "Substance Abuse" is the use of any substance(s) for non-therapeutic purposes; or use of medication for purposes other than those for which it is prescribed.

6. "Tolerance" is a physiological state resulting from regular use of a drug in which an increased dosage is needed to produce the same effect or a reduced effect is observed with a constant dose. Tolerance occurs to different degrees for various drug effects, including sedation, analgesia and constipation. Analgesic tolerance is the need to increase the dose of opioid to achieve the same level of analgesia. Such tolerance may or may not be evident during treatment and does not equate with addiction.

B. Notwithstanding any other provisions of these rules, a physician may prescribe, administer, or dispense controlled substances in Schedules II, IIN, III, IIIN, IV and V, or other drugs having addiction-forming and addiction-sustaining liability to a person in the usual course of treatment of that person for a diagnosed condition causing chronic pain.

C. Notwithstanding any other provisions of these rules, as to the prescribing, administration, or dispensation of controlled substances in Schedules II, IIN, III, IIIN, IV and V, or other drugs having addiction-forming and addiction-sustaining liability, use of said medications in the treatment of chronic pain should be done with caution. A physician may administer, dispense or prescribe said medications for the purpose of relieving chronic pain, provided that the following conditions are met:

(CONTINUED ON NEXT PAGE)

(-) *CRITERION 12:*
Healthcare decisions are restricted

CATEGORY B:
Mandated consultation

(+) *CRITERION 7:*
Physical dependence or analgesic tolerance are not confused with "addiction"

(+) *CRITERION 3:*
Opioids are part of professional practice

(+) *CRITERION 2:*
Pain management is part of healthcare practice

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REGULATIONS

Medical Board Regulation

1. Before initiating treatment utilizing a Schedules II, IIN, III, IIIN, IV or V controlled substance, or any other drug having addiction-forming and addiction-sustaining liability, the physician shall conduct an appropriate risk/benefit analysis by reviewing his or her own records of prior treatment or review the records of prior treatment which another treating physician has provided to the physician, that there is an indicated need for long-term controlled substance therapy. Such a determination shall take into account the specifics of each patients diagnosis, past treatments and suitability for long-term controlled substance use either alone or in combination with other indicated modalities for the treatment of chronic pain. This shall be clearly entered into the patient medical record and shall include consultation/referral reports to determine the underlying pathology or cause of the chronic pain.

2. Documentation in the patient record shall include a complete medical history and physical examination that indicates the presence of one or more recognized medical indications for the use of controlled substances.

3. Documentation of a written treatment plan which shall contain stated objectives as a measure of successful treatment and planned diagnostic evaluations, e.g., psychiatric evaluation or other treatments. The plan should also contain an informed consent agreement for treatment that details relative risks and benefits of the treatment course. This should also include specific requirements of the patient, such as using one physician and pharmacy if possible, and urine/serum medication level monitoring when requested.

4. Periodic review and documentation of the treatment course is conducted at reasonable intervals (no more than every six months) with modification of therapy dependent on the physician's evaluation of progress toward the stated treatment objectives. This should include referrals and consultations as necessary to achieve those objectives.

D. No physician shall administer, dispense or prescribe a controlled substance or other drug having addiction-forming and addiction-sustaining liability that is nontherapeutic in nature or non-therapeutic in the manner the controlled substance or other drug is administered, dispensed or prescribed.

E. No physician shall administer, dispense or prescribe a controlled substance for treatment of chronic pain to any patient who has consumed or disposed of any controlled substance or other drug having addiction-forming and addiction-sustaining liability other than in strict compliance with the treating physician's directions. These circumstances include those patients obtaining controlled substances or other abusable drugs from more than one physician and those patients who have obtained or attempted to obtain new prescriptions for controlled substances or other abusable drugs before a prior prescription should have been consumed according to the treating physician's directions. This requirement will not be enforced in cases where a patient has legitimately temporarily escalated a dose of their pain medication due to an acute exacerbation of their condition but have maintained a therapeutic dose level; however, it will be required of the treating physician to document in the patient record that such increase in dose level was due to a recognized indication and was within appropriate therapeutic dose ranges. Repetitive or continuing escalations should be a reason for concern and a re-evaluation of the present treatment plan shall be undertaken by the physician.

F. No physician shall prescribe any controlled substance or other drug having addictionforming or addiction-sustaining liability to a patient who is a drug addict for the purpose of "detoxification treatment" or "maintenance treatment" and no physician shall administer or dispense any narcotic controlled substance for the purpose of "detoxification treatment" or "maintenance treatment" unless they are properly registered in accordance with Section 303(g) *21 U.S.C. 823*(g). Nothing in this paragraph shall prohibit a physician from administering narcotic drugs to a person for the purpose of relieving acute withdrawal symptoms when necessary while arrangements are being made for referral for treatment. Not more than one (1) day's medication may be administered to the person or for the person's use at one time. Such emergency treatment may be carried out for not more than three (3) days. Nothing in this paragraph shall prohibit a physician from administering or dispensing narcotic controlled substances in a hospital to maintain or detoxify a person as an incidental adjunct to medical or surgical treatment of conditions other than addiction.

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REGULATIONS

Pharmacy Board Regulation

CMSR 50-018-301

Article XLIII. Prescription Monitoring Program.

1. The Board of Pharmacy shall establish and maintain, with the consultation of the Prescription Monitoring Advisory Board, an electronic system for monitoring and tracking prescriptions dispensed for controlled substances listed in Schedules II, III, IV or V that are dispensed by a pharmacy.

The Prescription Monitoring Program shall provide information regarding the inappropriate use of controlled substances in Schedule II, III, IV and V to pharmacies, practitioners and appropriate state or federal agencies in order to prevent the improper or illegal use of such controlled substances. This program shall not infringe on the legal use of controlled substances for the management of severe or intractable pain.

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(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Represents the principle of Balance, which states that the regulation of controlled substances should not interfere with legitimate medical use.

Pain & Policy Studies Group
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MISSISSIPPI

REGULATIONS

Hospice Standards

CMSR 15-016-001

CHAPTER 001. MINIMUM STANDARDS OF OPERATION FOR HOSPICE

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Subchapter 13 Administration.

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Rule 1.13.2 Medical Director

1. Each hospice shall have a Medical Director, who, on the basis of training, experience and interest, shall be knowledgeable about the psychosocial and medical aspects of hospice care.

2. The Medical Director shall be appointed by the governing body or its designee.

3. The Medical Director is expected to play an integral role in providing medical supervision to the hospice interdisciplinary group and in providing overall coordination of the patient's plan of care. The Medical Director's expertise in managing pain and symptoms associated with the patient's terminal disease is necessary, regardless of the setting in which the patient is receiving services to assure that the hospice patient has access quality hospice care.

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Subchapter 18 Governing Body.

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Rule 1.18.6 NOTE: The Medical Director or Physician Designee may be an employee or a volunteer of the hospice agency. The hospice agency may also contract for the services of the Medical Director or Physician Designee.

1. Qualifications - A Doctor of Medicine or Osteopathy licensed to practice in the State of Mississippi.

2. Responsibilities - The Medical Director or Physician designee assumes overall responsibility for the medical component of the hospice's patient care program and shall include, but not be limited to:

a. Serve as a consultant with the attending physician regarding pain and symptom control as needed;

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Subchapter 19 Patient Care Services.

Rule 1.19.1 Patient Care Standard

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4. An assessment visit shall be made by a registered nurse, who will assess the patient's needs with emphasis on pain and symptom control. This assessment shall occur within 48 hours of referral for admission, unless otherwise ordered by physician or unless a request for delay is made by patient/family.

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(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT*:* Establishes a mechanism (medical director's responsibility) for hospices to ensure that pain management is an essential part of patient care.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT*:* Establishes a mechanism (patient care standard) for hospices to ensure that pain management is an essential part of patient care.

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Madison, Wisconsin

MISSISSIPPI

REGULATIONS

Hospital Standards

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (policies and procedures) for hospitals to ensure that pain management is an essential part of patient care.

CMSR 15-016-041

CHAPTER 041. MINIMUM STANDARDS OF OPERATION FOR MISSISSIPPI HOSPITALS

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Subchapter 40 Nursing
Rule 41.30.13. Policies shall be developed to address the following:

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11. Pain Management.

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Rule 41.30.24. The in-service should include but not limit topics to pressure sore prevention, prevention of medication errors, pain management, patient's rights and dignity.

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(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (in-service training) for hospitals to ensure that pain management is an essential part of patient care.

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Madison, Wisconsin

MISSOURI

STATUTES

- CONTROLLED SUBSTANCES ACT
  Title 12. Public Health and Welfare; Chapter 195. Drug Regulations

- MEDICAL PRACTICE ACT (*No provisions found*)
  Title 22. Occupations and Professions; Chapter 334. Physicians and Surgeons, Therapists, Athletic Trainers, Health Care Providers

- INTRACTABLE PAIN TREATMENT ACT (*Part of Medical Practice Act*)
  Title 22. Occupations and Professions; Chapter 334. Physicians and Surgeons, Therapists, Athletic Trainers, Health Care Providers; Sections 334.105-334.107

- PHARMACY PRACTICE ACT (*No provisions found*)
  Title 22. Occupations and Professions; Chapter 338. Pharmacists and Pharmacies

REGULATIONS

- CONTROLLED SUBSTANCES REGULATIONS
  Title 19. Department of Health and Senior Services; Division 30. Division of Regulation and Licensure; Chapter 1. Controlled Substances

- MEDICAL BOARD REGULATIONS (*No provisions found*)
  Title 20. Department of Insurance, Financial Institutions and Professional Registration; Division 2150. State Board of Registration for the Healing Arts; Chapter 2. Licensing of Physicians and Surgeons

- PHARMACY BOARD REGULATIONS (*No provisions found*)
  Title 20. Department of Insurance, Financial Institutions and Professional Registration; Division 2220. State Board of Pharmacy

OTHER GOVERNMENTAL POLICIES

- MEDICAL BOARD GUIDELINE
  Missouri State Board of Healing Arts. *Missouri Guidelines for the Use of Controlled Substances for the Treatment of Pain*. Adopted: 2007.

- JOINT POLICY STATEMENT
  Missouri State Board of Healing Arts, Board of Nursing and Board of Pharmacy. *Joint Statement on Pain Management*. Adopted: December 2008.

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RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY KEY WORD SEARCHES

- HOSPICE SERVICES PROGRAM

  Title 13. Department of Social Services; Division 70. Division of Medical Services; Chapter 50. Hospice Services Program

- HOSPICE PROGRAM OPERATIONS

  Title 19. Department of Health and Senior Services; Division 30. Division of Regulation and Licensure; Chapter 35. Hospices

MISSOURI

STATUTES

Controlled Substances Act

§ 195.010 R.S.Mo.

§ 195.010. Definitions

The following words and phrases as used in sections 195.005 to 195.425, unless the context otherwise requires, mean:

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(15) "Drug dependent person", a person who is using a controlled substance and who is in a state of psychic or physical dependence, or both, arising from the use of such substance on a continuous basis. Drug dependence is characterized by behavioral and other responses which include a strong compulsion to take the substance on a continuous basis in order to experience its psychic effects or to avoid the discomfort caused by its absence;

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(35) "Practitioner", a physician, dentist, optometrist, podiatrist, veterinarian, scientific investigator, pharmacy, hospital or other person licensed, registered or otherwise permitted by this state to distribute, dispense, conduct research with respect to or administer or to use in teaching or chemical analysis, a controlled substance in the course of professional practice or research in this state, or a pharmacy, hospital or other institution licensed, registered, or otherwise permitted to distribute, dispense, conduct research with respect to or administer a controlled substance in the course of professional practice or research;

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(+) *CRITERION 3:*
Opioids are part of professional practice

(-) *CRITERION 11:*
Physical dependence or analgesic tolerance confused with "addiction"

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STATUTES

Intractable Pain Treatment Act

§ 334.105 R.S.Mo. – § 334.106 R.S.Mo.

§ 334.105. Intractable pain treatment act--definitions

1. *Sections 334.105* to *334.107* shall be known and may be cited as the "Intractable Pain Treatment Act".

2. For purposes of *sections 334.105* to *334.107*, the following terms mean:

(1) "Board", the state board of registration for the healing arts;

(2) "Intractable pain", a pain state in which the cause of pain cannot be removed or otherwise treated and which in the generally accepted course of medical practice no relief or cure of the cause of the pain is possible or none has been found after reasonable efforts that have been documented in the physician's medical records;

(3) "Physician", physicians and surgeons licensed pursuant to this chapter by the board;

(4) "Therapeutic purpose", the use of controlled substances in acceptable doses with appropriate indication for the treatment of pain. Any other use is nontherapeutic.

§ 334.106. Intractable pain treatment physician may prescribe controlled substances for therapeutic purposes, requirements--exceptions

1. Notwithstanding any other provision of law to the contrary, a physician may prescribe, administer or dispense controlled substances for a therapeutic purpose to a person diagnosed and treated by a physician for a condition resulting in intractable pain, if such diagnosis and treatment has been documented in the physician's medical records. No physician shall be subject to disciplinary action by the board solely for prescribing, administering or dispensing controlled substances when prescribed, administered or dispensed for a therapeutic purpose for a person diagnosed and treated by a physician for a condition resulting in intractable pain, if such diagnosis and treatment has been documented in the physician's medical records.

2. The provisions of subsection 1 of this section shall not apply to those persons being treated by a physician for chemical dependency because of their use of controlled substances not related to the therapeutic purposes of treatment of intractable pain.

3. The provisions of subsection 1 of this section provide no authority to a physician to prescribe, administer or dispense controlled substances to a person the physician knows or should know to be using controlled substances which use is not related to the therapeutic purpose.

4. Drug dependency or the possibility of drug dependency in and of itself is not a reason to withhold or prohibit the prescribing, administering or dispensing of controlled substances for the therapeutic purpose of treatment of a person for intractable pain, nor shall dependency relating solely to such prescribing, administering or dispensing subject a physician to disciplinary action by the board.

(-) *CRITERION 16:*
Provisions that are ambiguous

CATEGORY B:
Unclear intent leading to possible misinterpretation

COMMENT: Although similar language is used in Federal regulation, in the context of this statute this definition suggests that physicians would qualify for the immunity and, thus, relief from concerns about regulatory scrutiny provided by this statute only if they prescribe opioids after other treatments have been tried and failed, regardless of other clinical considerations.

(+) *CRITERION 3:*
Opioids are part of professional practice

(+) *CRITERION 2:*
Pain management is part of healthcare practice

(+) *CRITERION 5:*
Addresses fear of regulatory scrutiny

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY B:
Issues related to patients

COMMENT: Acknowledges that a patient's prior history or current status of drug abuse does not necessarily contraindicate appropriate pain management.

(-) *CRITERION 10:*
Implies opioids are not part of professional practice

(-) *CRITERION 16:*
Provisions that are ambiguous

CATEGORY A:
Arbitrary standards for legitimate prescribing

COMMENT: Although it is reasonable to expect physicians to avoid contributing to diversion, "acceptable dose" implies there is a known standard, but the standard is not specified.

(-) *CRITERION 12:*
Healthcare decisions are restricted

CATEGORY A:
Restrictions based on patient characteristics

(-) *CRITERION 16:*
Provisions that are ambiguous

CATEGORY C:
Conflicting or inconsistent policies or provisions

COMMENT: Appears to be inconsistency between these provisions relating to the use of opioids for a person with pain who is drug dependent.

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MISSOURI

REGULATIONS

Controlled Substances Regulations

19 CSR 30-1.011

30-1.011 Definitions

(1) As used in this chapter, the following terms shall have the meanings specified:

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(F) Individual practitioner means a physician, dentist, veterinarian, optometrist or other individual licensed, registered or otherwise permitted by the United States or Missouri to dispense a controlled substance in the course of professional practice, but does not include a pharmacist, a pharmacy or an institutional practitioner;

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(+) *CRITERION 3:*
Opioids are part of professional practice

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MISSOURI

OTHER GOVERNMENTAL POLICY

Medical Board Guideline

Missouri Guidelines for the Use of Controlled Substances for the Treatment of Pain

Effective January 2007, the Board of Healing Arts appointed a Task Force to review the current statutes, rules and guidelines regarding the treatment of pain. This Task Force consisted of both staff and Board members, with input from the Governor's Council on Pain and Symptom Management. They were charged with gathering information and to draft language for the Board to review.

In the report, the committee members made recommendations that included:

- ✓ Developing a pain and symptom management website for healthcare professionals and the general public.
- ✓ Encouraging hospitals to increase their medical and nursing staff's knowledge by providing guidelines for required curricula in pain and symptom management in their educational programs.
- ✓ Encouraging pharmacies within communities or among pharmacy chains to share information and stock adequate supplies of Schedule II medications to meet the needs of patients.
- ✓ Evaluating patients with complete history and physicals and adding previous pain physician(s) records with their current medical records.
- ✓ Documenting any pain agreements between the patients and the physician and add this along with an informed consent to the medical records.
- ✓ Making appropriate referrals.

The Missouri Guidelines are not intended to define complete or best practice but rather to communicate what the Board considers to be within the boundaries of professional practice. The guidelines state that patients should have access to appropriate and effective pain relief that will serve to improve the quality of life for those who suffer from pain as well as reduce the morbidity and costs associated with untreated or inappropriately treated pain.

The Missouri guidelines have been broken down into the following sections:

- Section I: Preamble
- Section II: Guidelines (Evaluation of the Patient: Treatment Plan; Informed Consent and Agreement for Treatment; Periodic Review; Consultation; Medical Records; Compliance with Controlled Substances Laws and Regulations)
- Section III: Definitions (Acute Pain; Addiction; Analgesic Tolerance; Chronic Pain; Pain; Physical Dependence; Pseudoaddiction; Substance Abuse; Tolerance)

To view and/or print a complete copy of the Missouri guidelines, please go to our website at www.pr.mo.gov/healingarts.asp

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MISSOURI

OTHER GOVERNMENTAL POLICY

Medical Board Guideline

(CONTINUED)

The Missouri Guidelines for the Use of Controlled Substances
for the Treatment of Pain

Section I: Preamble

The Missouri Board of Healing Arts recognizes that the people of the State of Missouri have access to appropriate and effective pain relief. The appropriate application of up-to-date knowledge and treatment modalities can serve to improve the quality of life for those patients who suffer from pain as well as reduce the morbidity and costs associated with untreated or inappropriately treated pain. The Board encourages physicians to view effective pain management as a part of quality medical practice for all patients with pain, acute or chronic, and it is especially important for patients who experience pain as a result of terminal illness. All physicians should become knowledgeable about effective methods of pain treatment as well as statutory requirements for prescribing controlled substances.

These guidelines have been developed to clarify the Boards' position on pain control, to alleviate physician uncertainty and to encourage better pain management.

The Board recognizes that controlled substances, including opioid analgesics, may be essential in the treatment of acute pain due to trauma or surgery and chronic pain, whether due to cancer or non-cancer origins. Physicians are referred to the U.S. Food and Drug Administration Consumer Magazine the March/April 2004 Issue Publication number FDA04-1336C entitled "Managing Chronic Pain", for a sound approach to the management of chronic pain. The medical management of pain should be based on current knowledge and research and include the use of both pharmacologic and nonpharmacologic modalities. During the treatment of pain the quantity and frequency of doses should be adjusted according to the intensity and duration of the pain. Physicians should recognize that tolerance and physical dependence are normal consequences of sustained use of opioid analgesics are not synonymous with addiction.

The Board is obligated under the laws of the State of Missouri to protect the public health and safety. The Board recognizes that prescribing of controlled substances, may lead to drug diversion and abuse by individuals who seek them for other than legitimate medical use. Physicians should be aware of the methods for preventing the diversion of drugs for illegitimate purposes.

Physicians should not fear disciplinary action from the Board or other state regulatory enforcement agencies for prescribing, dispensing or administering controlled substances, including opioid analgesics, for a legitimate medical purpose and based on sound clinical grounds. Sound clinical grounds include a working diagnosis for the etiology of the pain. The Board will consider prescribing, ordering, administering or dispensing controlled substances for pain to be for a legitimate medical purpose if based on accepted scientific knowledge of the treatment of pain or if based on sound clinical grounds. All such prescribing must be accompanied by clear documentation in the medical record of the treatment and in compliance with applicable state or federal law with the Board of Healing Arts § 334 RSMo; §334.105 RSMo; and §195 RSMo and with the Board of Narcotic and Dangerous Drugs and the Drug Enforcement Agency §21 USC.

[CONTINUED ON NEXT PAGE]

(+) *CRITERION 2:*
Pain management is part of healthcare practice

(+) *CRITERION 4:*
Encourages pain management

(+) *CRITERION 7:*
Physical dependence or analgesic tolerance are not confused with "addiction"

(+) *CRITERION 5:*
Addresses fear of regulatory scrutiny

(+) *CRITERION 3:*
Opioids are part of professional practice

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MISSOURI

OTHER GOVERNMENTAL POLICY

Medical Board Guideline

(CONTINUED)

Each case of prescribing for pain will be evaluated on an individual basis. The Board will not take disciplinary action against a physician for failing to adhere strictly to the provisions of these guidelines, if good cause is shown for such deviation. The physician's conduct will be evaluated to a great extent by the treatment outcome, taking into account whether the drug used is medically and/or pharmacologically recognized to be appropriate for the diagnosis, the patient's individual needs—including any improvement in functioning—and recognizing that some types of pain cannot be completely relieved. The Board will judge the validity of prescribing based on the physician's treatment of the patient and on available documentation, rather than on the quantity and chronicity of prescribing. The goal is to control the patient's pain while effectively addressing other aspects of the patient's functioning, including physical, psychological, social and work-related factors. The following guidelines are not intended to define complete or best practice, but rather to communicate what the Board considers to be within boundaries of professional practice.

Section II: Guidelines

The Board has adopted the following guidelines when evaluating the use of controlled
substances for pain control:

1. Evaluation of the Patient
A complete medical history and physical examination must be conducted and documented in the medical record. The medical record should document the nature and intensity of the pain, current and past treatments for pain, underlying or coexisting diseases or conditions, the effect of the pain on physical and psychological function, and history of substance abuse. The medical record also should document the presence of one or more recognized medical indications for the use of controlled substances.

2. Treatment Plan
The written treatment plan should state objectives that will be used to determine treatment success, such as pain relief and improved physical and psychosocial function, and should indicate if any further diagnostic evaluations or other treatments are planned. After treatment begins, the physician should adjust drug therapy to the individual medical needs of each patient. Other treatment modalities or a rehabilitation program may be necessary depending on the etiology of the pain and the extent to which the pain is associated with physical and psychosocial impairment.

3. Informed Consent and Agreement for Treatment
The physician should discuss the risks and benefits of the use of controlled substances with the patient, persons designated by the patient or with the patient's surrogate or guardian if the patient is incompetent. The patient should receive prescriptions from one physician and one pharmacy where possible. If the patient is determined to be at high risk for medication abuse or have a history of substance abuse, the physician should consider the use of a written agreement between physician and patient outlining patient responsibilities, including

- urine/serum medication levels screening when requested;
- number and frequency of all prescription refills; and
- reasons for which drug therapy may be discontinued (i.e., violation of agreement).

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(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT:
Acknowledges need for treatment flexibility for physicians to respond to individual clinical circumstances, as long as their prescribing maintains the standards of good medical practice.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Encourages healthcare professionals to incorporate in their practice the evaluations of, and discussions with patients about, the potential benefits and risks of treatment with opioids, which can better ensure a clinical indication of such treatment so that opioids will be used for medical purposes.

(+) *CRITERION 6:*
Prescription amount alone does not determine legitimacy

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Recognizes that the goal of pain treatment should include improvements in patient functioning and quality of life.

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University of Wisconsin Carbone Cancer Center
Madison, Wisconsin

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OTHER GOVERNMENTAL POLICY

Medical Board Guideline

(CONTINUED)

4. Periodic Review
At reasonable intervals based on the individual circumstances of the patient, the physician should review the course of treatment and any new information about the etiology of the pain. Continuation or modification of therapy should depend on the physician's evaluation of progress toward stated treatment objectives, such as improvement in patient's pain intensity and improved physical and/or psychosocial function, i.e., ability to work, need of health care resources, activities of daily living and quality of social life. If treatment goals are not being achieved, despite medication adjustments, the physician should reevaluate the appropriateness of continued treatment. The physician should monitor patient compliance in medication usage and related treatment plans.

5. Consultation
The physician should be willing to refer the patient as necessary for additional evaluation and treatment in order to achieve treatment objectives. Special attention should be given to those pain patients who are at risk for misusing their medications and those whose living arrangement pose a risk for medication misuse or diversion. The management of pain in patients with a history of substance abuse or with a comorbid psychiatric disorder may require extra care, monitoring, documentation and consultation with or referral to an expert in the management of such patients.

6. Medical Records
The physician should keep accurate records including complete medical history and
physical examination;

- diagnostic, therapeutic and laboratory results;
- evaluations and consultations;
- treatment objectives;
- discussion of risks and benefits;
- treatments;
- medications (including date, type, dosage and quantity prescribed);
- instructions and agreements; and
- periodic reviews.

Records should remain current and be maintained in an accessible manner and readily available for review.

7. Compliance With Controlled Substances Laws and Regulations
To prescribe, dispense or administer controlled substances, the physician must be licensed in the state and comply with applicable federal and state regulations. Physicians are referred to the Physicians Manual of the U.S. Drug Enforcement Administration and (any relevant documents issued by the state medical board) for specific rules governing controlled substances as well as applicable state regulations. The Physician's Manual can be found at the DEA Diversion website at www.deadiversion.usdoj.gov . The State guidelines can be found under Chapter 195.070 RSMo and 334.105 RSMo.

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(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Encourages healthcare professionals to understand and follow federal and state laws governing their practice, which can better ensure that practitioners follow the *balanced* approach represented by federal law and the laws in many states.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY B:
Issues related to patients

COMMENT:
Acknowledges that a patient's prior history or current status of drug abuse does not necessarily contraindicate appropriate pain management.

Pain & Policy Studies Group
University of Wisconsin Carbone Cancer Center
Madison, Wisconsin

MISSOURI

OTHER GOVERNMENTAL POLICY

Medical Board Guideline

(CONTINUED)

Section III: Definitions

For the purposes of these guidelines, the following terms are defined as follows:

Acute Pain
Acute pain is the normal, predicted physiological response to an adverse chemical, thermal or mechanical stimulus and is associated with surgery, trauma and acute illness. It is generally time-limited and is responsive to opioid therapy, among other therapies.

Addiction
Addiction is a neurobehavioral syndrome with genetic and environmental influences that results in psychological dependence on the use of substances for their psychic effects and is characterized by compulsive use despite harm. Addiction may also be referred to by terms such as "drug dependence" and "psychological dependence." Physical dependence and tolerance are normal physiological consequences of extended opioid therapy for pain and should not be considered addiction.

Analgesic Tolerance
Analgesic tolerance is the need to increase the dose of opioid to achieve the same level of analgesia. Analgesic tolerance may or may not be evident during opioid treatment and does not equate with addiction.

Chronic Pain
A pain state which is persistent and in which the cause of the pain cannot be removed or otherwise treated. Chronic pain may be associated with a long-term incurable or intractable medical condition or disease.

Pain
An unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage.

Pseudoaddiction
Pattern of drug-seeking behavior of pain patients who are receiving inadequate pain management that can be mistaken for addiction.

Substance Abuse
Substance abuse is the use of any substance(s) for non-therapeutic purposes or use of medication for purposes other than those for which it is prescribed.

Tolerance
Tolerance is a physiologic state resulting from regular use of a drug in which an increased dosage is needed to produce the same effect, or a reduced effect is observed with a constant dose.

Pain & Policy Studies Group
University of Wisconsin Carbone Cancer Center
Madison, Wisconsin

MISSOURI

OTHER GOVERNMENTAL POLICY

Joint Board Policy Statement

Joint Statement on Pain Management by the Missouri Board of Healing Arts, Board of Nursing and Board of Pharmacy

December 2008

Pain is one of the oldest medical problems and the most universal physical affliction. It also is one of the most common reasons for people to seek medical attention. Adequate pain management leads to enhanced functioning and increased quality of life. In contrast, inadequately controlled pain can have such profound consequences as disability, depression and despair. In addition, inadequately controlled pain can increase utilization of healthcare resources and expenditures.

The Missouri Boards of Healing Arts, Nursing and Pharmacy are in accord with the Joint Commission on Accreditation of Healthcare Organizations in recognizing that "Patients have the right to appropriate assessment and management of pain." Inappropriate treatment of pain includes non-treatment, undertreatment, overtreatment, and the continued use of ineffective treatments. It is, therefore, incumbent upon Missouri physicians, nurses, pharmacists and other health professionals to work cooperatively and effectively to address the multiple dimensions of pain and to provide maximum pain relief with minimal side effects.

In the interest of the public's health, the Missouri Boards of Healing Arts, Nursing and Pharmacy issue this joint statement. This statement is not intended to define complete or best practice, but rather to communicate guidelines for professional practice. These guidelines are not intended to interfere with a healthcare provider's professional duty to exercise that degree of learning and skill ordinarily possessed by competent members of the healthcare provider's profession.

To effectively assist patients in the management of pain, health care professionals should, within their scope of practice:

- Consistently and thoroughly assess all patients for pain. Identified pain should be evaluated with a complete history and physical, including laboratory and diagnostic testing, if indicated;
- Recognize the individual variables influencing pain and its management, including age, cognitive ability, culture, religion, socioeconomic status, and ethnicity;
- Assess common sequelae of untreated pain, including depression, anxiety, and social isolation;
- Document all aspects of pain assessment and care in a timely, clear, consistent, complete and accurate manner;
- Use a multi-disciplinary approach, when available, to develop and implement an individualized, outcome-based, written treatment plan that incorporates appropriate pharmacologic and/or non-pharmacologic and psychological interventions;
- Regularly evaluate and document the effectiveness of the treatment plan, using a consistent, developmentally appropriate, standardized assessment tool;
- Adjust the treatment plan as necessary to optimize comfort, quality of life, and functionality as defined by the patient and the treatment team;
- Anticipate and effectively manage side effects of pain medications;
- Educate patients, family members, and caregivers with respect to their rights and responsibilities regarding pain and its management;
- Minimize risks of diversion and abuse of controlled substances through appropriate assessment, monitoring, and documentation;

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(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY B:
Issues related to patients

COMMENT: Recognizes the patient's right to treatment of pain.

(+) *CRITERION 2:*
Pain management is part of healthcare practice

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Recognizes the need for a multidisciplinary approach to pain management.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Recognizes that inadequate treatment of pain is subject to disciplinary action just as other substandard practices might be.

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MISSOURI

OTHER GOVERNMENTAL POLICY

Joint Board Policy Statement

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY B:
Issues related to patients

COMMENT*:* Recognizes that a patient's prior history or current status of drug abuse does not necessarily contraindicate appropriate pain management.

(CONTINUED)

- Recognize that individuals with the disease of addiction may also experience pain and may require the use of analgesics, including opioids. Specialized management and/or referral may be necessary;
- Consult and refer to other providers in cases where patients have pain that cannot be effectively managed;
- Utilize evidence-based policies and protocols for pain management when possible;
- Apply appropriate, up-to-date knowledge and treatment; and
- Comply with all state and federal laws and regulations regarding prescribing, dispensing, and administering prescription drugs, including controlled substances.

Pertinent terms relating to pain management are defined as follows:

Acute Pain
Acute pain is the normal, predicted physiological response to an adverse chemical, thermal or mechanical stimulus and is associated with surgery, trauma and acute illness. It is generally time-limited and is responsive to opioid therapy, among other therapies.

Addiction
Addiction is a neurobehavioral syndrome with genetic and environmental influences that results in psychological dependence on the use of substances for their psychic effects and is characterized by compulsive use despite harm. Addiction may also be referred to by terms such as "drug dependence" and "psychological dependence." Physical dependence and tolerance are normal physiological consequences of extended opioid therapy for pain and should not be considered addiction.

Analgesic Tolerance
Analgesic tolerance is the need to increase the dose of opioid to achieve the same level of analgesia. Analgesic tolerance may or may not be evident during opioid treatment and does not equate with addiction.

Chronic Pain
A pain state which is persistent and in which the cause of the pain cannot be removed or otherwise treated. Chronic pain may be associated with a long-term incurable or intractable medical condition or disease.

Pain
An unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage.

Physical Dependence
Physical dependence on a controlled substance is a physiologic state of neuroadaptation which is characterized by the emergence of a withdrawal syndrome if drug use is stopped or decreased abruptly, or if an antagonist is administered. Physical dependence is an expected result of opioid use. Physical dependence, by itself, does not equate with addiction.

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(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT*:* Encourages healthcare professionals to understand and follow federal and state laws governing their practice, which can better ensure that practitioners follow the *balanced* approach represented by federal law and the laws in many states.

(+) *CRITERION 7:*
Physical dependence or analgesic tolerance are not confused with "addiction"

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Madison, Wisconsin

MISSOURI

OTHER GOVERNMENTAL POLICY

Joint Board Policy Statement

(CONTINUED)

Pseudoaddiction
Pattern of drug-seeking behavior of pain patients who are receiving inadequate pain management that can be mistaken for addiction.

Substance Abuse
Substance abuse is the use of any substance(s) for non-therapeutic purposes or use of medication for purposes other than those for which it is prescribed.

Tolerance
Tolerance is a physiologic state resulting from regular use of a drug in which an increased dosage is needed to produce the same effect, or a reduced effect is observed with a constant dose.

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MISSOURI

REGULATIONS

Hospice Services Program

13 CSR 70-50.010

70-50.010 Hospice Services Program

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The following services are hospice-covered services when specified in the individual's plan of care:

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(I) Short-term inpatient care required for procedures necessary for pain control or acute or chronic symptom management provided in a participating hospice inpatient unit, or a participating hospital, or nursing facility (NF) that additionally meets the special hospice standards regarding staffing and patient areas;

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(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (inpatient care) for hospices to ensure that pain management is an essential part of patient care.

REGULATIONS

Hospice Program Operations

19 CSR 30-35.010

30-35.010 Hospice Program Operations

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(G) Clinical Services. The hospice shall routinely provide through direct employees the following services:

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2. Medical director services. The medical director shall be a direct or contract employee. The medical director's or designee's services and responsibilities include:

A. Consulting with attending physicians regarding pain and symptom control;

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(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (medical director services) for hospices to ensure that pain management is an essential part of patient care.

2013

Pain & Policy Studies Group
University of Wisconsin Carbone Cancer Center
Madison, Wisconsin

MONTANA

STATUTES

- CONTROLLED SUBSTANCES ACT
  Title 50. Health and Safety; Chapter 32. Controlled Substances

- MEDICAL PRACTICE ACT (*No provisions found*)
  Title 37. Professions and Occupations; Chapter 3. Medicine

- PHARMACY PRACTICE ACT
  Title 37. Professions and Occupations; Chapter 7. Pharmacy

- INTRACTABLE PAIN TREATMENT ACT
  No policy found

REGULATIONS

- CONTROLLED SUBSTANCES REGULATIONS (*Part of Pharmacy Board Regulations*) (*No provisions found*)
  Title 24. Labor and Industry; Chapter 174. Board of Pharmacy;
  Sub-Chapter 14. Dangerous Drug Act

- MEDICAL BOARD REGULATIONS (*No provisions found*)
  Title 24. Labor and Industry; Chapter 156. Medical Examiners

- PHARMACY BOARD REGULATIONS (*No provisions found*)
  Title 24. Labor and Industry; Chapter 174. Board of Pharmacy

OTHER GOVERNMENTAL POLICIES

- MEDICAL BOARD GUIDELINE
  Montana Board of Medical Examiners. *Guidelines for the Use of Controlled Substances for the Treatment of Pain*. Adopted: January 23, 2009; Revised: March 27, 2009.

- JOINT BOARD POLICY STATEMENT
  Montana Board of Medical Examiners, Board of Nursing, and Board of Pharmacy. *Statement of the Prescribing and Filling of Controlled Substances in the Treatment of Chronic Pain*. Adopted: July 27, 2002.

RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY KEY WORD SEARCHES

- PROFESSIONAL PRACTICE
  Title 37. Professions and Occupations; Chapter 2. General Provisions Relating to Health Care Practitioners

Pain & Policy Studies Group
University of Wisconsin Carbone Cancer Center
Madison, Wisconsin

MONTANA

STATUTES

Controlled Substances Act

Mont. Code Anno., § 50-32-101

50-32-101 Definitions.

As used in this chapter, the following definitions apply:

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(24) "Practitioner" means:

(a) a physician, dentist, veterinarian, scientific investigator, or other person licensed, registered, or otherwise permitted to distribute, dispense, or conduct research with respect to or to administer a dangerous drug in the course of professional practice or research in this state;

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(+) *CRITERION 3:*
Opioids are part of professional practice

STATUTES

Pharmacy Practice Act

Mont. Code Anno., § 37-7-1506

37-7-1506 Providing prescription drug registry information.

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(7) The procedures established by the board under this section may not impede patient access to prescription drugs for legitimate medical purposes.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Represents the principle of Balance, which states that efforts to reduce the abuse and diversion of controlled substances should not interfere with legitimate medical use.

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Pain & Policy Studies Group
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Madison, Wisconsin

MONTANA

OTHER GOVERNMENTAL POLICY

Medical Board Guideline

GUIDELINES FOR THE USE OF CONTROLLED SUBSTANCES FOR THE TREATMENT OF PAIN

Section I: Preamble

The Montana Board of Medical Examiners recognizes that principles of quality medical practice dictate that the people of the State of Montana have access to appropriate and effective pain relief. The appropriate application of up-to-date knowledge and treatment modalities can serve to improve the quality of life for those patients who suffer from pain as well as reduce the morbidity and costs associated with untreated or inappropriately treated pain. For the purposes of this policy, the inappropriate treatment of pain includes nontreatment, undertreatment, overtreatment, and the continued use of ineffective treatments.

The diagnosis and treatment of pain is integral to the practice of medicine. The Board encourages physicians to view pain management as a part of quality medical practice for all patients, including children of all ages, with pain, acute or chronic, and it is especially urgent for patients who experience pain as a result of terminal illness.

Appropriate treatment of acute and chronic pain in the pediatric population has received considerable attention in the past decade, but no widely accepted protocols have been established. Pain issues in children range from the neonate (e.g. intensive care invasive procedures and circumcision) to chronic pain in teenagers (e.g. rheumatoid arthritis, corrective scoliosis procedures, cancer). Determination of the degree and duration of pain in young non-verbal children requires a different diagnostic and monitoring system than those used for adults. A broad spectrum of analgesics can be used in children with careful attention to dosage. Despite the inherent challenges, healthcare providers must recognize that although the expression of pain may be quite different in infants and children, diagnosis and treatment of both acute and chronic pain is no less important than in the adult population. A number of children's medical centers have established pain programs and can serve as an important resource.

All physicians should become knowledgeable about assessing patients' pain and effective methods of pain treatment, as well as statutory requirements for prescribing controlled substances. Accordingly, this policy has been developed to clarify the Board's position on pain control, particularly as related to the use of controlled substances, to alleviate physician uncertainty and to encourage better pain management.

Inappropriate pain treatment may result from physicians' lack of knowledge about pain management. Fears of investigation or sanction by federal, state and local agencies may also result in inappropriate treatment of pain. Appropriate pain management is the treating physician's responsibility. As such, the Board will consider the inappropriate treatment of pain to be a departure from standards of practice and will investigate such allegations, recognizing that some types of pain cannot be completely relieved, and taking into account whether the treatment is appropriate for the diagnosis.

The Board recognizes that controlled substances including opioid analgesics may be essential in the treatment of acute pain due to trauma or surgery and chronic pain, whether due to cancer or non-cancer origins. The Board will refer to current clinical practice guidelines and expert review in approaching cases involving management of pain. The medical management of pain should consider current clinical knowledge and scientific research and the use of pharmacologic and non-pharmacologic modalities according to the judgment of the physician. Pain should be assessed and treated promptly, and the quantity and frequency of doses should be adjusted according to the intensity, duration of the pain, and treatment outcomes. Physicians should recognize that tolerance and physical dependence are normal consequences of sustained use of opioid analgesics and are not the same as addiction.

(CONTINUED ON NEXT PAGE)

(+) *CRITERION 2:*
Pain management is part of healthcare practice

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Identifies the potential impact of important barriers on the provision of effective pain care.

(+) *CRITERION 8:*
Other provisions that may enhance pain treatment

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Recognizes that inadequate treatment of pain is subject to disciplinary action just as other substandard practices might be.

(+) *CRITERION 4:*
Encourages pain management

(+) *CRITERION 7:*
Physical dependence or analgesic tolerance are not confused with "addiction"

2013

Pain & Policy Studies Group
University of Wisconsin Carbone Cancer Center
Madison, Wisconsin

MONTANA

OTHER GOVERNMENTAL POLICY

Medical Board Guideline

(CONTINUED)

The Board of Medical Examiners is obligated under the laws of the State of Montana to protect the public health and safety. The Board recognizes that the use of opioid analgesics for other than legitimate medical purposes pose a threat to the individual and society and that the inappropriate prescribing of controlled substances, including opioid analgesics, may lead to drug diversion and abuse by individuals who seek them for other than legitimate medical use. Accordingly, the Board expects that physicians incorporate safeguards into their practices to minimize the potential for the abuse and diversion of controlled substances.

Physicians should not fear disciplinary action from the Board for ordering, prescribing, dispensing or administering controlled substances, including opioid analgesics, for a legitimate medical purpose and in the course of professional practice. The Board will consider prescribing, ordering, dispensing or administering controlled substances for pain to be for a legitimate medical purpose if based on sound clinical judgment. All such prescribing must be based on clear documentation of unrelieved pain. To be within the usual course of professional practice, a physician-patient relationship must exist and the prescribing should be based on a diagnosis and documentation of unrelieved pain. Compliance with applicable state or federal law is required.

The Board will judge the validity of the physician's treatment of the patient based on available documentation, rather than solely on the quantity and duration of medication administration. The goal is to control the patient's pain while effectively addressing other aspects of the patient's functioning, including physical, psychological, social and work-related factors.

Allegations of inappropriate pain management will be evaluated on an individual basis. The Board will not take disciplinary action against a physician for deviating from this policy when contemporaneous medical records document reasonable cause for deviation. The physician's conduct will be evaluated to a great extent by the outcome of pain treatment, recognizing that some types of pain cannot be completely relieved, and by taking into account whether the drug used is appropriate for the diagnosis, as well as improvement in patient functioning and/or quality of life.

Section II: Guidelines
The Board has adopted the following criteria when evaluating the physician's treatment of pain, including the use of controlled substances:

Evaluation of the Patient—A medical history and physical examination must be obtained, evaluated, and documented in the medical record. The medical record should document the nature and intensity of the pain, current and past treatments for pain, underlying or coexisting diseases or conditions, the effect of the pain on physical and psychological function, and history of substance abuse. The medical record also should document the presence of one or more recognized medical indications for the use of a controlled substance.

Treatment Plan—The written treatment plan should state objectives that will be used to determine treatment success, such as pain relief and improved physical and psychosocial function, and should indicate if any further diagnostic evaluations or other treatments are planned. After treatment begins, the physician should adjust drug therapy to the individual medical needs of each patient. Other treatment modalities or a rehabilitation program may be necessary depending on the etiology of the pain and the extent to which the pain is associated with physical and psychosocial impairment.

(CONTINUED ON NEXT PAGE)

(+) *CRITERION 5:*
Addresses fear of regulatory scrutiny

(+) *CRITERION 6:*
Prescription amount alone does not determine legitimacy

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT*:* Acknowledges need for treatment flexibility for physicians to respond to individual clinical circumstances, as long as their prescribing maintains the standards of good medical practice.

(+) *CRITERION 3:*
Opioids are part of professional practice

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT*:* Recognizes that the goals of pain treatment should extend beyond pain scores, to include improvements in patient functioning and quality of life.

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Pain & Policy Studies Group
University of Wisconsin Carbone Cancer Center
Madison, Wisconsin

MONTANA

OTHER GOVERNMENTAL POLICY

Medical Board Guideline

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Encourages healthcare professionals to incorporate in their practice the evaluations of, and discussions with patients about, the potential benefits and risks of treatment with opioids, which can better ensure a clinical indication of such treatment so that opioids will be used for medical purposes.

(CONTINUED)

Informed Consent and Agreement for Treatment—The physician should discuss the risks and benefits of the use of controlled substances with the patient, persons designated by the patient or with the patient's surrogate or guardian if the patient is without medical decision-making capacity. The patient should receive prescriptions from one physician and one pharmacy whenever possible. If the patient is at high risk for medication abuse or has a history of substance abuse, the physician should consider the use of a written agreement between physician and patient outlining patient responsibilities, including

- urine/serum medication levels screening when requested;
- number and frequency of all prescription refills; and
- reasons for which drug therapy may be discontinued (e.g., violation of agreement).

Periodic Review—The physician should periodically review the course of pain treatment and any new information about the etiology of the pain or the patient's state of health. Continuation or modification of controlled substances for pain management therapy depends on the physician's evaluation of progress toward treatment objectives. Satisfactory response to treatment may be indicated by the patient's decreased pain, increased level of function, or improved quality of life. Objective evidence of improved or diminished function should be monitored and information from family members or other caregivers should be considered in determining the patient's response to treatment. If the patient's progress is unsatisfactory, the physician should assess the appropriateness of continued use of the current treatment plan and consider the use of other therapeutic modalities.

Consultation—The physician should be willing to refer the patient as necessary for additional evaluation and treatment in order to achieve treatment objectives. Special attention should be given to those patients with pain who are at risk for medication misuse, abuse or diversion. The management of pain in patients with a history of substance abuse or with a comorbid psychiatric disorder may require extra care, monitoring, documentation and consultation with or referral to an expert in the management of such patients.

Medical Records—The physician should keep accurate and complete records to include

1. the medical history and physical examination,
2. diagnostic, therapeutic and laboratory results,
3. evaluations and consultations,
4. treatment objectives,
5. discussion of risks and benefits,
6. informed consent,
7. treatments,
8. medications (including date, type, dosage and quantity prescribed),
9. instructions and agreements and
10. periodic reviews.

Records should remain current and be maintained in an accessible manner and readily available for review.

Compliance With Controlled Substances Laws and Regulations—To prescribe, dispense or administer controlled substances, the physician must be licensed in the state and comply with applicable federal and state regulations. Physicians are referred to the Physicians Manual of the U.S. Drug Enforcement Administration for specific rules governing controlled substances as well as applicable state regulations.

(CONTINUED ON NEXT PAGE)

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY B:
Issues related to patients

COMMENT: Acknowledges that a patient's prior history or current status of drug abuse does not necessarily contraindicate appropriate pain management.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Encourages healthcare professionals to understand and follow federal and state laws governing their practice, which can better ensure that practitioners follow the *balanced* approach represented by federal law and the laws in many states.

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Pain & Policy Studies Group
University of Wisconsin Carbone Cancer Center
Madison, Wisconsin

MONTANA

OTHER GOVERNMENTAL POLICY

Medical Board Guideline

(CONTINUED)

Section III: Definitions
For the purposes of these guidelines, the following terms are defined as follows:

Acute Pain—Acute pain is the normal, predicted physiological response to a noxious chemical, thermal or mechanical stimulus and typically is associated with invasive procedures, trauma and disease. It is generally time-limited.

Addiction—Addiction is a primary, chronic, neurobiologic disease, with genetic, psychosocial, and environmental factors influencing its development and manifestations. It is characterized by behaviors that include the following: impaired control over drug use, craving, compulsive use, and continued use despite harm. Physical dependence and tolerance are normal physiological consequences of extended opioid therapy for pain and are not the same as addiction.

Chronic Pain—Chronic pain is a state in which pain persists beyond the usual course of an acute disease or healing of an injury, or that may or may not be associated with an acute or chronic pathologic process that causes continuous or intermittent pain over months or years.

Pain—An unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage.

Physical Dependence—Physical dependence is a state of adaptation that is manifested by drug class specific signs and symptoms that can be produced by abrupt cessation, rapid dose reduction, decreasing blood level of the drug, and/or administration of an antagonist. Physical dependence, by itself, does not equate with addiction.

Pseudoaddiction—The iatrogenic syndrome resulting from the misinterpretation of relief seeking behaviors as though they are drug-seeking behaviors that are commonly seen with addiction. The relief seeking behaviors resolve upon institution of effective analgesic therapy.

Substance Abuse—Substance abuse is the use of any substance(s) for non-therapeutic purposes or use of medication for purposes other than those for which it is prescribed.

Tolerance—Tolerance is a physiologic state resulting from regular use of a drug in which an increased dosage is needed to produce a specific effect, or a reduced effect is observed with a constant dose over time. Tolerance may or may not be evident during opioid treatment and does not equate with addiction.

Pain & Policy Studies Group
University of Wisconsin Carbone Cancer Center
Madison, Wisconsin

MONTANA

OTHER GOVERNMENTAL POLICY

Joint Board Policy Statement

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT*:* Clarifies for pharmacists the important distinction between drug-seeking behaviors resulting from poorly treated pain (i.e., pseudoaddiction) and drug-seeking behaviors related to abuse or addiction; this language identifies a potential clinical situation and attempts to lessen its impact on patient treatment.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Recognizes that the goal of pain treatment should include improvements in patient functioning and quality of life.

STATEMENT OF THE PRESCRIBING AND FILLING OF CONTROLLED SUBSTANCES IN THE TREATMENT OF CHRONIC PAIN

The Montana Board of Medical Examiners, Montana Board of Nursing and Montana Board of Pharmacy recognize that pain has historically been under treated due to an exaggerated fear of patient addiction and diversion of pain medication with corresponding fear of legal consequences and a lack of current knowledge concerning pain management. Untreated chronic pain can lead to clinical exacerbations, increased suffering and eventual disability. Patient requests for more pain medication can often be interpreted as drug seeking behavior, when inadequately treated pain is actually the cause.

Improper prescribing and dispensing of opioids will continue to be a concern of the Montana Board of Medical Examiners, Board of Nursing, and the Board of Pharmacy. However, appropriate prescribing of opioid analgesics should be encouraged by all of those involved in patient care. Both the physician or other healthcare provider and the pharmacist share responsibility for appropriate prescribing of opioid pain medication. The Board of Medical Examiners has established a policy for appropriate treatment of chronic pain, which is outlined below. With use of these guidelines and appropriate communication between practitioners and pharmacists, inappropriate use of opioid pain medications will be minimized. If a pharmacist has suspicion of the inappropriateness of a pain medication, he or she should contact the practitioner concerning this issue.

Treatment of chronic pain is multifactorial and treatment with modalities other than opioids should usually be utilized before opioids are prescribed. The use of alternative types of treatment should be considered periodically to reassess the necessity of continued opioid use. The following guidelines have been provided in the form of a policy letter from the Board of Medical Examiners to providers in the state:

Board of Medical Examiners recommendations:

• **Thorough history and physical examination**. Included in the history is assessment of the etiology of pain, physical and psychological function of the patient, substance abuse history, other treatments that have been attempted to control the patient's level of pain, identification of underlying or co-existing diseases or conditions and, as much as possible, statements by all treating physicians that the patient's pain is intractable and not controlled by other than the use of opioid analgesics.

• **Treatment plan**. A thoroughly documented, written treatment plan should be established and should include how treatment success will be evaluated, such as pain relief and improved physical or psychological functioning. Several treatment modalities should be utilized in most cases and should be done concurrently with the use of opiates. Periodic review by the physician should be accomplished to determine that there are no other appropriate treatment methods that would then be of additional benefit to the patient.

• **Informed consent**. The physician should discuss the risks and benefits of the use of controlled substances with the patient and/or guardian and this should be accomplished on an ongoing basis, not just at the initiation of treatment.

• **Appropriate referral**. If treatment objectives are not being realized or if patients appear to be at risk for misuse of medications, referral should be made to appropriate specialists including addiction medicine specialists and chronic pain specialists.

• **Documentation**. All the above recommendations and guidelines should be recorded accurately and completely in the patient's medical record.

[CONTINUED ON NEXT PAGE]

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Identifies the potential impact of important barriers on the provision of effective pain care.

(+) *CRITERION 3:*
Opioids are part of professional practice

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT*:* Recognizes the need for a multidisciplinary approach to pain management.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Encourages healthcare professionals to incorporate in their practice the evaluations of, and discussions with patients about, the potential benefits and risks of treatment with opioids, which can better ensure a clinical indication of such treatment so that opioids will be used for medical purposes.

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Pain & Policy Studies Group
University of Wisconsin Carbone Cancer Center
Madison, Wisconsin

MONTANA

OTHER GOVERNMENTAL POLICY

Joint Board Policy Statement

(CONTINUED)

A pharmacist evaluating a controlled substance prescription should consider the following points:

- Are you able to verify the identity of the prescriber and the patient?
- What is the physical condition and demeanor of the patient with respect to the drug being prescribed? Is the prescribed drug therapeutically appropriate to the patient's diagnosis?
- Does the patient live within the general area of the pharmacy? If not, is the distance great enough to make it unlikely the patient would travel so far to fill a legitimate prescription?
- Does the drug prescribed have a pattern of abuse, and does the patient have any known history of drug abuse or misuse that might contraindicate the use of this drug?
- Is the prescription consistent with the prescribing patterns of the practitioner, including the type and amount of drug prescribed? Does the practitioner write for a greater than usual percentage of controlled substances? Are you aware of any prior disciplinary or criminal action involving the practitioner?
- Are the drugs prescribed consistent with the practitioner's specialty and scope of practice? Does the prescription contain an unusual combination of drugs, or drugs that antagonize one another?
- Does the quantity of drug prescribed and refills authorized differ appreciably from recognized and accepted prescribing practices?

Studies have shown that the abuse potential of opioids is generally low in healthy volunteers who do not abuse drugs. Practitioners are encouraged to reverse the trend of under treatment of pain, yet remain aware of the dangers of diversion and nonmedical use of controlled substances. It is imperative the pharmacists and prescribers continue to strive for open and clear lines of communication regarding their patient's use and possible misuse of medications. The Board of Medical Examiners, Nursing and Pharmacy seek to assure that no Montana resident will needlessly suffer due to under treated pain and encourage both prescribers and pharmacists to do their part by responsibly prescribing and dispensing opioids.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT*:* Represents the principle of Balance, which states that efforts to reduce the abuse and diversion of controlled substances should not interfere with legitimate medical use.

(+) *CRITERION 4:*
Encourages pain management

2013

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Madison, Wisconsin

MONTANA

STATUTES

Professional Practice

Mont. Code Anno., § 37-2-101

37-2-101 Definitions.

As used in this part, the following definitions apply:

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(5) "Medical practitioner" means any person licensed by the state of Montana to engage in the practice of medicine, dentistry, osteopathy, podiatry, optometry, or a nursing specialty as described in *37-8-202* and in the licensed practice to administer or prescribe drugs.

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(+) *CRITERION 3:*
Opioids are part of professional practice

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Madison, Wisconsin

NEBRASKA

STATUTES

- CONTROLLED SUBSTANCES ACT
  Chapter 28. Crimes and Punishments; Article 4. Drugs and Narcotics

- MEDICAL PRACTICE ACT
  Chapter 38. Health Occupations and Professions; Article 20. Medicine and Surgery Practice Act

- PHARMACY PRACTICE ACT (*No provisions found*)
  Chapter 38. Health Occupations and Professions; Article 28. Pharmacy Practice Act

- INTRACTABLE PAIN TREATMENT ACT
  No policy found

REGULATIONS

- CONTROLLED SUBSTANCES REGULATIONS
  No policy found

- MEDICAL BOARD REGULATIONS (*Governs Osteopathic Board*)
  Title 172. Professional and Occupational Licensure (Department of Health and Human Services); Chapter 88. Regulations Governing the Practice of Medicine and Surgery and Osteopathic Medicine and Surgery

- PHARMACY BOARD REGULATIONS
  Title 172. Professional and Occupational Licensure (Department of Health and Human Services); Chapter 128. Practice of Pharmacy

  Title 175. Health Care Facilities and Services Licensure (Department of Health and Human Services); Chapter 8. Pharmacies

OTHER GOVERNMENTAL POLICIES

- MEDICAL BOARD GUIDELINE
  Nebraska Board of Medicine and Surgery. *Guidelines for the Use of Controlled Substances for the Treatment of Pain*. Adopted: December 14, 2012.

RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY KEY WORD SEARCHES

- PAIN MANAGEMENT ACT
  Chapter 71. Public Health and Welfare; Article 24. Drugs; (d) Pain Management

- HOSPICE SERVICES
  Title 175. Health Care Facilities and Services Licensure (Department of Health and Human Services); Chapter 16. Hospice Services

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Madison, Wisconsin

NEBRASKA

STATUTES

Controlled Substances Act

R.R.S. Neb. § 28-401

§ 28-401. Terms, defined

As used in the Uniform Controlled Substances Act, unless the context otherwise requires:

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(20) Practitioner shall mean a physician, a physician assistant, a dentist, a veterinarian, a pharmacist, a podiatrist, an optometrist, a certified nurse midwife, a certified registered nurse anesthetist, a nurse practitioner, a scientific investigator, a pharmacy, a hospital, or any other person licensed, registered, or otherwise permitted to distribute, dispense, prescribe, conduct research with respect to, or administer a controlled substance in the course of practice or research in this state, including an emergency medical service as defined in section 71-5175;

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(+) CRITERION 3:
Opioids are part of professional practice

STATUTES

Medical Practice Act

R.R.S. Neb. § 38-2024

§ 38-2024. Practice of medicine and surgery, defined.

For purposes of the Uniform Credentialing Act, and except as provided in *section 38-2025* or as otherwise provided by law, the following classes of persons shall be deemed to be engaged in the practice of medicine and surgery:

(1) Persons who publicly profess to be physicians or surgeons or publicly profess to assume the duties incident to the practice of medicine, surgery, or any of their branches;

(2) Persons who prescribe and furnish medicine for some illness, disease, ailment, injury, pain, deformity, or any physical or mental condition, or treat the same by surgery;

(3) Persons holding themselves out to the public as being qualified in the diagnosis or treatment of diseases, ailments, pain, deformity, or any physical or mental condition, or injuries of human beings;

(4) Persons who suggest, recommend, or prescribe any form of treatment for the intended palliation, relief, or cure of any physical or mental ailment of any person;

(5) Persons who maintain an office for the examination or treatment of persons afflicted with ailments, diseases, injuries, pain, deformity, or any physical or mental condition of human beings;

(6) Persons who attach to their name the title of M.D., surgeon, physician, physician and surgeon, or any word or abbreviation and who indicate that they are engaged in the treatment or diagnosis of ailments, diseases, injuries, pain, deformity, infirmity, or any physical or mental condition of human beings; and

(7) Persons who are physically located in another state but who, through the use of any medium, including an electronic medium, perform for compensation any service which constitutes the healing arts that would affect the diagnosis or treatment of an individual located in this state.

(+) CRITERION 2:
Pain management is part of healthcare practice

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Madison, Wisconsin

NEBRASKA

REGULATIONS

Medical Board Regulations

Nebraska Admin. Code Title 172, Ch. 88

CHAPTER 88. REGULATIONS GOVERNING THE PRACTICE OF MEDICINE AND SURGERY AND OSTEOPATHIC MEDICINE AND SURGERY

001 SCOPE OF REGULATIONS These regulations are intended to implement the laws governing the practice of Medicine and Surgery and Osteopathic Medicine and Surgery pursuant to Neb. Rev. Stat. " 71-1,102 to 71-1,107.30, 71-1,137 to 71-1,141 and the Uniform Licensing Law.

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88-010.02 Unprofessional Conduct: Unprofessional conduct means any departure from or failure to conform to the standards of acceptable and prevailing practice of medicine and surgery or the ethics of the profession, regardless of whether a person, patient, or entity is injured, but does not include a single act of ordinary negligence. Unprofessional conduct also means conduct that is likely to deceive or defraud the public or is detrimental to the public interest. Unprofessional conduct includes but is not limited to:

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23. Except as otherwise permitted by law, prescribing, selling, administering, distributing, ordering, or giving to an addict or any person previously drug dependent, any drug legally classified as a controlled substance;

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(-) *CRITERION 12:*
Medical decisions are restricted

CATEGORY A:
Restrictions based on patient characteristics

COMMENT: Nebraska law does not seem to create an exemption for patients with pain and a history of addiction.

Pain & Policy Studies Group
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Madison, Wisconsin

NEBRASKA

REGULATIONS

Pharmacy Board Regulations

Nebraska Admin. Code Title 175, Ch. 8

CHAPTER 8. PHARMACIES

8-001 SCOPE AND AUTHORITY: These regulations govern licensure of Pharmacies. The regulations are authorized by and implement the Health Care Facility Licensure Act, *Neb. Rev. Stat. sections 71-401* to 71-462.

8-002 DEFINITIONS

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Healing arts means a health profession in which a licensed practitioner offers or undertakes to diagnose, treat, operate on, or prescribe for any human pain, injury, disease, deformity, or physical or mental condition.

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128-009 UNPROFESSIONAL CONDUCT: In addition to the unlawful or unprofessional acts listed in *Neb. Rev. Stat. §§ 71-147* through *71-148*, the following conduct will be considered unprofessional acts as defined by the Board per *Neb. Rev. Stat. § 71-147(10)*:

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7. Except as otherwise permitted by law, dispensing, selling, administering, distributing, ordering, or giving to a person, known by the pharmacist to be an addict or any person previously drug dependent, any drug legally classified as a controlled substance;

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(+) *CRITERION 2:*
Pain management is part of healthcare practice

(-) *CRITERION 12:*
Medical decisions are restricted

CATEGORY A:
Restrictions based on patient characteristics

COMMENT: Nebraska law does not seem to create an exemption for patients with pain and a history of addiction.

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Pain & Policy Studies Group
University of Wisconsin Carbone Cancer Center
Madison, Wisconsin

NEBRASKA

OTHER GOVERNMENTAL POLICY

Medical Board Guideline

GUIDELINES FOR THE USE OF
CONTROLLED SUBSTANCES FOR THE TREATMENT OF PAIN

Section I: Preamble

"Drug overdose deaths were second only to motor vehicle crash deaths among leading causes of unintentional injury death in 2007 in the United States." Centers for Disease Control and Prevention (CDC) "Unintentional Drug Poisoning in the United States", July, 2010. http://www.cdc.gov/homeandrecreationalsafety/pdf/poison-issue-brief.pdf

The Nebraska Board of Medicine and Surgery recognizes that principles of quality medical practice dictate that the people of the State of Nebraska have access to appropriate and effective pain relief. The appropriate application of up-to-date knowledge and treatment modalities can improve the quality of life for those patients who suffer from pain as well as reduce the morbidity and costs associated with untreated or inappropriately treated pain. For the purposes of this policy, the inappropriate treatment of pain includes non-treatment, under-treatment, over-treatment, or the continued use of ineffective treatments.

The diagnosis and treatment of pain is integral to the practice of medicine. The Board encourages physicians to view pain management as a part of quality medical practice for all patients with pain, acute or chronic. Pain management is especially urgent for patients who experience pain as a result of terminal illness. All physicians should become knowledgeable about assessing pain and effective methods of pain treatment, as well as statutory requirements for prescribing controlled substances. Accordingly, this policy has been developed to clarify the Board's position on pain control, particularly as related to the use of controlled substances, as well as to alleviate physician uncertainty and to encourage better pain management.

Inappropriate pain treatment can result from a lack of knowledge about pain management. Fears of investigation or sanction by federal, state, or local agencies can also result in inappropriate treatment of pain. Appropriate pain management is the treating physician's responsibility. As such, the Board will consider the inappropriate treatment of pain to be a departure from standards of practice and will investigate such allegations, recognizing that some types of pain cannot be completely relieved, and taking into account whether the treatment is appropriate for the diagnosis.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT*:* Recognizes that inadequate treatment of pain is subject to disciplinary action just as other substandard practices might be.

(+) *CRITERION 4:*
Encourages pain management

(+) *CRITERION 2:*
Pain management is part of healthcare practice

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Identifies the potential impact of important barriers on the provision of effective pain care.

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Pain & Policy Studies Group
University of Wisconsin Carbone Cancer Center
Madison, Wisconsin

NEBRASKA

OTHER GOVERNMENTAL POLICY

Medical Board Guideline

(CONTINUED)

The Board recognizes that controlled substances including opioid analgesics, are essential in the treatment of acute pain due to trauma or surgery and chronic pain, whether due to cancer or non-cancer origins. The Board will refer to current clinical practice guidelines and expert review in approaching cases involving management of pain. The medical management of pain should consider current clinical knowledge and scientific research and the use of pharmacologic and non-pharmacologic modalities according to the judgment of the physician. Pain should be assessed and treated promptly, and the quantity and frequency of doses should be adjusted according to the intensity, duration of the pain, and treatment outcomes. Physicians should recognize that tolerance and physical dependence are normal consequences of sustained use of opioid analgesics and are not the same as addiction.

The Nebraska Board of Medicine and Surgery is obligated under the laws of the State of Nebraska to protect the public health and safety. The Board recognizes that the use of opioid analgesics for other than legitimate medical purposes poses a threat to the individual and society and that the inappropriate prescribing of controlled substances, including opioid analgesics, can lead to drug diversion and abuse by individuals who seek them for other than legitimate medical uses. Accordingly, the Board expects that physicians incorporate safeguards into their practices to minimize the potential for the abuse and diversion of controlled substances.

Physicians should not fear disciplinary action from the Board for ordering, prescribing, dispensing or administering controlled substances, including opioid analgesics, for a legitimate medical purpose and in the course of professional practice. The Board will consider prescribing, ordering, dispensing or administering controlled substances for pain to be for a legitimate medical purpose if based on sound clinical judgment. All such prescribing must be based on clear documentation of unrelieved pain. To be within the usual course of professional practice, a physician-patient relationship must exist and the prescribing should be based on a medical diagnosis and the documentation of unrelieved pain. Compliance with applicable state or federal law is required.

The Board will judge the validity of the physician's treatment of the patient based on available documentation, rather than solely on the quantity and duration of medication administration. The goal is to control the patient's pain while effectively addressing other aspects of the patient's functioning, including physical, psychological, social and work-related factors.

Allegations of inappropriate pain management will be evaluated on an individual basis. The board will not take disciplinary action against a physician for deviating from this policy when contemporaneous medical records document reasonable cause for deviation. The physician's conduct will be evaluated to a great extent by the outcome of pain treatment, recognizing that some types of pain cannot be completely relieved, and by taking into account whether the drug used is appropriate for the diagnosis, as well as improvement in the patient's functioning and/or quality of life.

(CONTINUED ON NEXT PAGE)

(+) *CRITERION 5:*
Addresses fear of regulatory scrutiny

(+) *CRITERION 6:*
Prescription amount alone does not determine legitimacy

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT*:*
Acknowledges need for treatment flexibility for physicians to respond to individual clinical circumstances, as long as their prescribing maintains the standards of good medical practice.

(+) *CRITERION 7:*
Physical dependence or analgesic tolerance are not confused with "addiction"

(+) CRITERION 3:
Opioids are part of professional practice

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Recognizes that the goal of pain treatment should include improvements in patient functioning and quality of life.

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Pain & Policy Studies Group
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Madison, Wisconsin

NEBRASKA

OTHER GOVERNMENTAL POLICY

Medical Board Guideline

(CONTINUED)

Section II: Guidelines

The Board has adopted the following criteria when evaluating the physician's treatment of pain, including the use of controlled substances:

Evaluation of the Patient—A medical history and physical examination must be obtained, evaluated, and documented in the medical record. The medical record should document the nature and intensity of the pain, current and past treatments for pain, underlying or coexisting diseases or conditions, the effect of the pain on physical and psychological function, and history of substance abuse. The medical record also should document the presence of one or more recognized medical indications for the use of a controlled substance.

Treatment Plan—The written treatment plan should state objectives that will be used to determine treatment success, such as pain relief and improved physical and psychosocial function, and should indicate if any further diagnostic evaluations or other treatments are planned. After treatment begins, the physician should adjust drug therapy to the individual medical needs of each patient. Other treatment modalities or a rehabilitation program could be necessary depending on the etiology of the pain and the extent to which the pain is associated with physical and psychosocial impairment.

Informed Consent and Agreement for Treatment—The physician should discuss the risks and benefits of the use of controlled substances with the patient, or with persons designated by the patient or with the patient's surrogate or guardian if the patient is without medical decision-making capacity. The patient should receive prescriptions from one physician and one pharmacy whenever possible. If the patient is at high risk for medication abuse or has a history of substance abuse, the physician should consider the use of a written agreement between physician and patient outlining patient responsibilities, including

- urine/serum medication levels screening when requested;
- number and frequency of all prescription refills; and
- reasons for which drug therapy can be discontinued (e.g., violation of agreement).

Periodic Review—The physician should periodically review the course of pain treatment and any new information about the etiology of the pain or the patient's state of health. Continuation or modification of controlled substances for pain management therapy depends on the physician's evaluation of progress toward treatment objectives. Satisfactory response to treatment can be indicated by the patient's decreased pain, increased level of function, or improved quality of life. Objective evidence of improved or diminished function should be monitored and information from family members or other caregivers should be considered in determining the patient's response to treatment. If the patient's progress is unsatisfactory, the physician should assess the appropriateness of continued use of the current treatment plan and consider the use of other therapeutic modalities.

Consultation—The physician should be willing to refer the patient as necessary for additional evaluation and treatment in order to achieve treatment objectives. Special attention should be given to those patients with pain who are at risk for medication misuse, abuse or diversion. The management of pain in patients with a history of substance abuse or with a comorbid psychiatric disorder usually requires extra care, monitoring, documentation and consultation with or referral to an expert in the management of such patients.

(CONTINUED ON NEXT PAGE)

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Encourages healthcare professionals to incorporate in their practice the evaluations of, and discussions with patients about, the potential benefits and risks of treatment with opioids, which can better ensure a clinical indication of such treatment so that opioids will be used for medical purposes.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY B:
Issues related to patients

COMMENT:
Acknowledges that a patient's prior history or current status of drug abuse does not necessarily contraindicate appropriate pain management.

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Pain & Policy Studies Group
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NEBRASKA

OTHER GOVERNMENTAL POLICY

Medical Board Guideline

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Encourages healthcare professionals to understand and follow federal and state laws governing their practice, which can better ensure that practitioners follow the *balanced* approach represented by federal law and the laws in many states.

(CONTINUED)

Medical Records—The physician should keep accurate and complete records to include

1. the medical history and physical examination,
2. diagnostic, therapeutic, and laboratory results,
3. evaluations and consultations,
4. treatment objectives,
5. discussion of risks and benefits,
6. informed consent,
7. treatments,
8. medications (including date, type, dosage and quantity prescribed),
9. instructions and agreements,
10. periodic reviews.

Records should remain current and be maintained in an accessible manner and readily available for review.

Compliance With Controlled Substances Laws and Regulations—To prescribe, dispense, or administer controlled substances, the physician must be licensed in the State of Nebraska and comply with applicable federal and state regulations. Physicians are referred to the Physicians Manual of the U.S. Drug Enforcement Administration and to any relevant documents issued by the Nebraska Board of Medicine and Surgery and the Nebraska Department of Health and Human Services for specific rules governing controlled substances as well as applicable state statutes and regulations. The Federation of State Medical Boards (FSMB) has published and makes available a book entitled "Responsible Opioid Prescribing – A Clinician's Guide" by Scott M. Fishman, M.D.

Section III: Definitions
For the purposes of these guidelines, the following terms are defined as follows:

Acute Pain—Acute pain is the normal, predicted physiological response to a noxious chemical, thermal or mechanical stimulus and typically is associated with invasive procedures, trauma and disease. It is generally time-limited.

Addiction—Addiction is a primary, chronic, neurobiologic disease, with genetic, psychosocial, and environmental factors influencing its development and manifestations. It is characterized by behaviors that include the following: impaired control over drug use, craving, compulsive use, and continued use despite harm. Physical dependence and tolerance are normal physiological consequences of extended opioid therapy for pain and are not the same as addiction.

Chronic Pain—Chronic pain is a state in which pain persists beyond the usual course of an acute disease or healing of an injury, or that can or cannot be associated with an acute or chronic pathologic process that causes continuous or intermittent pain over months or years.

Pain—An unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage.

Physical Dependence—Physical dependence is a state of adaptation that is manifested by drug class-specific signs and symptoms that can be produced by abrupt cessation, rapid dose reduction, decreasing blood level of the drug, and/or administration of a pharmacologic antagonist. Physical dependence, by itself, does not equate with addiction.

Pseudoaddiction—The iatrogenic syndrome resulting from the misinterpretation of relief-seeking behaviors as though they are the drug-seeking behaviors commonly seen with addiction. The relief-seeking behaviors resolve upon institution of effective analgesic therapy.

Substance Abuse—Substance abuse is the use of any substance(s) for non-therapeutic purposes or use of medication for purposes other than those for which it is prescribed.

Tolerance—Tolerance is a physiologic state resulting from regular use of a drug in which an increased dosage is needed to produce a specific effect, or a reduced effect is observed with a constant dose over time. Tolerance can or cannot be evident during opioid treatment and does not equate with addiction.

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NEBRASKA

STATUTES

Pain Management Act

R.R.S. Neb. § 71-2418

§ 71-2418. Legislative findings

(1) The Legislature finds that many controlled substances have useful and legitimate medical and scientific purposes and are necessary to maintain the health and general welfare of the people of Nebraska. Principles of quality medical practice dictate that the people of Nebraska have access to appropriate and effective pain relief.

(2) The Legislature finds that the appropriate application of up-to-date knowledge and treatment modalities can serve to improve the quality of life for those patients who suffer from pain. The Legislature therefore encourages physicians to view effective pain management as a part of quality medical practice for all patients with pain, acute or chronic, including those patients who experience pain as a result of terminal illness.

(3) The Legislature finds that a physician should be able to prescribe, dispense, or administer a controlled substance in excess of the recommended dosage for the treatment of pain so long as such dosage is not administered for the purpose of causing, or the purpose of assisting in causing, death for any reason and so long as it conforms to policies and guidelines for the treatment of pain adopted by the Board of Medicine and Surgery.

(4) The Legislature finds that a health care facility, hospice, or third-party payor should not forbid or restrict the use of controlled substances appropriately administered for the treatment of pain.

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R.R.S. Neb. § 71-2420

§ 71-2420. Board of Medicine and Surgery; duties

The Board of Medicine and Surgery shall adopt policies and guidelines for the treatment of pain to ensure that physicians who are engaged in the appropriate treatment of pain are not subject to disciplinary action, and the board shall consider policies and guidelines developed by national organizations with expertise in pain management for this purpose.

(+) CRITERION 1:
Controlled substances are necessary for public health

(+) CRITERION 4:
Encourages pain management

(+) CRITERION 6:
Prescription amount alone does not determine legitimacy

(+) CRITERION 8:
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Attempts to provide a secure environment for physicians prescribing in their healthcare facility.

(+) CRITERION 5:
Addresses fear of regulatory scrutiny

(+) CRITERION 3:
Opioids are part of professional practice

(+) CRITERION 2:
Pain management is part of healthcare practice

(+) CRITERION 8:
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Clarifies for physicians the important distinction between physician-assisted suicide and prescribing controlled substances for pain relief; this language identifies a clinical misperception that is pervasive in end-of-life care and attempts to lessen its impact on patient treatment, and the practitioners who provide it.

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NEBRASKA

REGULATIONS

Hospice Services

Nebraska Admin. Code Title 175, Ch. 16

CHAPTER 16. HOSPICE SERVICES

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16-006 STANDARDS OF OPERATION, CARE, AND TREATMENT: Each hospice must be organized to promote the attainment of its objectives and purposes. The major organizational divisions in each hospice must include a governing authority, administration, and a medical staff. In addition, the basic organization, responsibility, and operation of each licensed hospice must assure adequate protection to hospice patients and compliance with state statutes.

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16-006.06 Patient Rights: The governing authority must establish a bill of rights that will be equally applicable to all patients. The hospice must protect and promote the exercise of these rights. Patients must have the right to:

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16. Expect pain relief. Measures will be instituted to ensure comfort;

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(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT*:* Establishes a mechanism (patient bill of rights) for hospices to ensure that pain management is an essential part of patient care.

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NEVADA

STATUTES

- CONTROLLED SUBSTANCES ACT
  Title 40. Public Health and Safety; Chapter 453. Controlled Substances

- MEDICAL PRACTICE ACT
  Title 54. Professions, Occupations and Businesses; Chapter 630. Physicians, Physician Assistants, Medical Assistants, Perfusionists, and Practitioners of Respiratory Care

- OSTEOPATHIC PRACTICE ACT
  Title 54. Professions, Occupations and Businesses; Chapter 633. Osteopathic Medicine

- PHARMACY PRACTICE ACT (*No provisions found*)
  Title 54. Professions, Occupations and Businesses; Chapter 639. Pharmacists and Pharmacies

- INTRACTABLE PAIN TREATMENT ACT
  No policy found

REGULATIONS

- CONTROLLED SUBSTANCES REGULATIONS (*No provisions found*)
  Chapter 453. Controlled Substances
  Chapter 458. Abuse of Alcohol and Drugs

- MEDICAL BOARD REGULATIONS
  Chapter 630. Physicians, Perfusionists, Physician Assistants and Practitioners of Respiratory Care

- OSTEOPATHIC BOARD REGULATIONS
  Chapter 633. Osteopathic Medicine

- PHARMACY BOARD REGULATIONS (*No provisions found*)
  Chapter 639. Pharmacists and Pharmacy

OTHER GOVERNMENTAL POLICIES

No policies found

RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY KEY WORD SEARCHES

No policies found

Pain & Policy Studies Group
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NEVADA

STATUTES

Controlled Substances Act

Nev. Rev. Stat. Ann. § 453.098 - 453.099

§ 453.098. "Narcotic addict" defined

"Narcotic addict" means a person of any age who has developed a compulsion to continue taking or who has developed a psychic or physical dependence on the effects of a narcotic drug.

§ 453.099. "Narcotic addiction" defined

"Narcotic addiction" means compulsion to continue taking or psychic or physical dependence on the effects of a narcotic drug.

Nev. Rev. Stat. Ann. § 453.256

§ 453.256. Prescriptions; requirements for dispensing certain substances; penalty

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9. As used in this section:

(a) "Facsimile machine" means a device which sends or receives a reproduction or facsimile of a document or photograph which is transmitted electronically or telephonically by telecommunications lines.

(b) "Medical treatment" includes dispensing or administering a narcotic drug for pain, whether or not intractable.

(c) "Parenteral solution" has the meaning ascribed to it in NRS 639.0105

Nev. Rev. Stat. Ann. § 453.257

§ 453.257. Filling second or subsequent prescriptions

A pharmacist shall not fill a second or subsequent prescription for a controlled substance listed in Schedule II for the same patient unless the frequency of prescriptions is in conformity with the directions for use. The need for any increased amount shall be verified by the practitioner in writing or personally by telephone.

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Nev. Rev. Stat. Ann. § 453.1545

453.1545. Board and division required to develop computerized program to track prescriptions for controlled substances; reporting of illegal activity; confidentiality of information obtained from program; gifts, grants and donations.

1. The Board and the Division shall cooperatively develop a computerized program to track each prescription for a controlled substance listed in schedule II, III or IV that is filled by a pharmacy that is registered with the Board or that is dispensed by a practitioner who is registered with the Board. The program must:

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(c) Not infringe on the legal use of a controlled substance for the management of severe or intractable pain.

(+) *CRITERION 2:*
Pain management is part of healthcare practice

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Recognizes that a prescription monitoring program should not interfere with legitimate medical use of controlled substances.

(-) *CRITERION 11:*
Physical dependence or analgesic tolerance confused with "addiction"

(+) *CRITERION 3:*
Opioids are part of professional practice

(-) *CRITERION 14:*
Undue prescription requirements

COMMENT: Although it is reasonable to expect pharmacists to avoid knowingly filling prescriptions that would contribute to diversion, strict enforcement of such a provision could be a burden to the pharmacist.

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NEVADA

STATUTES

Medical Practice Act

Nev. Rev. Stat. Ann. § 630.253

630.253. Active licensees: Continuing education.

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5. A holder of a license to practice medicine may substitute not more than 2 hours of continuing education credits in pain management or addiction care for the purposes of satisfying an equivalent requirement for continuing education in ethics.

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Nev. Rev. Stat. Ann. § 630.3066

630.3066. Prescribing or administering certain controlled substances for treatment of intractable pain not grounds for initiating disciplinary action.

A physician is not subject to disciplinary action solely for:

1. Prescribing or administering to a patient under his care a controlled substance which is listed in schedule II, III, IV or V by the state board of pharmacy pursuant to *NRS 453.146*, if the controlled substance is lawfully prescribed or administered for the treatment of intractable pain in accordance with regulations adopted by the board.

2. Engaging in any activity in accordance with the provisions of chapter 453A of NRS.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (continuing education) for homes for the terminally ill to ensure that pain management is an essential part of patient care.

(+) *CRITERION 5:*
Addresses fear of regulatory scrutiny

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STATUTES

Osteopathic Practice Act

Nev. Rev. Stat. Ann. § 633.521

633.521. Prescribing or administering certain drugs or controlled substances or engaging in activity relating to medical use of marijuana not grounds for disciplinary action under certain circumstances.

An osteopathic physician is not subject to disciplinary action solely for:

1. Prescribing or administering to a patient under his care:

(a) Amygdalin (laetrile), if the patient has consented to the use of the substance.

(b) Procaine hydrochloride with preservatives and stabilizers (Gerovital H3).

(c) A controlled substance which is listed in schedule II, III, IV or V by the State Board of Pharmacy pursuant to *NRS 453.146*, if the controlled substance is lawfully prescribed or administered for the treatment of intractable pain in accordance with accepted standards for the practice of osteopathic medicine.

2. Engaging in any activity in accordance with the provisions of chapter 453A of NRS.

(+) CRITERION 5: Addresses fear of regulatory scrutiny

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NEVADA

REGULATIONS

Medical Board Regulations

NAC 630.187

630.187 Adoption by reference of Model Guidelines for the Use of Controlled Substances for the Treatment of Pain. (NRS 630.130)

1. The board hereby adopts by reference the Model Guidelines for the Use of Controlled Substances for the Treatment of Pain, May 1998, published by the Federation of State Medical Boards of the United States, Inc., and any subsequent revision of the publication that has been approved by the board for use in this state. Each revision of the publication shall be deemed approved by the board unless it disapproves of the revision within 60 days after the date of publication of the revision.

2. The most recent publication of the Model Guidelines for the Use of Controlled Substances for the Treatment of Pain that has been approved by the board will be available for inspection at the office of the Board of Medical Examiners, 1105 Terminal Way, Suite 301, Reno, Nevada or may be obtained, free of charge, from the Federation of State Medical Boards of the United States, Inc., Federation Place, 400 Fuller Wiser Road, Suite 300, Euless, Texas 76039-3855 or from the Federation of State Medical Boards of the United States, Inc., at the Internet address http://www.fsmb.org/pubform.htm. The board shall:

(a) Review each revision of the publication to ensure its suitability for this state; and

(b) File a copy of each revision of the publication it approves with the secretary of state and the state library and archives administrator.

MODEL GUIDELINES FOR THE USE OF
CONTROLLED SUBSTANCES FOR THE TREATMENT OF PAIN

Section I: Preamble
The Nevada Board of Medical Examiners recognizes that principles of quality medical practice dictate that the people of the State of Nevada have access to appropriate and effective pain relief. The appropriate application of up-to-date knowledge and treatment modalities can serve to improve the quality of life for those patients who suffer from pain as well as to reduce the morbidity and costs associated with untreated or inappropriately treated pain. The Board encourages physicians to view effective pain management as a part of quality medical practice for all patients with pain, acute or chronic, and it is especially important for patients who experience pain as a result of terminal illness. All physicians should become knowledgeable about effective methods of pain treatment as well as statutory requirements for prescribing controlled substances.

Inadequate pain control may result from physicians' lack of knowledge about pain management or an inadequate understanding of addiction. Fears of investigation or sanction by federal, state, and local regulatory agencies may also result in inappropriate or inadequate treatment of chronic pain patients. Accordingly, these guidelines have been developed to clarify the Board's position on pain control, specifically as related to the use of controlled substances, to alleviate physician uncertainty and to encourage better pain management.

The Board recognizes that controlled substances, including opioid analgesics, may be essential in the treatment of acute pain due to trauma or surgery and chronic pain, whether due to cancer or non-cancer origins. Physicians are referred to the *U.S. Agency for Health Care and Research Clinical Practice Guidelines* for a sound approach to the management of acute[1] pain and cancer-related[2] pain. The medical management of pain should be based upon current knowledge and research and include the use of both pharmacologic and non-pharmacologic modalities. Pain should be assessed and treated promptly, and the quantity and frequency of doses should be adjusted according to the intensity and duration of the pain. Physicians should recognize that tolerance and physical dependence are normal consequences of sustained use of opioid analgesics and are not synonymous with addiction.

[CONTINUED ON NEXT PAGE]

(+) *CRITERION 2:*
Pain management is part of healthcare practice

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Identifies the potential impact of important barriers on the provision of effective pain care.

(+) *CRITERION 7:*
Physical dependence or analgesic tolerance are not confused with "addiction"

(+) *CRITERION 4:*
Encourages pain management

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NEVADA

REGULATIONS

Medical Board Regulations

[CONTINUED]

The Nevada Board of Medical Examiners is obligated under the laws of the State of Nevada to protect the public health and safety. The Board recognizes that inappropriate prescribing of controlled substances, including opioid analgesics, may lead to drug diversion and abuse by individuals who seek them for other than legitimate medical use. Physicians should be diligent in preventing the diversion of drugs for illegitimate purposes.

Physicians should not fear disciplinary action from the Board or other state regulatory or enforcement agency for prescribing, dispensing, or administering controlled substances, including opioid analgesics, for a legitimate medical purpose and in the usual course of professional practice. The Board will consider prescribing, ordering, administering, or dispensing controlled substances for pain to be for a legitimate medical purpose if based on accepted scientific knowledge of the treatment of pain or if based on sound clinical grounds. All such prescribing must be based on clear documentation of unrelieved pain and in compliance with applicable state or federal law.

Each case of prescribing for pain will be evaluated on an individual basis. The Board will not take disciplinary action against a physician for failing to adhere strictly to the provisions of these guidelines, if good cause is shown for such deviation. The physician's conduct will be evaluated to a great extent by the treatment outcome, taking into account whether the drug used is medically and/or pharmacologically recognized to be appropriate for the diagnosis, the patient's individual needs - including any improvement in functioning - and recognizing that some types of pain cannot be completely relieved.

The Board will judge the validity of prescribing based on the physician's treatment of the patient and on available documentation, rather than on the quantity and chronicity of prescribing. The goal is to control the patient's pain for its duration while effectively addressing other aspects of the patient's functioning, including physical, psychological, social and work-related factors. The following guidelines are not intended to define complete or best practice, but rather to communicate what the Board considers to be within the boundaries of professional practice.

Section II: Guidelines

The Board has adopted the following guidelines when evaluating the use of controlled substances for pain control:

1. *Evaluation of the Patient.*

A complete medical history and physical examination must be conducted and documented in the medical record. The medical record should document the nature and intensity of the pain, current and past treatments for pain, underlying or coexisting diseases or conditions, the effect of the pain on physical and psychological function, and history of substance abuse. The medical record should also document the presence of one or more recognized medical indications for the use of a controlled substance.

2. *Treatment Plan.*

The written treatment plan should state objectives that will be used to determine treatment success, such as pain relief and improved physical and psychosocial function, and should indicate if any further diagnostic evaluations or other treatments are planned. After treatment begins, the physician should adjust drug therapy to the individual medical needs of each patient. Other treatment modalities or a rehabilitation program may be necessary depending on the etiology of the pain and the extent to which the pain is associated with physical and psychosocial impairment.

[CONTINUED ON NEXT PAGE]

(+) *CRITERION 5:*
Addresses fear of regulatory scrutiny

(+) *CRITERION 6:*
Prescription amount alone does not determine legitimacy

(+) *CRITERION 8:*
Other provisions that may enhance pain treatment

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Recognizes that the goal of pain treatment should include improvements in patient functioning and quality of life.

(+) *CRITERION 3:*
Opioids are part of professional practice

(+) *CRITERION 8:*
Other provisions that may enhance pain treatment

CATEGORY A:
Issues related to healthcare professionals

COMMENT:
Acknowledges need for additional flexibility for physicians as long as their prescribing maintains the standards of good medical practice.

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NEVADA

REGULATIONS

Medical Board Regulations

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Encourages healthcare professionals to incorporate in their practice the evaluations of, and discussions with patients about, the potential benefits and risks of treatment with opioids, which can better ensure a clinical indication of such treatment so that opioids will be used for medical purposes.

[CONTINUED]

3. *Informed Consent and Agreement for Treatment.*

The physician should discuss the risks and benefits of the use of controlled substances with the patient, persons designated by the patient, or with the patient's surrogate or guardian if the patient is incompetent. The patient should receive prescriptions from one physician and one pharmacy where possible. If the patient is determined to be at high risk for medication abuse or have a history of substance abuse, the physician may employ the use of a written agreement between physician and patient outlining patient responsibilities including

1.urine/serum medication levels screening when requested

2.number and frequency of all prescription refills; and

3. reasons for which drug therapy may be discontinued (i.e. violation of agreement).

4. *Periodic Review.*

At reasonable intervals based upon the individual circumstance of the patient, the physician should review the course of treatment and any new information about the etiology of the pain. Continuation or modification of therapy should depend on the physician's evaluation of progress toward stated treatment objectives such as improvement in patient's pain intensity and improved physical and/or psychosocial function, i.e., ability to work need of health care resources, activities of daily living, and quality of social life. If treatment goals are not being achieved, despite medication adjustments, the physician should re-evaluate the appropriateness of continued treatment. The physician should monitor patient compliance in medication usage and related treatment plans.

5. *Consultation.*

The physician should be willing to refer the patient as necessary for additional evaluation and treatment in order to achieve treatment objectives. Special attention should be given to those pain patients who are at risk for misusing their medications and those whose living arrangement pose a risk for medication misuse or diversion. The management of pain in patients with a history of substance abuse or with a comorbid psychiatric disorder may require extra care, monitoring, documentation, and consultation with or referral to an expert in the management of such patients.

6. *Medical Records.*

The physician should keep accurate and complete records to include (1) the medical history and physical examination; (2) diagnostic, therapeutic and laboratory results; (3) evaluations and consultations; (4) treatment objectives; (5) discussion of risks and benefits; (6) treatments; (7) medications (including date, type, dosage, and quantity prescribed); (8) instructions and agreements; and (9) periodic reviews. Records should remain current, and be maintained in an accessible manner, and readily available for review.

7. *Compliance with Controlled Substances Laws and Regulations.*

To prescribe, dispense, or administer controlled substances, the physician must be licensed in the state, and comply with applicable federal and state regulations. Physicians are referred to *the Physicians Manual of the U.S. Drug Enforcement Administration* and applicable state regulations for rules governing controlled substances.

[CONTINUED ON NEXT PAGE]

(+) *CRITERION 8:*
Other provisions that may enhance pain treatment

CATEGORY B:
Issues related to patients

COMMENT:
Acknowledges that a patient's prior history or current status of drug abuse does not necessarily contraindicate appropriate pain management.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Encourages healthcare professionals to understand and follow federal and state laws governing their practice, which can better ensure that practitioners follow the *balanced* approach represented by federal law and the laws in many states.

2013

Pain & Policy Studies Group
University of Wisconsin Carbone Cancer Center
Madison, Wisconsin

NEVADA

REGULATIONS

Medical Board Regulations

[CONTINUED]

Section III: Definitions

For the purposes of these guidelines, the following terms are defined as follows:

***Acute pain*:** Acute pain is the normal, predicted physiological response to an adverse chemical, thermal, or mechanical stimulus and is associated with surgery, trauma and acute illness. It is generally time-limited and is responsive to opioid therapy, among other therapies.

***Addiction*:** Addiction is a neurobehavioral syndrome with genetic and environmental influences that results in psychological dependence on the use of substances for their psychic effects and is characterized by compulsive use despite harm. Addiction may also be referred to by terms such as "drug dependence" and "psychological dependence." Physical dependence and tolerance are normal physiological consequences of extended opioid therapy for pain and should not be considered addiction.

***Analgesic Tolerance*:** Analgesic tolerance is the need to increase the dose of opioid to achieve the same level of analgesia. Analgesic tolerance may or may not be evident during opioid treatment and does not equate with addiction.

Chronic Pain: A pain state which is persistent and in which the cause of the pain cannot be removed or otherwise treated. Chronic pain may be associated with a long-term incurable or intractable medical condition or disease.

Pain: An unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage.

Physical Dependence: Physical dependence on a controlled substance is a physiologic state of neuro-adaptation which is characterized by the emergence of a withdrawal syndrome if drug use is stopped or decreased abruptly, or if an antagonist is administered. Physical dependence is an expected result of opioid use. Physical dependence, by itself, does not equate with addiction.

Pseudoaddiction: Pattern of drug-seeking behavior of pain patients who are receiving inadequate pain management that can be mistaken for addiction.

Substance Abuse: Substance abuse is the use of any substance(s) for non-therapeutic purposes; or use of medication for purposes other than those for which it is prescribed.

Tolerance: Tolerance is a physiologic state resulting from regular use of a drug in which an increased dosage is needed to produce the same effect or a reduced effect is observed with a constant dose.

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References:

1. Acute Pain Management Guideline Panel. Acute Pain Management: Operative or Medical Procedures and Trauma. Clinical Practice Guideline. AHCPR Publication No. 92-0032. Rockville, Md. Agency for Health Care Policy and Research. U.S. Department of Health and Human Resources, Public Health Service. February 1992.

2. Jacox A, Carr DB, Payne R. et al. Management of Cancer Pain. Clinical Practice Guideline No. 9. AHCPR Publication No. 94-0592. Rockville, Md. Agency for Health Care Policy and Research, U.S. Department of Health and Human Resources, Public Health Service. March 1994.

NEVADA

REGULATIONS

Medical Board Regulations

(-) *CRITERION 16:*
Provisions that are ambiguous

CATEGORY B:
Unclear intent leading to possible misinterpretation

COMMENT: Although similar language is used in Federal regulation, in the context of this statute this definition suggests that physicians would qualify for the immunity and, thus, relief from concerns about regulatory scrutiny provided by this statute only if they prescribe opioids after other treatments have been tried and failed, regardless of other clinical considerations.

NAC 630.255

NAC 630.255 Exemption from grounds: "Intractable pain" defined. (NRS 630.135)

For the purposes of NRS 630.3066, "intractable pain" means a condition of discomfort for which the cause cannot be removed or otherwise treated and for which a method of providing relief, or of which a cure for the cause, has not been found after reasonable efforts have been taken in accordance with accepted standards for the practice of medicine, including, but not limited to, evaluation by an attending physician and one or more physicians specializing in the treatment of the area, system, or organ of the body which is believed to be the source of the discomfort.

(-) *CRITERION 10:*
Implies opioids are not part of professional practice

(-) *CRITERION 12:*
Healthcare decisions are restricted

CATEGORY B:
Mandated consultation

REGULATIONS

Osteopathic Board Regulations

(-) *CRITERION 16:*
Provisions that are ambiguous

CATEGORY A:
Arbitrary standards for legitimate prescribing

COMMENT: Although it is reasonable to expect osteopathic physicians to avoid contributing to diversion, "excessive" implies there is a known standard, but the standard is not specified.

NAC 633.350

633.350 Unethical conduct.

1. For the purposes of this chapter and chapter 633 of NRS, a licensee engages in unethical conduct if he:

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(f). Prescribes a controlled substance in a manner or an amount that the board determines is excessive;

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NEW HAMPSHIRE

STATUTES

- CONTROLLED SUBSTANCES ACT
  Title XXX. Occupations and Professions; Chapter 318-B. Controlled Drug Act

- MEDICAL PRACTICE ACT
  Title XXX. Occupations and Professions; Chapter 329. Physicians and Surgeons

- PHARMACY PRACTICE ACT (*No provisions found*)
  Title XXX. Occupations and Professions; Chapter 318. Pharmacists and Pharmacies

- INTRACTABLE PAIN TREATMENT ACT
  No policy found

REGULATIONS

- CONTROLLED SUBSTANCES REGULATIONS (*No provisions found*)
  Department of Health and Human Services; Commissioner;
  Chapter He-C 500. Public Health and Safety;

- MEDICAL BOARD REGULATIONS
  Board of Medicine

- PHARMACY BOARD REGULATIONS (*No provisions found*)
  Pharmacy Board

OTHER GOVERNMENTAL POLICIES

- MEDICAL BOARD GUIDELINE
  New Hampshire Board of Medicine. Guidelines for the Use of Controlled Substances in the Management of Chronic Pain. Adopted: May 11, 2000.

RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY KEY WORD SEARCHES

- STUDY COMMISSION
  Title X. Public Health; Chapter 126-W. Commission to Study Palliative Care and Associated Quality of Life Initiatives

- ASSISTED LIVING RESIDENCE-RESIDENTIAL CARE LICENSING
  Department of Health and Human Services; Division of Public Health;
  Chapter He-P 800. Residential Care and Health Facility Rules;
  Part He-P 804. Assisted Living Residence-Residential Care Licensing

- ASSISTED LIVING RESIDENCE-SUPPORTED RESIDENTIAL HEALTH CARE LICENSING
  Department of Health and Human Services; Division of Public Health;
  Chapter He-P 800. Residential Care and Health Facility Rules;
  Part He-P 805. Assisted Living Residence-Supported Residential Health Care Licensing

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- RULES FOR RESIDENTIAL TREATMENT AND REHABILITATION FACILITIES
  Department of Health and Human Services; Division of Public Health;
  Chapter He-P 800. Residential Care and Health Facility Rules;
  Part He-P 807. Rules for Residential Treatment and Rehabilitation Facilities

- HOME HEALTH CARE PROVIDERS
  Department of Health and Human Services; Division of Public Health;
  Chapter He-P 800. Residential Care and Health Facility Rules;
  Part He-P 809. Home Health Care Providers

- HOME HOSPICE CARE PROVIDER
  Department of Health and Human Services; Division of Public Health;
  Chapter He-P 800. Residential Care and Health Facility Rules;
  Part He-P 823. Home Hospice Care Provider

- HOSPICE HOUSE
  Department of Health and Human Services; Division of Public Health;
  Chapter He-P 800. Residential Care and Health Facility Rules; Part He-P 824. Hospice House

NEW HAMPSHIRE

STATUTES

Controlled Substances Act

RSA § 318-B:1

§ 318-B:1. Definitions

The following words and phrases, as used in this chapter, shall have the following meanings, unless the context otherwise requires:

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IX. "Drug dependence" means a state of physical addiction or psychic dependence, or both, upon a drug following use of that drug upon a repeated periodic or continuous basis except:

(a) Upon a morphine-type drug as an incident to current medical treatment of a demonstrable physical disorder, other than produced by the use of the drug itself, or

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X. "Drug-dependent person" means any person who has developed a state of psychic or physical dependence, or both, upon a controlled drug following administration of that drug upon a repeated periodic or continuous basis. No person shall be classified as drug dependent who is dependent:

(a) Upon a morphine-type drug as an incident to current medical treatment of a demonstrable physical disorder other than drug dependence, or

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RSA § 318-B:10

§ 318-B:10 Professional Use of Narcotic Drugs.

I. A practitioner other than a veterinarian, in good faith, in the course of his professional practice, and for a legitimate medical purpose, may administer and prescribe controlled drugs, or the practitioner may cause the same to be administered by a nurse or intern under his direction and supervision. In a bona fide emergency situation, the practitioner may dispense a controlled drug to a patient under his care but only in a quantity not to exceed a 48-hour supply for all schedule II substances or a 7-day supply of schedule III, IV, or V substances.

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IX. If, in the judgment of a physician licensed under RSA 329, appropriate pain management warrants a high dosage of controlled drugs and the benefit of the relief expected outweighs the risk of the high dosage, the licensed physician may administer or cause to be administered such a dosage, even if its use may increase the risk of death, so long as it is not furnished for the purpose of causing, or the purpose of assisting in causing, death for any reason and so long as it falls within rules of the board of medicine.

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(-) *CRITERION 16:*
Provisions that are ambiguous

CATEGORY B:
Unclear intent leading to possible misinterpretation

COMMENT: Would a "demonstrable physical disorder" include a chronic condition with an undiagnosable etiology?

(+) *CRITERION 3:*
Opioids are part of professional practice

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY B:
Issues related to patients

COMMENT: Exemption of certain patients from being labeled either "drug dependent" or a "drug dependent person" nevertheless continues to allow other patients to be labeled as such.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Clarifies for physicians the important distinction between physician-assisted suicide and prescribing controlled substances for pain relief; this language identifies a clinical misperception that is pervasive in end-of-life care and attempts to lessen its impact on patient treatment, and the practitioners who provide it.

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NEW HAMPSHIRE

STATUTES

Medical Practice Act

RSA 329:9

329:9 Rulemaking Authority.

The board shall adopt rules, pursuant to *RSA 541-A*, relative to:

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XV. Procedural and substantive requirements for assessing, compromising and collecting administrative fines against licensees as authorized under *RSA 329:17*, VII(g) and against licensees and nonlicensees as authorized by *RSA 329:2*, II(d).

XV-a. Procedures for appropriate pain management pursuant to *RSA 318-B:10*, IX.

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(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (adopt rules) for the Board to ensure that pain management is an essential part of patient care.

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NEW HAMPSHIRE

REGULATIONS

Medical Board Regulations

N.H. Admin. Rules, Med 501.02

Med 501.02 Standards of Conduct.

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(i) When prescribing any controlled substance for use in pain control, licensees shall:

(1) Document prescription for such controlled substances according to Med 501.02(d) and (e);

(2) Utilize appropriate treatment standards for the treatment of chronic pain, including :

a. proper patient evaluation;

b. creation of a treatment plan;

c. a written pain agreement, if indicated;

d. appropriate consultations;

e. periodic review and follow-up;

f. appropriate toxicology screening, if indicated.

(3) Comply with all federal and state controlled substances laws, rules, and regulations;

(4) Adhere to the principles outlined in the Chou, Fanciullo, et al, "Clinical Guidelines for the Use of Opioid Therapy in Chronic Noncancer Pain", The Journal of Pain, Volume 10, Issue 2, pages 113-130.e22, February 2009; and

(5) Adhere to the principles outlined in the Clinical Guidelines for the Use of Buprenorphine in the Treatment of Opioid Addiction, A Treatment Improvement Protocol by the U.S. Department of Health and Human Services (2004) found at www.pcssmentor.org.

(j) Deviation from these treatment standards shall constitute unprofessional conduct within the meaning of *RSA 329:17*,VI,(c) and a violation of Med 501.01(a).

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT*:* Encourages healthcare professionals to understand and follow federal and state laws governing their practice, which can better ensure that practitioners follow the *balanced* approach represented by federal law and the laws in many states.

(-) *CRITERION 15:*
Other provisions that may impede pain management

COMMENT: Although the desire for specificity in regulation is understandable, this provision contradicts the flexibility that is stated in the clinical guidelines. Making any deviation a basis for "unprofessional conduct" does not allow for treatment flexibility based on reasonable cause and imposes a potential for professional liability based on clinical practice guidelines that may not apply to all patients and clinical situations.

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NEW HAMPSHIRE

OTHER GOVERNMENTAL POLICY

Medical Board Guideline

Pain Guidelines

The New Hampshire Board of Medicine has adopted guidelines for pain management in hopes of fostering the best pain treatment for the citizens of this State. The Board encourages physicians to view effective pain management as a part of quality medical practice for all patients with pain, be it acute or chronic, due to either malignant or benign disease, and particularly when associated with terminal illness. For many physicians, fear of investigation or sanction for dispensing large or prolonged narcotic prescriptions has impeded effective and appropriate treatment. Accordingly, these guidelines have been developed to clarify the Board's position of pain control specifically as related to the use of controlled substances, to alleviate physician uncertainty, and to encourage better pain management. This format was derived from many sources including N.H. Physicians specializing in pain management, the N.H. State Medical Society, and the Federation of State Medical Boards.

Physicians should not fear disciplinary action from the Board or other state regulatory or enforcement agency for prescribing or administering controlled substances for a legitimate medical purpose and in the usual course of professional practice. The Board has concern in those cases where inadequate pain control results from either lack of current knowledge of pain management or inappropriate fear of investigation for providing narcotics where indicated.

The N.H. Board remains obligated under the laws of the State of New Hampshire to protect the public health and safety. The Board recognizes that inappropriate prescribing of controlled substances including opioid analgesics, may lead to drug diversion and abuse by individuals who seek them for other than legitimate medical use. Improper prescribing or documentation will continue to be investigated.

The guidelines are not rigid rules. They serve as a model for physician practice, and to communicate what the Board considers to be within the boundaries of professional practice. While the Board will likely not take disciplinary action against a physician for failing to adhere strictly to the provisions of this protocol, "significant deviation" from the guidelines will likely result in investigation and/or sanction of a physician practice. Key features of the guidelines include accurate documentation, some form of a treatment plan, acceptance of the plan by the patient, and appropriate evaluations and/or consultations. Compliance with all controlled substances laws and regulations is mandatory.

The Board will judge the validity of prescribing based on the physician's treatment of the patient and on available documentation, rather than on the quantity and chronicity of prescribing. The goal is to control the patient's pain for its duration while effectively addressing other aspects of the patient's functioning, including physical, psychological, social and work related factors. This Board hopes to encourage superior pain management by physicians, and clarify appropriate pain relieving practice with the institution of these guidelines.

(CONTINUED ON NEXT PAGE)

(+) *CRITERION 2:*
Pain management is part of healthcare practice

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to patients

COMMENT:
Acknowledges need for treatment flexibility for physicians to respond to individual clinical circumstances, as long as their prescribing maintains the standards of good medical practice.

(+) *CRITERION 6:*
Prescription amount alone does not determine legitimacy

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Identifies the potential impact of important barriers on the provision of effective pain care.

(+) *CRITERION 5:*
Addresses fear of regulatory scrutiny

(+) *CRITERION 8:*
Other provisions that may enhance pain treatment

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Recognizes that the goal of pain treatment should include improvements in patient functioning and quality of life.

(+) *CRITERION 4:*
Pain management is encouraged

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NEW HAMPSHIRE

OTHER GOVERNMENTAL POLICY

Medical Board Guideline

(CONTINUED)

GUIDELINES FOR THE USE OF CONTROLLED SUBSTANCES IN THE MANAGEMENT OF CHRONIC PAIN

Evaluation of the Patient

An accurate and complete medical history and physical examination must be documented in the medical record. The medical record should document the nature and intensity of the pain and relevant coexisting condition (including current or past substance abuse.) The results of relevant diagnostic studies, other evaluations and consults should be part of the record.

Treatment Plan

A treatment plan should state objectives that will be used to determine treatment success, such as pain relief, and/or improved physical or psycho social function. The record should indicate if any further diagnostic evaluations or treatments are planned. Other treatment modalities might include a rehabilitation program, physical therapy or the like, or other treatment plan deemed appropriate for the patient's treatment objectives. After treatment begins, the physician should adjust drug therapy to the individual needs of each patient.

Informed Consent and Agreement for Treatment

The physician should discuss the risks and benefits of the use of controlled substances with the patient, appropriate significant other, and/or guardian. The patient should receive prescriptions from one physician and one pharmacy when chronic narcotic use is adopted, and should authorize communication between both parties. Frequently, the physician may elect to use a written agreement with the patient, especially where rick of medication abuse is a concern. A written agreement may; (1) indicate a specific pharmacy and prescribing physician; (2) give permission for communication between care providers; (3) detail amount and frequency of medication and prescription refills; (4) define expected follow-up and participation in any other pain treatment activities; (5) provide reasons for which opioid therapy may be discontinued; (6) include an agreement to have urine/serum medication or drug levels/screens when requested; and (7) document other inclusions appropriate for management of the individual patient.

Periodic Review

At reasonable intervals, the physician should review the course of opioid treatment and any new information about the etiology and the impact of the pain. Continuation or modification of opioid therapy should depend on the physician's evaluation of progress toward stated treatment objectives. If reasonable treatment goals are not being achieved, despite medication adjustments, the physician should monitor patient compliance in medication usage and related treatment plans.

Consultation

The physician should refer the patient for additional evaluation and treatment as necessary and reasonable in order to achieve adequate control of the pain and any other treatment objectives. Special attention should be given to those pain patients who are at risk for misusing their medications and those whose living arrangement pose a risk for medication misuse or diversion. The management of pain in patients with a history of substance abuse, or with comorbid psychiatric disorder, requires extra care in structuring, monitoring, and documentation. When indicated and available, consultation with, or referral to, an expert in the management of chronic pain is advised.

(CONTINUED ON NEXT PAGE)

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Encourages healthcare professionals to incorporate in their practice the evaluations of, and discussions with patients about, the potential benefits and risks of treatment with opioids, which can better ensure a clinical indication of such treatment so that opioids will be used for medical purposes.

(+) *CRITERION 8:*
Other provisions that may enhance pain treatment

CATEGORY A:
Issues related to healthcare professionals

COMMENT:
Acknowledges that a patient's prior history or current status of drug abuse does not necessarily contraindicate appropriate pain management

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NEW HAMPSHIRE

OTHER GOVERNMENTAL POLICY

Medical Board Guideline

(CONTINUED)

Medical Records

The physician should keep accurate and complete records to include documentation of; (1) medical history and physical examination; (2) relevant diagnostic, therapeutic and laboratory results; (3) results of evaluation and consultation; (4) treatment objectives; (5) discussion of risks and benefits; (6) treatments and treatment responses; (7) medications (including date, type, dosage, refills, and quantity prescribed); (8) instructions and agreements; and (9) periodic reviews. Records should remain current, be maintained in an accessible manner an be readily available for review.

Compliance with Controlled Substances Law and Regulations

To prescribe controlled substances the physician must be licensed in the State of New Hampshire, have valid controlled substances registration and comply with federal and state regulation for issuing controlled substances prescriptions. Physicians should refer to the federal, state and local regulatory agencies for guidance, by writing the Board of Medicine, 2 Industrial Park Drive, Concord, New Hampshire 03301.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Encourages healthcare professionals to understand and follow federal and state laws governing their practice, which can better ensure that practitioners follow the *balanced* approach represented by federal law and the laws in many states.

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NEW HAMPSHIRE

STATUTES

Commission to Study Palliative Care and Associated Quality of Life Initiatives

RSA 126-W:1

126-W:1. Commission to Study Palliative Care and Associated Quality of Life Initiatives; Membership; Duties.

I. There is established a commission to study palliative care and associated quality of life initiatives. The members of the commission shall be appointed within 45 days of the effective date of this chapter and shall be as follows:

(a) One member of the senate, appointed by the president of the senate.

(b) Three members of the house of representatives, appointed by the speaker of the house of representatives.

(c) The commissioner of the department of health and human services, or designee.

(d) The commissioner of the insurance department, or designee.

(e) A licensed hospice and palliative care physician, appointed by the New Hampshire Medical Society.

(f) A licensed hospice and palliative care nurse, appointed by the New Hampshire Nurses' Association.

(g) A licensed social worker specializing in palliative care, appointed by the New Hampshire chapter of the National Association of Social Workers.

(h) A representative of a hospital with a dedicated palliative care program, appointed by the New Hampshire Hospital Association.

(i) A representative of a Medicare certified home health and hospice agency, appointed by the Home Care Association of New Hampshire.

(j) A representative of the New Hampshire Hospice and Palliative Care Organization, appointed by the organization.

(k) A representative of spiritual care professionals specializing in palliative care, appointed by the New Hampshire Council of Churches.

(l) A representative of a nursing home facility, appointed by the New Hampshire Health Care Association.

(m) Two public members, appointed by the governor.

II. Legislative members of the commission shall receive mileage at the legislative rate when attending to the duties of the commission.

III. The commission's duties shall include, but not be limited to:

(a) Assessing the general knowledge of the citizens of New Hampshire regarding palliative care and hospice services.

(b) Evaluating the access, effectiveness, utilization, and timeliness of palliative and hospice care.

(c) Considering requiring continuing education credits for professional relicensure of health care providers involved with palliative, hospice, and pain management services.

(d) Reviewing options for increasing the knowledge and use by the public of advanced directives, including directions to the providers regarding life sustaining treatment.

(e) Discussing potential deficits in third party payments for hospice or palliative care services as a barrier for use of palliative and hospice care.

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(+) *CRITERION 3:*
Opioids are part of professional practice

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (possible continuing education) to ensure that pain management is an essential part of patient care.

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NEW HAMPSHIRE

REGULATIONS

Assisted Living Residence-Supported Residential Care Licensing

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (assessment) for residential healthcare facilities to ensure that pain management is an essential part of patient care. (Although not required by this provision, pain assessment should be followed up with appropriate treatment.)

N.H. Admin. Rules, He-P 804.16

He-P 804.16 Required Services.

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(f) If the RAT identifies the need for a nursing assessment, the nursing assessment shall be completed within 72 hours of the completion of the RAT.

(g) The nursing assessment, completed in accordance with (f) above, shall include:

(1) A medication review;

(2) A review of the resident's clinical record; and

(3) Assessment for pain, vital signs, physical, cognitive, mental and behavioral status, as well as an assessment as to how the resident is psychologically adapting to his or her social environment.

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REGULATIONS

Assisted Living Residence-Supported Residential Health Care Licensing

N.H. Admin. Rules, He-P 805.16

He-P 805.16 Required Services.

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(h) The nursing assessment, completed in accordance with (g) above, shall include:

(1) A medication review;
(2) A review of the resident's clinical record; and
(3) Assessment for pain, vital signs, physical, cognitive, mental and behavioral status, as well as an assessment as to how the resident is psychologically adapting to his or her social environment.

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(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (assessment) for residential healthcare facilities to ensure that pain management is an essential part of patient care. (Although not required by this provision, pain assessment should be followed up with appropriate treatment.)

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NEW HAMPSHIRE

REGULATIONS

Rules for Residential Treatment and Rehabilitation Facilities

N.H. Admin. Rules, He-P 807.16
He-P 807.16 Required Services.
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(m) The licensee shall have each client obtain a health examination by a licensed practitioner within 30 days prior to admission or within 72 hours following admission to the RTRF.

(n) The health examination in (m) above shall include:

(1) Diagnoses, if any;

(2) The medical history;

(3) Medical findings, including the presence or absence of communicable disease;

(4) Vital signs;

(5) Prescribed and over-the-counter medications;

(6) Allergies;

(7) Dietary needs; and

(8) Pain assessment for neuro-rehabilitation clients.

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(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (assessment) for residential treatment and rehabilitation facilities to ensure that pain management is an essential part of patient care. (Although not required by this provision, pain assessment should be followed up with appropriate treatment.)

REGULATIONS

Home Health Care Providers

N.H. Admin. Rules, He-P 809.15
He-P 809.15 Required Services.
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(u) Written notes shall be documented in the client's record at the time of each visit for:

(1) All care and services provided by the HHCP and shall include the:

a. Date and time of the care or service;

b. Description of the care or service;

c. Progress notes, including, as applicable;

1. Changes in the client's physical, functional and mental abilities;

2. Changes in the client's behaviors such as eating or sleeping patterns; and

3. The client's pain management, if applicable; and

d. Signature and title of the person providing the care or service; and

(2) Any unusual incident involving the client when HHCP personnel are in the client's home.

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(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (documentation) for home health providers to ensure that pain management is an essential part of patient care.

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NEW HAMPSHIRE

REGULATIONS

Home Hospice Care Provider

N.H. Admin. Rules, He-P 823.16

He-P 823.16 Patient Services.

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(e) Patients who are accepted for services shall have a nursing assessment at the following intervals to determine the level of care and services required by the patient:

(1) Within 48 hours of admission; and
(2) At least every 90 days thereafter.

(f) The assessment required by (e) above shall contain, at a minimum, the following:

(1) Pertinent diagnoses including mental status;
(2) A pain assessment, including symptom control and vital signs;

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(i) The interdisciplinary hospice care team shall:

(1) Establish the care plan;
(2) Be the primary care delivery team for a patient and his or her family through the total duration of hospice care; and
(3) Be responsible for supervising any patient care and services provided by others.

(j) The interdisciplinary team shall, in conjunction with the patient and the patient's personal representative, and their family, develop an individualized care plan, which reflects the changing care needs of the patient and family.

(k) The care plan required by (j) above shall include:

(1) The date the problem or need was identified;
(2) A description of the problem or need;
(3) The goal for the patient;
(4) The action or approach to be taken by HHCP personnel;
(5) The responsible person(s) or position; and
(6) The interventions used to address problems identified in the assessment including:

a. Medications ordered;

b. Pain control interventions, both pharmacological and non-pharmacological;

c. Symptom management treatment; and

d. Services required including frequency of visits.

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(t) Progress notes shall be written by personnel, as appropriate, at the time of each visit and shall include at a minimum:

(1) Changes in the patient's physical, functional and mental abilities;
(2) Changes in the patients behaviors such as eating or sleeping patterns;
(3) The patient's relief of pain, if applicable; and
(4) Newly identified needs of the patient and or their family.

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(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (assessment) for home hospice to ensure that pain management is an essential part of patient care. (Although not required by this provision, pain assessment should be followed up with appropriate treatment.)

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (documentation) for home hospice to ensure that pain management is an essential part of patient care.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (interdisciplinary team) for home hospice to ensure that pain management is an essential part of patient care.

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NEW HAMPSHIRE

REGULATIONS

Hospice House

N.H. Admin. Rules, He-P 824.15

He-P 824.15 Required Services.

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(e) The HH shall provide or arrange for the provision of short-term in-patient stays in a hospital or nursing home during those times when the patient's pain or symptoms are unable to be managed in the HH.

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N.H. Admin. Rules, He-P 824.16

He-P 824.16 Patient Admission Criteria, Temporary Absence, Transfer and Discharge.

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(e) Patients who are admitted or accepted for services shall:

(1) Have a nursing assessment at the following intervals to determine the level of care and services required by the patient:

a. Within 48 hours of admission; and

b. Thereafter as required by the CMS conditions of participation; and

(2) Have a signed and dated order for any service for which such order is required by the practice acts of the person providing care, renewed at least every 90 days.

(f) The assessment required by (e)(1) above shall contain, at a minimum, the following:

(1) Pertinent diagnoses including mental status;

(2) A pain assessment, including symptom control and vital signs;

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(k) The interdisciplinary team shall, in conjunction with the patient, the patient's personal representative, and their family, develop an individualized care plan, which reflects the changing care needs of the patient and family.

(l) The care plan required by (k) above shall include:

(1) The date the problem or need was identified;

(2) A description of the problem or need;

(3) The goal for the patient;

(4) The action or approach to be taken by HH personnel;

(5) The responsible person(s) or position; and

(6) The interventions used to address problems identified in the assessment including:

a. Medications ordered;

b. Pain control interventions, both pharmacological and non-pharmacological;

c. Symptom management treatment; and

d. Services required including frequency of visits.

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(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT*:* Establishes a responsibility for hospice houses to ensure that pain management is an essential part of patient care.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT*:* Establishes a mechanism (assessment) for home hospice to ensure that pain management is an essential part of patient care. (Although not required by this provision, pain assessment should be followed up with appropriate treatment.)

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT*:* Establishes a mechanism (interdisciplinary team) for home hospice to ensure that pain management is an essential part of patient care.

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NEW JERSEY

STATUTES

- CONTROLLED SUBSTANCES ACT
  Title 24. Food and Drugs; Subtitle 3. Dangerous Substances and Narcotic Drugs; Chapter 21. Dangerous Substances Control

- MEDICAL PRACTICE ACT
  Title 45. Professions and Occupations; Subtitle 1. Professions and Occupations Subject to State Boards of Registration and Examination; Chapter 9. Physicians and Surgeons

- PHARMACY PRACTICE ACT
  Title 45. Professions and Occupations; Subtitle 1. Professions and Occupations Subject to State Boards of Registration and Examination; Chapter 14. Pharmacists

- INTRACTABLE PAIN TREATMENT ACT
  No policy found

REGULATIONS

- CONTROLLED SUBSTANCES REGULATIONS
  Title 13. Law and Public Safety; Chapter 45H. Controlled Dangerous Substances

- MEDICAL BOARD REGULATIONS
  Title13. Law and Public Safety. Chapter 35. Board of Medical Examiners

- PHARMACY BOARD REGULATIONS
  Title13. Law and Public Safety. Chapter 39. State Board of Pharmacy

OTHER GOVERNMENTAL POLICIES

No policy found

RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY KEY WORD SEARCHES

- CODE OF CRIMINAL JUSTICE
  Title 2C. The New Jersey Code of Criminal Justice; Subtitle 2. Specific Offenses; Part 5. Offenses Against the Public, Public Order, Health and Decency; Chapter 35. Controlled Substances

- HEALTH CARE FACILITIES
  Title 26. Health and Vital Statistics; Chapter 2H. Health Care Facilities

- NURSING HOMES
  Title 30. Institutions and Agencies; Subtitle 8. Nursing Homes in General

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- PRESCRIPTION MONITORING PROGRAM
  Title 45. Professions and Occupations; Subtitle 1. Professions and Occupations Subject to State Boards of Registration and Examination; Chapter 1. General Provisions

- LICENSING STANDARDS FOR ASSISTED LIVING FACILITIES
  Title 8. Department of Health and Senior Services; Chapter 36. Standards for Licensure of Assisted Living Residences, Comprehensive Personal Care Homes, and Assisted Living Programs

- LICENSING STANDARDS FOR LONG-TERM CARE FACILITIES
  Title 8. Department of Health and Senior Services; Chapter 39. Standards for Licensure of Long-Term Care Facilities

- LICENSING STANDARDS FOR AMBULATORY CARE FACILITIES
  Title 8. Department of Health and Senior Services; Chapter 43A. Manual of Standards for Licensing of Ambulatory Care Facilities

- PAIN MANAGEMENT PROCEDURES
  Title 8. Department of Health and Senior Services; Chapter 43E. General Licensure Procedures and Enforcement of Licensure Regulations

- LICENSING STANDARDS FOR HOSPITALS
  Title 8. Department of Health and Senior Services; Chapter 43G. Hospital Licensing Standards

- AIDS COMMUNITY CARE ALTERNATIVE PROGRAM SERVICES
  Title 10. Human Services; Chapter 60. Home Care Services; Subchapter 7. AIDS Community Care Alternatives Program

- LAW AND PUBLIC SAFETY
  Title 13. Law and Public Safety. Chapter 34C. Alcohol & Drug Counselor Committee

NEW JERSEY

STATUTES

Controlled Substances Act

N.J. Stat. § 24:21-2

§ 24:21-2. Definitions

Definitions. As used in this act:

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"Drug dependent person" means a person who is using a controlled dangerous substance and who is in a state of psychic or physical dependence, or both, arising from the use of that controlled dangerous substance on a continuous basis. Drug dependence is characterized by behavioral and other responses, including but not limited to a strong compulsion to take the substance on a recurring basis in order to experience its psychic effects, or to avoid the discomfort of its absence.

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"Practitioner" means a physician, dentist, veterinarian, scientific investigator, laboratory, pharmacy, hospital or other person licensed, registered, or otherwise permitted to distribute, dispense, conduct research with respect to, or administer a controlled dangerous substance in the course of professional practice or research in this State.

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(-) *CRITERION 11:*
Physical dependence or analgesic tolerance confused with "addiction"

(+) *CRITERION 3:*
Opioids are part of professional practice

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NEW JERSEY

STATUTES

Medical Practice Act

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (continuing education) to ensure that end-of-life care, including pain management, is an essential part of patient care.

N.J. Stat. § 45:9-7.7

§ 45:9-7.7. Continuing medical education for physicians, end-of-life care; rules, regulations

a. The State Board of Medical Examiners shall require that the number of credits of continuing medical education required of each person licensed as a physician, as a condition of biennial registration pursuant to section 1 of P.L.1971, c.236 (*C.45:9-6.1*), include two credits of educational programs or topics related to end-of-life care, subject to the provisions of section 10 of P.L.2001, c.307 (*C.45:9-7.1*), including, but not limited to, its authority to waive the provisions of this section for a specific individual if the board deems it appropriate to do so.

b. The State Board of Medical Examiners, pursuant to the "Administrative Procedure Act," P.L.1968, c.410 (*C.52:14B-1* et seq.), shall adopt such rules and regulations as are necessary to effectuate the purposes of this section.

(+) *CRITERION 2:*
Pain management is part of healthcare practice

N.J. Stat. § 45:9-5.1

§ 45:9-5.1. Definitions

Within the meaning of this chapter (45:9-1 et seq.), except as herein otherwise provided, and except for the purposes of the exemptions hereinafter contained in sections 45:9-14.1 to 45:9-14.10, inclusive, the phrase "the practice of medicine or surgery" and the phrase "the practice of medicine and surgery" shall include the practice of any branch of medicine and/or surgery, and any method of treatment of human ailment, disease, pain, injury, deformity, mental or physical condition, and the term "physician and surgeon" or "physician or surgeon" shall be deemed to include practitioners in any branch of medicine and/or surgery or method of treatment of human ailment, disease, pain, injury, deformity, mental or physical condition.

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N.J. Stat. § 45:9-14.3

§ 45:9-14.3. "Practice of osteopathy" defined; osteopathy license does not permit what

Within the meaning of the provisions of section *45:9-14.4*, the practice of osteopathy shall include the diagnosing, treating, operating or prescribing for any human disease, pain, injury, deformity, mental or physical condition; provided, however, that a license to practice osteopathy shall not permit the holder thereof to prescribe, administer or dispense drugs for internal use in the treatment of any human ailment, disease, pain, injury, deformity, mental or physical condition or to perform such surgical operations as require cutting.

(+) *CRITERION 2:*
Pain management is part of healthcare practice

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STATUTES

Pharmacy Practice Act

N.J. Stat. § 45:14-41

§ 45:14-41. Definitions relative to pharmacists

As used in this act:

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"Practitioner" means an individual currently licensed, registered or otherwise authorized by the jurisdiction in which the individual practices to administer or prescribe drugs in the course of professional practice.

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(+) *CRITERION 3:*
Opioids are part of professional practice

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NEW JERSEY

REGULATIONS

Controlled Substances Regulations

N.J.A.C. 8:65-7.2

§ 8:65-7.2 Definitions

The following words and terms when used in this subchapter, shall have the following meanings, unless the context clearly indicates otherwise.

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"Individual practitioner" means a physician, dentist, veterinarian, or other individual licensed, registered, or otherwise permitted, by the United States, the jurisdiction in which he practices, or in New Jersey, to dispense a controlled substance in the course of professional practice, but does not include a pharmacist, a pharmacy, or an institutional practitioner.

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(+) *CRITERION 3:*
Opioids are part of professional practice

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NEW JERSEY

REGULATIONS

Medical Board Regulations

N.J.A.C. 13:35-6.19

§ 13:35-6.19 Duty to report changes in status

(a) The following words and terms, when used in this section, shall have the following meanings unless the context clearly indicates otherwise.

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"Health care facility" means a facility or institution, whether public or private, engaged in providing medical services, including diagnosis or treatment of human disease, pain, injury, deformity or physical condition, including, but not limited to, a general hospital, special hospital, mental hospital, health maintenance organizations, public health center, diagnostic center, treatment center, rehabilitation center, extended care facility, skilled nursing home, nursing home, intermediate care facility, tuberculosis hospital, chronic disease hospital, maternity hospital, outpatient clinic, dispensary, home health care agency, boarding home for the sheltered care of adult persons, and bio-analytical laboratory or central services facilities serving one or more such institutions but excluding institutions that provide healing solely by prayer.

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N.J.A.C. § 13:35-7.6

§ 13:35-7.6 Limitations on prescribing, administering or dispensing of controlled substances; special exceptions for management of pain

(a) When prescribing, dispensing or administering controlled substances, a practitioner shall ensure that a patient's medical history has been taken and physical examination accomplished, including an assessment of physical and psychological function, underlying or coexisting diseases or conditions, any history of substance abuse and the nature, frequency and severity of any pain. The medical record shall reflect:

1. A recognized medical indication for the use of the controlled substance;

2. The complete name of the controlled substance;

3. The dosage, strength and quantity of the controlled substance; and

4. The instructions as to frequency of use.

(b) With respect to Schedule II controlled substances, unless the requirements of (c) below are met, a practitioner shall not authorize a quantity calculated to exceed 120 dosage units or a 30-day supply, whichever is less.

(c) A practitioner may exceed the 120 dosage unit or 30-day supply limitations for Schedule II controlled substances in (b) above in the following circumstances:

1. For the 120 dosage unit limitation, the practitioner follows a treatment plan designed to achieve effective pain management, which has been tailored to the needs of a patient who is suffering pain from cancer, intractable pain or terminal illness. The treatment plan shall state objectives by which treatment success is to be evaluated, such as pain relief and improved physical and psychological function, and shall indicate if any further diagnostic evaluations or other treatments are planned. The practitioner shall discuss the risks and benefits of the use of controlled substances with the patient, guardian or authorized representative;

2. With regards to the 30-day supply limitation, a practitioner may prescribe the use of an implantable infusion pump which is utilized to achieve pain management for patients suffering from cancer, intractable pain or terminal illness. A prescription for such an implantable infusion pump may provide up to a 90-day supply, as long as the physician evaluates and documents the patient's continued need at least every 30 days; and

[CONTINUED ON NEXT PAGE]

(+) *CRITERION 2:*
Pain management is part of healthcare practice

(-) *CRITERION 16:*
Provisions that are ambiguous

CATEGORY C:
Conflicting or inconsistent policies or provisions

COMMENT: This provision may create confusion, and even be in conflict, when considered in conjunction with Sec. 45:9-22.19 of the Medical Practice Act, which does not include a dosage unit limitation.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Recognizes that the goal of pain treatment should include improvements in patient functioning and quality of life.

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REGULATIONS

Medical Board Regulations

[CONTINUED]

3. With regards to the 30-day supply limitation, a practitioner may prescribe multiple prescriptions authorizing a patient to receive a total of up to a 90-day supply of a Schedule II controlled dangerous substance provided that:

i. Each separate prescription is issued for a legitimate medical purpose by the practitioner acting in the usual course of professional practice;

ii. The practitioner provides written instructions on each prescription, other than the first prescription if it is to be filled immediately, indicating the earliest date on which a pharmacy may fill each prescription;

iii. The practitioner determines that providing the patient with multiple prescriptions in this manner does not create an undue risk of diversion or abuse; and

iv. The practitioner complies with all other applicable State and Federal laws and regulations.

(d) When controlled substances are continuously prescribed for management of pain for three months or more, the practitioner:

1. Shall review, at a minimum of every three months, the course of treatment, any new information about the etiology of the pain and the patient's progress toward treatment objectives;

2. Shall remain alert to problems associated with physical and psychological dependence; and

3. Shall periodically make reasonable efforts, unless clinically contraindicated, to either stop the use of the controlled substance, decrease the dosage, try other drugs such as nonsteroidal anti-inflammatories, or treatment modalities in an effort to reduce the potential for abuse or the development of physical or psychological dependence.

(e) If treatment objectives are not being met, the practitioner:

1. Shall assess the appropriateness of continued treatment with controlled substances or undertake a trial of other drugs or treatment modalities; and

2. Shall consider referring the patient for independent evaluation or treatment in order to achieve treatment objectives.

(f) A practitioner shall remain alert to the possibility that controlled substances may be misused or diverted. A practitioner managing pain in a patient with a history of substance abuse shall exercise extra care by way of monitoring, documentation and possible consultation with addiction medicine specialists, and should consider the use of an agreement between the practitioner and the patient concerning controlled substance use and consequences for misuse.

(g) The practitioner shall keep accurate and complete records including that information required by (a) above as well as:

1. The medical history and physical examination of the patient;

2. Other evaluations and consultations;

3. Treatment plan objectives;

4. Evidence of informed consent;

5. Treatments and drugs prescribed or provided, as in (a) above;

6. Any agreements with the patient; and

7. Periodic reviews conducted.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY B:
Issues related to patients

COMMENT:
Acknowledges that a patient's prior history or current status of drug abuse does not necessarily contraindicate appropriate pain management.

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REGULATIONS

Pharmacy Board Regulations

N.J.A.C. 13:39-1.2

§ 13:39-1.2 Definitions

The following words and terms when used in this chapter shall have the following meanings, unless the context clearly indicates otherwise.

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"Practitioner" means an individual currently licensed, registered or otherwise authorized by the jurisdiction in which the individual practices to administer or prescribe drugs and/or devices in the course of professional practice.

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(+) *CRITERION 3:*
Opioids are part of professional practice

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NEW JERSEY

STATUTES

Code of Criminal Justice

N.J. Stat. § 2C:35-2

§ 2C:35-2. Definitions

As used in this chapter:

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"Drug or alcohol dependent person" means a person who as a result of using a controlled dangerous substance or controlled substance analog or alcohol has been in a state of psychic or physical dependence, or both, arising from the use of that controlled dangerous substance or controlled substance analog or alcohol on a continuous or repetitive basis. Drug or alcohol dependence is characterized by behavioral and other responses, including but not limited to a strong compulsion to take the substance on a recurring basis in order to experience its psychic effects, or to avoid the discomfort of its absence.

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"Practitioner" means a physician, dentist, veterinarian, scientific investigator, laboratory, pharmacy, hospital or other person licensed, registered, or otherwise permitted to distribute, dispense, conduct research with respect to, or administer a controlled dangerous substance or controlled substance analog in the course of professional practice or research in this State.

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(-) *CRITERION 11:*
Physical dependence or analgesic tolerance confused with "addiction"

(+) *CRITERION 3:*
Opioids are part of professional practice

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STATUTES

Health Care Facilities

N.J. Stat. § 26:2H-5b

§ 26:2H-5b. Routine monitoring of pain as fifth vital sign required

a. The Commissioner of Health and Senior Services shall prescribe, by regulation, requirements to be adopted by health care facilities licensed pursuant to P.L. 1971, c. 136 (*C. 26:2H-1* et seq.) for the routine monitoring of pain as a fifth vital sign in patients, in addition to blood pressure, pulse, respiration and temperature.

For the purpose of this subsection, the commissioner shall require health care facilities to:

(1) routinely inquire whether a patient is in pain;

(2) maintain policies and procedures as prescribed by the commissioner for asking patients to rate their degree of pain for a specified period of time and to record their responses; and

(3) routinely record levels of pain intensity on patient charts.

b. The requirements to be adopted pursuant to subsection a. of this section shall take effect no later than the 180th day after the effective date of this act.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (law regarding pain as fifth vital sign) for health care facilities to ensure that pain management is an essential part of patient care.

N.J. Stat. § 26:2H-12.8

§ 26:2H-12.8. Rights of persons admitted to a general hospital

Every person admitted to a general hospital as licensed by the State Department of Health and Senior Services pursuant to P.L. 1971, c. 136 (*C. 26:2H-1* et al.) shall have the right:

a. To considerate and respectful care consistent with sound nursing and medical practices, which shall include being informed of the name and licensure status of a student nurse or facility staff member who examines, observes or treats the patient and the right to expect and receive appropriate assessment, management and treatment of pain as an integral component of that person's care;

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(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a responsibility for hospitals to ensure that pain management is an essential part of patient care.

N.J. Stat. § 26:2H-128

§ 26:2H-128. Rights of residents of assisted living facilities, comprehensive personal care homes

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b. Every resident of an assisted living facility or comprehensive personal care home that is licensed in the State shall have the right to:

(1) receive personalized services and care in accordance with the resident's individualized general service or health service plan;

(2) receive a level of care and services that address the resident's changing physical and psychosocial status;

(3) have the resident's independence and individuality;

(4) be treated with respect, courtesy, consideration, and dignity;

(5) make choices with respect to services and lifestyle;

(6) privacy;

(7) have or not to have families' and friends' participation in resident service planning and implementation;

(8) receive pain management as needed, in accordance with Department of Health regulations;

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(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a responsibility for assisted living facilities to ensure that pain management is an essential part of patient care.

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STATUTES

Nursing Homes

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a responsibility for hospices to ensure that pain management is an essential part of patient care.

N.J. Stat. § 30:13-5

§ 30:13-5. Rights of nursing home residents

Every resident of a nursing home shall:

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j. Have the right to a safe and decent living environment and considerate and respectful care that recognizes the dignity and individuality of the resident, including the right to expect and receive appropriate assessment, management and treatment of pain as an integral component of that person's care consistent with sound nursing and medical practices.

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STATUTES

Prescription Monitoring Program

N.J. Stat. § 45:1-44

§ 45:1-44. Definitions

As used in sections 25 through 30 of P.L.2007, c.244 (*C.45:1-45* through *C.45:1-50*):

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"Practitioner" means an individual currently licensed, registered or otherwise authorized by this State or another state to prescribe drugs in the course of professional practice.

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(+) *CRITERION 3:*
Opioids are part of professional practice

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REGULATIONS

Licensing Standards for Assisted Living Facilities

N.J.A.C. 8:36-4.1

§ 8:36-4.1 Posting and distribution of statement of resident rights

(a) Each assisted living provider will post and distribute a statement of resident rights for all residents of assisted living residences, comprehensive personal care homes, and assisted living programs. Each resident is entitled to the following rights:

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8. The right to receive pain management as needed, in accordance with N.J.A.C. 8:43E-6;

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N.J.A.C. 8:36-5.6

§ 8:36-5.6 Staffing requirements

(a) The facility or program shall maintain and implement written staffing schedules. Actual hours worked by each employee shall be documented.
(b) The facility or program shall develop and implement a staff orientation and a staff education plan, including plans for each service and designation of person(s) responsible for training. All personnel shall receive orientation at the time of employment and at least annual in-service education regarding, at a minimum, the following:

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6. Pain management; and

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(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (staff orientation and education) for assisted living facilities to ensure that pain management is an essential part of patient care.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (statement of resident rights) for assisted living facilities to ensure that pain management is an essential part of patient care.

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REGULATIONS

Licensing Standards for Long-Term Care Facilities

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a responsibility for hospitals to ensure that pain management is an essential part of patient care.

N.J.A.C. 8:39-27.1

§ 8:39-27.1 Mandatory policies, procedures and practices for quality of care

(a) The facility shall provide and ensure that each resident receives all care and services needed to enable the resident to attain and maintain the highest practicable level of physical (including pain management), emotional and social well-being, in accordance with individual assessments and care plans.

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REGULATIONS

Licensing Standards for Ambulatory Care Facilities

N.J.A.C. 8:43A-16.2

§ 8:43A-16.2. Rights of each patient

(a) Each patient receiving services in an ambulatory care facility shall have the following rights:

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14. To expect and receive appropriate assessment, management and treatment of pain as an integral component of that person's care in accordance with N.J.A.C. 8:43E-6.

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(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a responsibility for ambulatory care facilities to ensure that pain management is an essential part of patient care.

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REGULATIONS

Pain Management Procedures

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (pain management standards) for healthcare facilities to ensure that pain management is an essential part of patient care.

N.J.A.C. 8:43E-6.1

§ 8:43E-6.1 Pain management standards; scope

The standards set forth in this subchapter apply to all health care facilities licensed in accordance with *N.J.S.A. 26:2H-1* et seq.

§ 8:43E-6.2 Purpose

The rules in this subchapter are intended to promote the health, safety, and welfare of patients or residents of health care facilities by establishing requirements for the assessment, monitoring and management of pain.

§ 8:43E-6.3 Definitions

The following words and terms, as used in this subchapter, shall have the following meanings, unless the context clearly indicates otherwise:

"Pain" means an unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage.

"Pain management" means the assessment of pain and, if appropriate, treatment in order to assure the needs of patients or residents of health care facilities who experience problems with pain are met. Treatment of pain may include the use of medications or application of other modalities and medical devices such as, but not limited to, heat or cold, massage, transcutaneous electrical nerve stimulation (TENS), acupuncture, and neurolytic techniques such as radiofrequency coagulation and cryotherapy.

"Pain rating scale" means a tool that is age cognitive and culturally specific to the patient or resident population to which it is applied and which results in an assessment and measurement of the intensity of pain.

"Pain treatment plan" means a plan, based on information gathered during a patient/resident pain assessment, that identifies the patient's/resident's needs and specifies appropriate interventions to alleviate pain, to the extent feasible and medically appropriate.

§ 8:43E-6.4 Pain assessment procedures

(a) A facility shall formulate a system for assessing and monitoring patients'/residents' pain using a pain rating scale.

1. A facility serving different patient/resident populations shall utilize more than one pain scale, as appropriate.

(b) Assessment of a patient's/resident's pain shall occur, at a minimum, upon admission, on the day of a planned discharge, and when warranted by changes in a patient's/resident's condition, self-reporting of pain and/or evidence of behavioral cues indicative of the presence of pain. In the case of individuals receiving home health care services, assessment shall coincide with a visit by staff of the home health service agency and assessment on the day of discharge is not required if the individual has been admitted to an inpatient or residential health care facility and discharge from the home health service agency takes place after the admission.

(c) If pain is identified, a pain treatment plan shall be developed and implemented within the health care facility or the patient/resident shall be referred for treatment or consultation.

(d) If the patient/resident is cognitively impaired or non-verbal, the facility shall utilize pain rating scales for the cognitively impaired and non-verbal patient/resident. Additionally, the facility shall seek information from the patient's/resident's family, caregiver or other representative, if available and known to the facility. The results of the pain rating scales and the response to the additional inquiry shall be documented in the patient's/resident's medical record.

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NEW JERSEY

REGULATIONS

Pain Management Procedures

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT*:* Establishes a mechanism (written policies and procedures) to provide patients information/education about pain management.

(CONTINUED)

(e) Pain assessment findings shall be documented in the patient's/resident's medical record. This shall include, but not be limited to, the date, pain rating, treatment plan and patient/resident response.

(f) The facility shall establish written policies and procedures governing the management of pain that are reviewed at least every three years and revised more frequently as needed. They shall include at least the following:

1. A written procedure for systematically conducting periodic assessment of a patient's/resident's pain, as specified in (b) above. At a minimum, the procedure must specify pain assessment upon admission, upon discharge, and when warranted by changes in a patient's/resident's condition and self-reporting of pain;

2. Criteria for the assessment of pain, including, but not limited to: pain intensity or severity, pain character, pain frequency or pattern, or both; pain location, pain duration, precipitating factors, responses to treatment and the personal, cultural, spiritual, and/or ethnic beliefs that may impact an individual's perception of pain;

3. A written procedure for the monitoring of a patient's/resident's pain;

4. A written procedure to insure the consistency of pain rating scales across departments within the health care facility;

5. Requirements for documentation of a patient's/resident's pain status on the medical record;

6. A procedure for educating patients/residents and, if applicable, their families about pain management when identified as part of their treatment; and

7. A written procedure for systematically coordinating and updating the pain treatment plan of a patient/resident in response to documented pain status.

§ 8:43E-6.5 Staff education and training programs

(a) Each facility shall develop, revise as necessary and implement a written plan for the purpose of training and educating staff on pain management. The plan shall include mandatory educational programs that address at least the following:

1. Orientation of new staff to the facility's policies and procedures on pain assessment and management;

2. Training of staff in pain assessment tools; behaviors potentially indicating pain; personal, cultural, spiritual and/or ethnic beliefs that may impact a patient's/resident's perception of pain; new equipment and new technologies to assess and monitor a patient's/resident's pain status;

3. Incorporation of pain assessment, monitoring and management into the initial orientation and ongoing education of all appropriate staff; and

4. Patient/resident rights.

(b) Implementation of the plan shall include records of attendance for each program.

§ 8:43E-6.6 Pain management continuous quality improvement

The facility's continuous quality improvement program shall include a systematic review and evaluation of pain assessment, management and documentation practices. The facility shall develop a plan by which to collect and analyze data in order to evaluate outcomes or performance. Data analysis shall focus on recommendations for implementing corrective actions and improving performance.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT*:* Establishes a mechanism (training programs) to provide practitioners information/education about pain management.

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NEW JERSEY

REGULATIONS

Licensing Standards for Hospitals

N.J.A.C. 8:43G-4.1

§ 8:43G-4.1. Patient rights

(a) Every New Jersey hospital patient shall have the following rights, none of which shall be abridged by the hospital or any of its staff. The hospital administrator shall be responsible for developing and implementing policies to protect patient rights and to respond to questions and grievances pertaining to patient rights. These rights shall include at least the following:

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31 To expect and receive appropriate assessment, management and treatment of pain as an integral component of that person's care, in accordance with N.J.A.C. 8:43E-6.

N.J.A.C. 8:43G-22.2

§ 8:43G-22.2 Pediatrics and pediatric intensive care policies and procedures

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(d) The pediatric services shall participate in developing anesthesia and pain management policies for infants and children.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (written policies) for hospitals to ensure that pain management is an essential part of patient care

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NEW JERSEY

REGULATIONS

AIDS Community Care Alternative Program Services

N.J.A.C. 10:60-7.4

§ 10:60-7.4 ACCAP services

(a) All Medicaid or NJ KidCare-Plan A services, except for nursing facility services, are available under ACCAP in accord with an individualized plan of care. Additionally, the following services are available to the eligible beneficiary:

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7. Hospice care: This provides optimum comfort measures (including pain control), support and dignity to beneficiaries certified by an attending physician as terminally ill, with a life expectancy of up to six months. Family and/or other caregivers are also given support and direction while caring for the dying beneficiary. Services shall be provided by a Medicaid/NJ KidCare approved, Medicare certified hospice agency and available to a beneficiary on a daily, 24-hour basis. Hospice services include: skilled nursing visits; hospice agency medical director services; medical social service visits; occupational therapy, physical therapy and speech-language pathology services; intravenous therapy; durable medical equipment; medication related to symptom control of terminal illness and case management. Reimbursement shall be at an established fee paid on a per diem basis.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT*:* Recognizes that pain management is an essential part of hospice care.

REGULATIONS

Law and Public Safety

N.J.A.C. 13:34C-2.2

§ 13:34C-2.2 Application procedure: licensed clinical alcohol and drug counselor

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(b) An applicant shall furnish evidence that the applicant has:

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x. Pharmacology and physiology, which includes topics related to physiology of alcohol/drug use, abuse, dependency and addiction; neurophysiology of chemical use; psychopharmacology; therapeutic and appropriate use of pharmaceutical drugs; physical health and the use/abuse of drugs; psychiatric medications in the treatment of mental illness and dual diagnoses; appropriate use of prescribed medications for recovering chemically dependent clients/patients; treatment of chronic pain and clinical testing of body fluids and hair;

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(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT*:* Requires AODA practitioners to receive information/education about pain management.

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NEW MEXICO

STATUTES

- CONTROLLED SUBSTANCES ACT (*No provisions found*)
  Chapter 30. Criminal Offenses; Article 31. Controlled Substances

- MEDICAL PRACTICE ACT
  Chapter 61. Professional and Occupational Licenses; Article 6. Medicine and Surgery

- OSTEOPATHIC PRACTICE ACT (*No provisions found*)
  Chapter 61. Professional and Occupational Licenses; Article 10. Osteopathic Medicine and Surgery

- PHARMACY PRACTICE ACT (*No provisions found*)
  Chapter 61. Professional and Occupational Licenses; Article11. Pharmacy

- INTRACTABLE PAIN TREATMENT ACT
  No policy found

REGULATIONS

- CONTROLLED SUBSTANCES REGULATIONS (*Part of Pharmacy Board Regulations*)
  Title 16. Occupational and Professional Licensing; Chapter19. Pharmacists; Part 20. Controlled Substances

- MEDICAL BOARD REGULATIONS
  Title 16. Occupational and Professional Licensing; Chapter10. Medicine and Surgery Practitioners

- OSTEOPATHIC BOARD REGULATIONS (*No provisions found*)
  Title 16. Occupational and Professional Licensing; Chapter17. Osteopathic Medicine and Surgery Practitioners

- PHARMACY BOARD REGULATIONS
  Title 16. Occupational and Professional Licensing; Chapter19. Pharmacists

OTHER GOVERNMENTAL POLICIES

- JOINT BOARD POLICY STATEMENT
  New Mexico Boards of Medical Practice, Nursing, and Pharmacy. Joint Statement on Management of Chronic Pain. Adopted: June 5, 2005.

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RELEVANT POLICIES OR PROVISIONS IDENTIFIED BY KEY WORD SEARCHES

- PAIN RELIEF ACT
  Chapter 24. Health and Safety; Article 2D. Pain Relief

- OPIOID TREATMENT PROGRAMS
  Title 7. Health; Chapter 32. Alcohol and Drug Abuse; Part 8. Opioid Treatment Programs

NEW MEXICO

STATUTES

Medical Practice Act

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT*:* Establishes a mechanism (guidelines) for the board to ensure that pain management is an essential part of patient care.

N.M. Stat. Ann. § 61-6-5

§ 61-6-5. Duties and powers. (Repealed effective July 1, 2016.)

The board shall:

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O. establish and maintain rules related to the management of pain based on review of national standards for pain management.

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N.M. Stat. Ann. § 61-6-6

§ 61-6-6. Definitions.

As used in Chapter 61, Article 6 NMSA 1978:

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J. "the practice of medicine" consists of:

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(5) offering or undertaking to diagnose, correct or treat in any manner or by any means, methods, devices or instrumentalities any disease, illness, pain, wound, fracture, infirmity, deformity, defect or abnormal physical or mental condition of any person;

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(+) *CRITERION 2:*
Pain management is part of healthcare practice

N.M. Stat. Ann. § 61-6-15

§ 61-6-15. License may be refused, revoked or suspended; licensee may be fined, censured or reprimanded; procedure; practice after suspension or revocation; penalty; unprofessional and dishonorable conduct defined; fees and expenses.

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D. "Unprofessional or dishonorable conduct", as used in this section, means, but is not limited to because of enumeration, conduct of a licensee that includes the following:

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(35) undertreatment of pain as provided by board rule;

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(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT*:* Recognizes inadequate treatment of pain as subject to disciplinary action just as other substandard practices might be.

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NEW MEXICO

REGULATIONS

Controlled Substances Regulations

16.19.20.41 NMAC

§ 16.19.20.41. PRESCRIPTIONS

A. A prescription for a controlled substance may be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice, and who is registered under the Controlled Substances Act. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription.

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16.19.29.6 NMAC

§ 16.19.29.6. OBJECTIVE

The objective of Part 29 of Chapter 19 is to promote the public health and welfare by detecting and preventing substance abuse and encouraging appropriate treatment of pain and other conditions for which controlled substances are prescribed. The purpose of the system is to improve access to controlled substances for legitimate medical needs by allowing a practitioner or a pharmacist to obtain a patient's pharmaceutical history related to controlled substances. The program's objectives will include education of the public and health care professionals regarding the nature and extent of the problem of drug abuse, appropriate prescribing and use of controlled substances, and the medical treatment options for abusers of controlled substances and pain management.

(+) *CRITERION 3:*
Opioids are part of professional practice

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT*:* Represents the principle of Balance, which states that the regulation of controlled substances should not interfere with legitimate medical use.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT*:* Establishes a mechanism (education) to provide practitioners information/education about pain management.

REGULATIONS

Medical Board Regulations

16.10.8.8 NMAC

§ 16.10.8.8. UNPROFESSIONAL OR DISHONORABLE CONDUCT

As defined in the Medical Practice Act, Section 61-6-15,D,(29), "unprofessional or dishonorable conduct" includes, but is not limited to, the following:

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D. excessive prescribing or administering of drugs;

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(-) *CRITERION 16:*
Provisions that are ambiguous

CATEGORY A:
Arbitrary standards for legitimate prescribing

COMMENT: Although it is reasonable to expect physicians to avoid contributing to diversion, "excessive" implies there is a known standard, but the standard is not specified.

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NEW MEXICO

REGULATIONS

Medical Board Regulations

16.10.14.1 – 16.10.14.12 NMAC

§ 16.10.14.1. ISSUING AGENCY

New Mexico Medical Board, hereafter called the board.

§ 16.10.14.2. SCOPE

This part applies to all New Mexico medical board licensees who hold a federal drug enforcement administration registration.

§ 16.10.14.3. STATUTORY AUTHORITY

These rules are promulgated pursuant to and in accordance with the Medical Practice Act, *sections 61-6-1 through 61-6-35 NMSA* 1978 and the Pain Relief Act, *sections 24-2D-1 NMSA* through 24-2D-6.

§ 16.10.14.4. DURATION

Permanent

§ 16.10.14.5. EFFECTIVE DATE

January 20, 2003, unless a later date is cited at the end of a section.

§ 16.10.14.6. OBJECTIVE

It is the position of the board that practitioners have an obligation to treat chronic pain and that a wide variety of medicines including controlled substances and other drugs may be prescribed for that purpose. When such medicines and drugs are used, they should be prescribed in adequate doses and for appropriate lengths of time after a thorough medical evaluation has been completed.

(+) *CRITERION 4:* *Encourages pain management*

§ 16.10.14.7. DEFINITIONS

A. "Addiction" is a neurobehavioral syndrome with genetic and environmental influences that results in psychological dependence on the use of substances for their psychic effects. It is characterized by behaviors that include one or more of the following: impaired control over drug use; compulsive use; continued use despite harm; and, craving. Physical dependence and tolerance are normal physiological consequences of extended opioid therapy for pain and should not by themselves be considered addiction.

(+) *CRITERION 7:* *Physical dependence or analgesic tolerance are not confused with "addiction"*

B. "Acute pain" means the normal, predicted physiological response to a noxious chemical or thermal or mechanical stimulus, typically associated with invasive procedures, trauma or disease and is generally time-limited.

C. "Chronic pain" means pain that persists after reasonable medical efforts have been made to relieve the pain or its cause and that continues, either continuously or episodically, for longer than three consecutive months. "Chronic pain" does not, for purpose of the Pain Relief Act requirements, include pain associated with a terminal condition or with a progressive disease that, in the normal course of progression, may reasonably be expected to result in a terminal condition.

D. "Clinical expert" means a person who, by reason of specialized education or substantial relevant experience in pain management, has knowledge regarding current standards, practices and guidelines.

E. "Drug abuser" means a person who takes a drug or drugs for other than legitimate medical purposes.

F. "Pain" means acute or chronic pain or both.

G. "Physical dependence" means a state of adaptation that is manifested by a drug-specific withdrawal syndrome that can be produced by abrupt cessation, rapid dose reduction, decreasing blood level of the drug, administration of an antagonist, or a combination of these.

(CONTINUED ON NEXT PAGE)

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NEW MEXICO

REGULATIONS

Medical Board Regulations

(CONTINUED)

H. "Prescription monitoring program" means a centralized system to collect, monitor, and analyze electronically, for controlled substances, prescribing and dispensing data submitted by pharmacies and dispensing practitioners. The data are used to support efforts in education, research, enforcement and abuse prevention.

I. "Therapeutic purpose" means the use of pharmaceutical and non-pharmaceutical medical treatment that conforms substantially to accepted guidelines for pain management.

J. "Tolerance" means a state of adaptation in which exposure to a drug induces changes that result in a diminution of one or more of the drug's effects over time.

§ 16.10.14.8. REGULATIONS

The following regulations shall be used by the board to determine whether a health care practitioner's prescriptive practices are consistent with the appropriate treatment of pain.

A. The treatment of pain with various medicines or controlled substances is a legitimate medical practice when accomplished in the usual course of professional practice. It does not preclude treatment of patients with addiction, physical dependence or tolerance who have legitimate pain. However, such patients do require very close monitoring and precise documentation.

B. The prescribing, ordering, administering or dispensing of controlled substances to meet the individual needs of the patient for management of chronic pain is appropriate if prescribed, ordered, administered or dispensed in compliance with the following.

(1) A practitioner shall complete a physical examination and include an evaluation of the patient's psychological and pain status. The medical history shall include any previous history of significant pain, past history of alternate treatments for pain, potential for substance abuse, coexisting disease or medical conditions, and the presence of a medical indication or contra-indication against the use of controlled substances.

(2) A practitioner shall be familiar with and employ screening tools as appropriate, as well as the spectrum of available modalities, in the evaluation and management of pain. The practitioner shall consider an integrative approach to pain management.

(3) A written treatment plan shall be developed and tailored to the individual needs of the patient, taking age, gender, culture, and ethnicity into consideration, with stated objectives by which treatment can be evaluated, e.g. by degree of pain relief, improved physical and psychological function, or other accepted measure. Such a plan shall include a statement of the need for further testing, consultation, referral or use of other treatment modalities.

(4) The practitioner shall discuss the risks and benefits of using controlled substances with the patient or surrogate or guardian, and shall document this discussion in the record.

(CONTINUED ON NEXT PAGE)

(+) *CRITERION 2:*
Pain management is part of healthcare practice

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY B:
Issues related to patients

COMMENT*:* Recognizes that a patient's prior history or current status of drug abuse does not necessarily contraindicate appropriate pain management.

(+) *CRITERION 3:*
Opioids are part of professional practice

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Encourages healthcare professionals to incorporate in their practice the evaluations of, and discussions with patients about, the potential benefits and risks of treatment with opioids, which can better ensure a clinical indication of such treatment so that opioids will be used for medical purposes.

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NEW MEXICO

REGULATIONS

Medical Board Regulations

(CONTINUED)

(5) Complete and accurate records of care provided and drugs prescribed shall be maintained. When controlled substances are prescribed, the name of the drug, quantity, prescribed dosage and number of refills authorized shall be recorded. Prescriptions for opioids shall include indications for use. For chronic pain patients treated with controlled substance analgesic(s), the prescribing practitioner shall use a written agreement for treatment with the patient outlining patient responsibilities. As part of a written agreement, chronic pain patients shall receive all chronic pain management prescriptions from one practitioner and one pharmacy whenever possible.

(6) The management of patients needing chronic pain control requires monitoring by the attending or the consulting practitioner. The practitioner shall periodically review the course of treatment for chronic pain, the patient's state of health, and any new information about the etiology of the chronic pain at least every six months. In addition, a practitioner shall consult, when indicated by the patient's condition, with health care professionals who are experienced (by the length and type of their practice) in the area of chronic pain control; such professionals need not be those who specialize in pain control.

(7) If, in a practitioner's medical opinion, a patient is seeking pain medication for reasons that are not medically justified, the practitioner is not required to prescribe controlled substances for the patient.

C. Pain management for patients with substance use disorders shall include:

(1) a contractual agreement;

(2) appropriate consultation;

(3) drug screening when other factors suggest an elevated risk of misuse or diversion; and

(4) a schedule for re-evaluation at appropriate time intervals at least every six months.

D. The board will evaluate the quality of care on the following basis: appropriate diagnosis and evaluation; appropriate medical indication for the treatment prescribed; documented change or persistence of the recognized medical indication; and, follow-up evaluation with appropriate continuity of care. The board will judge the validity of prescribing based on the practitioner's treatment of the patient and on available documentation, rather than on the quantity and chronicity of prescribing. The goal is to control the patient's pain for its duration while effectively addressing other aspects of the patient's functioning, including physical, psychological, social, and work-related factors.

E. The board will review both over-prescription and under-prescription of pain medications using the same standard of patient protection.

F. A practitioner who appropriately prescribes controlled substances and who follows this section would be considered to be in compliance with this rule and not be subject to discipline by the board, unless there is some violation of the Medical Practice Act or board rules.

(-) *CRITERION 16:*
Provisions that are ambiguous

CATEGORY B:
Unclear intent leading to possible misinterpretation

COMMENT: Within the context of this regulation, it is unclear how "appropriate consultation" would be determined and who would make this determination.

(+) *CRITERION 6:*
Prescription amount alone does not determine legitimacy

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT*:* Recognizes that inadequate treatment of pain is subject to disciplinary action just as other substandard practices might be.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Recognizes that the goal of pain treatment should include improvements in patient functioning and quality of life.

(+) *CRITERION 5:*
Addresses fear of regulatory scrutiny

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NEW MEXICO

REGULATIONS

Medical Board Regulations

(CONTINUED)

§ 16.10.14.9. PHYSICIAN, PHYSICIAN ASSISTANTS AND ANESTHESIOLOGIST ASSISTANTS TREATED WITH OPIATES

Physicians, physician assistants or anesthesiologist assistants who have chronic pain and are being treated with opiates shall be evaluated by a pain clinic or, by an M.D. or D.O. pain specialist, and must have a complete, independent neuropsychological evaluation, as well as clearance from their physician, before returning to or continuing in practice. In addition, they must remain under the care of a physician for as long as they remain on opiates while continuing to practice.

§ 16.10.14.10. PRESCRIPTION MONITORING PROGRAM (PMP) REQUIREMENTS

The intent of the New Mexico medical board in requiring participation in the PMP is to assist practitioners in balancing the safe use of controlled substances with the need to impede illegal and harmful activities involving these pharmaceuticals.

A. A health care practitioner who holds a federal drug enforcement administration registration and a New Mexico controlled substance registration shall register with the board of pharmacy to become a regular participant in PMP inquiry and reporting.

B. A health care practitioner shall, before prescribing, ordering, administering or dispensing a controlled substance listed in Schedule II, III or IV, obtain a patient PMP report for the preceding 12 months when one of the following situations exists:

(1) the patient is a new patient of the practitioner, in which situation a patient PMP report for the previous 12 months shall only be required when Schedules II, III, and IV drugs are prescribed for a period greater than 10 days; and

(2) during the continuous use of opioids by established patients a PMP shall be requested and reviewed a minimum of once every six months.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT*:* Represents the principle of Balance, which states that the regulation of controlled substances should not interfere with legitimate medical use.

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NEW MEXICO

REGULATIONS

Medical Board Regulations

§ 16.10.14.11. PAIN MANAGEMENT CONTINUING EDUCATION

This section applies to all New Mexico medical board licensees who hold a federal drug enforcement administration registration and licensure to prescribe opioids. Pursuant to the Pain Relief Act, in order to ensure that all such health care practitioners safely prescribe for pain management and harm reduction, the following rules shall apply.

A. Immediate requirements effective November 1, 2012. Between November 1, 2012 and no later than June 30, 2014, all New Mexico medical board licensees who hold a federal drug enforcement administration registration and licensure to prescribe opioids, shall complete no less than five continuing medical education hours in appropriate courses that shall include:

(1) an understanding of the pharmacology and risks of controlled substances,

(2) a basic awareness of the problems of abuse, addiction and diversion,

(3) awareness of state and federal regulations for the prescription of controlled substances.

(4) management of the treatment of pain, and

(5) courses may also include a review of this rule (*16.10.14 NMAC*) the applicability of such courses toward fulfillment of the continuing medical education requirement is subject to medical board approval. Practitioners who have taken continuing medical education hours in these educational elements between July 1, 2011 and November 1, 2012, may apply those hours toward the required five continuing medical education hours described in this subsection.

B. Triennial requirements for physicians. Beginning with the July 1, 2014 triennial renewal date, as part of the 75 continuing medical education hours required during each triennial renewal cycle, all New Mexico medical board physician licensees who hold a federal drug enforcement administration registration and license to prescribe opioids, shall be required to complete and submit five continuing medical education hours. Appropriate courses shall include all of the educational elements described in Subsection A of this section. The applicability of such courses toward fulfillment of the continuing medical education requirement is subject to medical board approval. These hours may be earned at any time during the three-year period immediately preceding the triennial renewal date. The five continuing medical education hours completed prior to July 1, 2014, as defined in Subsection A above, may be included as part of the required continuing medical education hours in pain management in either the triennial cycle in which these hours are completed, or the triennial cycle immediately thereafter.

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§ 16.10.14.12. NOTIFICATION

In addition to the notice of procedures set forth in the State Rules Act, *Section 14-4-1 et seq NMSA* 1978, the board shall separately notify the following persons of the Pain Relief Act and Part 14 of the New Mexico medical board *rule, 16.10.14 NMAC*;

A. health care practitioners under its jurisdiction; and

B. a health care practitioner being investigated by the board in relation to the practitioner's pain management services.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (mandatory continuing education) to provide practitioners information/education about pain management.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a responsibility to communicate to practitioners about acceptable practice governing pain management.

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NEW MEXICO

REGULATIONS

Pharmacy Board Regulations

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Represents the principle of Balance, which states that the regulation of controlled substances should not interfere with legitimate medical use.

16.19.29.6 NMAC

§ 16.19.29.6. OBJECTIVE

The objective of Part 29 of Chapter 19 is to promote the public health and welfare by detecting and preventing substance abuse and encouraging appropriate treatment of pain and other conditions for which controlled substances are prescribed. The purpose of the system is to improve access to controlled substances for legitimate medical needs by allowing a practitioner or a pharmacist to obtain a patient's pharmaceutical history related to controlled substances. The program's objectives will include education of the public and health care professionals regarding the nature and extent of the problem of drug abuse, appropriate prescribing and use of controlled substances, and the medical treatment options for abusers of controlled substances and pain management.

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NEW MEXICO

OTHER GOVERNMENTAL POLICY

Joint Board Policy Statement

Joint Statement on the Management of Chronic Pain

Pain management is a significant issue in health care today. Estimates of Americans experiencing pain range from 50-75 million persons annually. Thirty to fifty percent of patients undergoing cancer treatment experience pain. The effects of unmanaged pain are serious and wide-ranging and, yet, pain is widely under-treated. Untreated or inadequately treated pain impacts patients' quality of life and increases health care costs. Factors cited in the under-treatment of pain include concerns about causing addiction or tolerance; inadequate knowledge of controlled substances and pain management; fear of scrutiny and discipline by regulatory agencies; inadequate assessment; and patient reluctance to report pain or to take pain medications.

The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) guidelines on pain management state, "Patients have the right to appropriate assessment and management of pain." (Emphasis added). It is, therefore, incumbent upon New Mexico physicians, nurses and pharmacists to work cooperatively and effectively to address the dimensions of pain and to provide maximum pain relief with minimal side effects. Towards that end, and in the interest of public protection, the New Mexico Boards of Medical Practice, Nursing and Pharmacy issue the following joint statement.

To effectively assist patients in the management of chronic pain, health care professionals should, within their scope of practice:

- Consistently and thoroughly assess all patients for pain. If the patient reports untreated or inadequately treated chronic pain, the pain should be evaluated with a complete history and physical with laboratory and diagnostic testing, if indicated;
- Work collaboratively in a multi-disciplinary approach to develop and implement an individualized, written treatment plan utilizing pharmacologic and non-pharmacologic interventions with specific objectives for the patient;
- Regularly evaluate the effectiveness of the treatment plan, using a consistent, developmentally appropriate, standardized pain scale, and make adjustments as needed;
- Document all aspects of pain assessment and care in a timely, clear, consistent, complete and accurate manner;
- Anticipate and effectively manage side effects of pain medications;
- Provide adequate and culturally appropriate information to patients and family members or caregivers to support patients in making informed decisions and participate in the management of their pain;
- Be aware of the risks of diversion and abuse of controlled substances and take appropriate steps to minimize there risks;
- Recognize individuals with chemical dependency may experience pain requiring medications, including opioids, and may require specialized management;
- Consult with, and refer patients to, other providers when appropriate;
- Develop organization-appropriate and evidence-based policies and protocols for pain management;
- Become and remain knowledgeable regarding effective pain management; and
- Comply with all state and federal laws and regulations regarding prescribing, dispensing, and administering legend drugs, including controlled substances.

(+) *CRITERION 4:*
Encourages pain management

(+) *CRITERION 2:*
Pain management is part of healthcare practice

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Recognizes the need for a multidisciplinary approach to pain management.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Encourages healthcare professionals to understand and follow federal and state laws governing their practice, which can better ensure that practitioners follow the *balanced* approach represented by federal law and the laws in many states.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Identifies the potential impact of important barriers on the provision of effective pain care.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY A:
Issues related to healthcare professionals

COMMENT: Recognizes a practitioner's responsibility to provide patients information about pain management and palliative care when considering treatment plans.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY B:
Issues related to patients

COMMENT: Acknowledges that a patient's prior history or current status of drug abuse does not necessarily contraindicate appropriate pain management.

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NEW MEXICO

STATUTES

Pain Relief Act

N.M. Stat. Ann. § 24-2D-1 – § 24-2D-5.2

§ 24-2D-1. Short title

This act may be cited as the "Pain Relief Act".

§ 24-2D-2. Definitions

As used in the Pain Relief Act [*24-2D-1 NMSA* 1978]:

A. "accepted guideline" means the most current clinical pain management guideline developed by the American geriatrics society or the American pain society or a clinical pain management guideline based on evidence and expert opinion that has been accepted by the New Mexico medical board;

B. "acute pain" means the normal, predicted physiological response to a noxious chemical or thermal or mechanical stimulus, typically associated with invasive procedures, trauma or disease and generally time-limited;

C. "board" means the licensing board of a health care provider;

D. "chronic pain" means pain that persists after reasonable medical efforts have been made to relieve the pain or its cause and that continues, either continuously or episodically, for longer than three consecutive months. "Chronic pain" does not include pain associated with a terminal condition or with a progressive disease that, in the normal course of progression, may reasonably be expected to result in a terminal condition;

E. "clinical expert" means a person who by reason of specialized education or substantial relevant experience in pain management has knowledge regarding current standards, practices and guidelines;

F. "disciplinary action" means any formal action taken by a board against a health care provider, upon a finding of probable cause that the health care provider has engaged in conduct that violates the board's practice act;

G. "health care provider" means a person licensed or otherwise authorized by law to provide health care in the ordinary course of business or practice of the person's profession and who has prescriptive authority within the limits of the person's license;

H. "pain" means acute and chronic pain; and

I. "therapeutic purpose" means the use of pharmaceutical and non-pharmaceutical medical treatment that conforms substantially to accepted guidelines for pain management.

§ 24-2D-3. Disciplinary action; evidentiary requirements

A. A health care provider who prescribes, dispenses or administers medical treatment for the purpose of relieving pain and who can demonstrate by reference to an accepted guideline that the provider's practice substantially complies with that guideline and with the standards of practice identified in *Section 24-2D-4 NMSA* 1978 shall not be disciplined pursuant to board action or criminal prosecution, unless the showing of substantial compliance with an accepted guideline by the health care provider is rebutted by clinical expert testimony. If no currently accepted guidelines are available, then rules issued by the board may serve the function of such guidelines for purposes of the Pain Relief Act [*24-2D-1 NMSA* 1978]. The board rules shall conform to the intent of that act. Guidelines established primarily for purposes of coverage, payment or reimbursement do not qualify as an "accepted guideline" when offered to limit treatment options otherwise covered within the Pain Relief Act.

B. In the event that a disciplinary action or criminal prosecution is pursued, the board or prosecutor shall produce clinical expert testimony supporting the finding or charge of violation of disciplinary standards or other legal requirements on the part of the health care provider. A showing of substantial compliance with an accepted guideline shall only be rebutted by clinical expert testimony.

(CONTINUED ON NEXT PAGE)

(+) *CRITERION 3:*
Opioids are part of professional practice

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT*:* Establishes a mechanism (immunity) to protect physicians treating intractable pain from criminal prosecution.

(+) *CRITERION 5:*
Addresses fear of regulatory scrutiny

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT*:* Identifies the possibility of reimbursement as an important barrier to the appropriate use of opioids analgesics.

Pain & Policy Studies Group
University of Wisconsin Carbone Cancer Center
Madison, Wisconsin

NEW MEXICO

STATUTES

Pain Relief Act

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY B:
Issues related to patients

COMMENT*:* Acknowledges that a patient's prior history or current status of drug abuse does not contraindicate appropriate pain manaaement.

(+) *CRITERION 6:*
Prescription amount alone does not determine legitimacy

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT*:* Establishes a responsibility to communicate to practitioners about acceptable practices governing pain management.

(CONTINUED)

C. The provisions of this section apply to health care providers in the treatment of pain, regardless of a patient's prior or current chemical dependency or addiction. Each board shall adopt rules establishing standards and procedures for the application of the Pain Relief Act [*24-2D-1 NMSA* 1978], including pain management for patients with substance use disorders.

D. In an action brought by a board against a health care provider based on treatment of a patient for pain, the board shall consider the totality of the circumstances and shall not use as the sole basis of the action:

(1) a patient's age;

(2) a patient's diagnosis;

(3) a patient's prognosis;

(4) a patient's history of drug abuse;

(5) the absence of consultation with a pain specialist; or

(6) the quantity of medication prescribed or dispensed.

§ 24-2D-4. Disciplinary action; prohibitions

Nothing in the Pain Relief Act [*24-2D-1 NMSA* 1978] shall prohibit discipline or prosecution of a health care provider for:

A. failing to maintain complete, accurate and current records documenting the physical examination and medical history of the patient, the basis for the clinical diagnosis of the patient and the treatment plan for the patient;

B. writing false or fictitious prescriptions for controlled substances scheduled in the federal Comprehensive Drug Abuse Prevention and Control Act of 1970 or *Sections 26-1-23* and *30-31-18 NMSA* 1978;

C. prescribing, administering or dispensing pharmaceuticals in violation of the provisions of the federal Comprehensive Drug Abuse Prevention and Control Act of 1970 or *Sections 26-1-23* and *30-31-18 NMSA* 1978; or

D. diverting medications prescribed for a patient to the provider's personal use or to other persons.

§ 24-2D-5. Notification

The board shall notify the following persons of the Pain Relief Act [*24-2D-1 NMSA* 1978] and accepted guidelines:

A. health care providers under its jurisdiction; and

B. a health care provider being investigated by the board in relation to the provider's pain management practices.

§ 24-2D-5.1. Pain management continuing education

A board shall require non-cancer pain management continuing education as determined by its rules for health care providers under the board's jurisdiction who hold a federal drug enforcement administration registration and licensure to prescribe opioids.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT*:* Establishes a mechanism (adopting rules) to establish standards and procedures for the appropriate treatment of patients with pain.

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT*:* Establishes a mechanism (encouraging continuing education) to provide practitioners information/education about pain management and palliative care.

Pain & Policy Studies Group
University of Wisconsin Carbone Cancer Center
Madison, Wisconsin

NEW MEXICO

STATUTES

Pain Relief Act

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT: Establishes a mechanism (advisory council) to improve pain management.

(CONTINUED)

§ 24-2D-5.2. Prescription drug misuse and overdose prevention and pain management advisory council created; duties

A. The "prescription drug misuse and overdose prevention and pain management advisory council" is created and shall be administratively attached to the department of health. Members of the council shall be appointed by the governor to consist of one representative each from the department of health, the New Mexico medical board, the board of nursing, the board of pharmacy, the board of osteopathic medical examiners, the board of acupuncture and oriental medicine, the New Mexico board of dental health care, the board of chiropractic examiners, the university of New Mexico health sciences center, a statewide medical association, a statewide association of pharmacists, a statewide association of nurse practitioners, a statewide association of certified registered nurse anesthetists and a statewide association of osteopathic physicians; one person who is a pain management specialist; one person who is a consumer health care advocate; and one person who has no direct ties or pecuniary interest in the health care field.

B. The council shall meet at least quarterly to review the current status of prescription drug misuse and overdose prevention and current pain management practices in New Mexico and national prescription drug misuse and overdose prevention and pain management standards and educational efforts for both consumers and professionals. The council shall also recommend pain management and clinical guidelines. Members who are not public employees shall receive per diem and mileage as provided in the Per Diem and Mileage Act [*10-8-1 NMSA* 1978]. Public employee members shall receive mileage from their respective employers for attendance at council meetings.

§ 24-2D-6. Scope of act

Nothing in the Pain Relief Act [*24-2D-1 NMSA* 1978] shall be construed as expanding the authorized scope of practice of health care providers.

NEW MEXICO

REGULATIONS

Opioid Treatment Programs

(+) *CRITERION 8:*
Other provisions that may enhance pain management

CATEGORY C:
Regulatory or policy issues

COMMENT*:* Establishes a responsibility for OTP staff to refer methadone-maintained patients who have chronic pain for treatment of their pain

7.32.8.26 NMAC

§ 7.32.8.26. DIVERSE POPULATIONS

A. The program sponsor shall ensure that:
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(9) an individual who requires administration of opioid treatment medication only for relief of chronic pain is:

(a) identified during the physical examination or assessment;

(b) not admitted for opioid medication treatment; and

(c) referred for medical services; and

(d) for a patient with a chronic pain disorder who is also physically dependent the OTP makes a good faith effort to coordinate treatment and services with the medical practitioner treating the patient for pain management.

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