Table of Contents

Executive Summary
Acknowledgments, Citation, Notes to the Reader

Section I: Purpose and Audience
Section II: Policy Research Terms
Section III: Background about Pain Relief and Public Policy
Section IV: Research Methodology
Section V: The Central Principle of Balance
Section VI: The Imperative to Evaluate Federal and State Policy for Balance
Section VII: The Research Criteria
Section VIII: Results – Profiles of Federal and State Pain Policies
Section IX: Example Language to Improve Pain-Related Policy

Appendix A: Federation of State Medical Board’s Model Policy for the Use of Controlled Substances for the Treatment of Pain
Appendix B: Recommended Readings
Appendix C: What Can State Legislatures and Agencies do to Improve Pain Management?
Appendix D: Regulatory Systems and Pain Management

Figure 1: Recent Trends in State Pain-Specific Policy
Table 1: International Authoritative Sources
Table 2: National Authoritative Sources
Table 3: States with Prescription Monitoring Programs

References
A gap continues to exist between the possibility and the reality of adequate pain management. Unrelieved pain is considered a serious public health problem in the United States for many underserved populations, including children, the elderly, minorities, nursing home patients, and people with limited financial resources. Although there are many effective ways to treat pain, there is a medical consensus that opioid analgesics are indispensable for a variety of pain types, particularly if pain is severe. Opioid analgesics also are abused, so their production and distribution is strictly regulated under federal and state controlled substances laws. However, there also is a consensus that control of controlled substances should not interfere with their availability for legitimate medical purposes.

A number of barriers interfere with the prescribing, dispensing, and administering of opioid analgesics and, ultimately, with patient access to pain relief, including:

- healthcare system issues, such as low institutional priority of pain relief and inadequacies in professional training and clinical practices,
- stigma associated with addiction and drug abuse,
- drug law enforcement actions, and the perception of them, creating practitioner fear of being sanctioned, and
- restrictions in controlled substances and professional practice policies.

In 2000, the Pain & Policy Studies Group (PPSG) designed a policy research project and published findings from the first-ever evaluation of federal and state pain policies, entitled Achieving Balance: A Guide to Evaluation of Federal and State Policies (Evaluation Guide 2000). These findings were the result of a policy analysis based on a Central Principle of Balance. Balance is fundamental to international and national drug control policy and asserts that efforts to prevent diversion and abuse of opioid analgesics are important and necessary but should not interfere with medical practice and patient care. Balanced policy recognizes the need for and legitimacy of controlled substances for pain management. The PPSG developed 16 criteria based on the Central Principle of Balance and used them to identify policy language with the potential either to enhance (called “positive provisions”) or impede (called “negative provisions”) patient access to opioid analgesics (see Section II for more information). A team of PPSG policy researchers collected hundreds of relevant federal and state policies and used the criteria to evaluate them. The results provided evidence that the number of positive and negative provisions found in pain policies vary greatly from state to state. The evidence was presented in the form of policy Profiles for each state and the Federal government.

After 2000, a number of states modified their pain policies, making use of a model regulatory policy prepared by the Federation of State Medical Boards of the U.S., as well as the findings presented in the Evaluation Guide 2000. In order to document that policies were changing, the PPSG conducted a second evaluation of policies adopted during the three-year period following the Evaluation Guide 2000. PPSG updated its policy collection through March 2003, used the same criteria to evaluate all new or amended policies, and published the second edition of the Evaluation Guide (Evaluation Guide 2003). The methodology for the Evaluation Guide 2003 was substantially the same as the first. The Evaluation Guide 2003 presented the results of the second evaluation of federal and state policies, and included examples of positive policy language that could be adopted to further improve state policies.

In July 2003, the Evaluation Guide 2003 was published, followed in September by a Progress Report Card (2003). The Progress Report Card 2003 compared the results from the Evaluation Guide 2003 with the results from 2000, using a grade that was calculated based on the quality of
each state’s policy environment at those two points in time. As a result, the Progress Report Card 2003 presented a single metric (a state grade) that can be used to measure change in a state’s pain policies over time. The Progress Report Card 2003 also described in some detail the positive changes that occurred in state pain policy between 2000 and 2003. For example, between 2000 and 2003, 16 states had enough policy change to show an improvement in their grade, and no state’s grade decreased. The Evaluation Guide 2003 and Progress Report Card 2003 were made available on the PPSG website, an email announcement was made to the PPSG national news distribution list, and hard-copies of each report were mailed to the medical and pharmacy boards, medical societies, pain initiatives, and legislative reference librarians in each state, as well as to relevant government agencies and to those who made direct requests. A general press release was issued to national health reporters, and individualized press releases were created for states that had grade improvements. In addition, a call-in was organized to inform Last Acts Partners and state cancer pain initiative members of the reports and how they could be used to improve state pain policy.

To provide current information about states’ pain policies, the PPSG conducted a new evaluation of policies current as of March 2006, resulting in this report (entitled Achieving Balance in Federal and State Pain Policy: A Guide to Evaluation, Third edition (Evaluation Guide 2006)). This new evaluation used a modified methodology that expanded the types of policies that were evaluated (see Section IV for a description of the methodology changes). The policy evaluation findings also were used to calculate grades for each state for 2006, included in a companion report entitled Achieving Balance in State Pain Policy: A Progress Report Card, Second edition (Progress Report Card 2006).

PPSG Evaluation Resources for Pain Policy:

2000

2003

2006

Commentary

The Evaluation Guide 2006 is not a “position statement” about pain policies. Rather, it is the result 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 take different approaches to policy formulation, we assert that there is a Central Principle that should guide efforts to establish a balanced regulatory environment for pain management. Achieving this goal does not mean that all state policies must look alike; rather, laws must strike an appropriate balance between appropriately governing controlled medications and those who prescribe and dispense, and ensuring their availability for those who legitimately need them for the relief of pain and suffering.
The pain problem has drawn the attention of a variety of professions, including medicine, pharmacy, nursing, social work, law, state law enforcement, and bioethics. In addition, professional, private, and public organizations are developing patient information and professional education resources, and calling for the removal of regulatory barriers. As an increasing number of individuals and organizations turn their attention toward the policy interface between the drug control/practice regulation and efforts to relieve pain, it is our hope that they will make use of the State Profiles from the Evaluation Guide 2006, the Progress Report Card 2006, and the many other relevant resources that are provided in this document and elsewhere on the PPSG website at www.painpolicy.wisc.edu.

There can be pitfalls and unintended consequences in reforming 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 the influence of the policy; policy change with no implementation, even when the policy's message is clear and positive, may contribute little to influencing 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 care standards. A state's policy must not only be balanced, but understood as balanced.

Acknowledgement of support

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. Developing the Evaluation Guide 2006 and the Progress Report Card 2006 was supported by “Benchmarking State Policies for Cancer Pain and Palliative Care” (SIRSG-06-095-01) from the American Cancer Society, a grant from the Susan G. Komen Breast Cancer Foundation, and through a cooperative agreement with the Lance Armstrong Foundation.
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NOTES TO THE READER

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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 March 2006. 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 and its companion Progress Report Card are available on the PPSG website at www.painpolicy.wisc.edu. Comments and suggestions are welcome and may be directed to:

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PURPOSE

This is the third edition of Achieving Balance in Federal and State Pain Policy: A Guide to Evaluation (Evaluation Guide 2006); its purpose, as with the first two editions, is to promote more balanced and consistent U.S. federal and state policy relating to the 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 using a methodology that was conceptualized, developed, and tested over a 15 year period (Gilson, Maurer, & Joranson, 2005). The Evaluation Guide 2006, used in conjunction with Achieving Balance in State Pain Policy: A Progress Report Card (Second Edition), provides a framework for deciding which policies should be removed, as well as recommended language to guide the development of new and more balanced policies. Balance in pain policy 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, we can establish a more positive regulatory and practice environment for 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 2006:

(1) provides updated background information about pain policy (see Appendix B for recommended readings),
(2) explains the Central Principle of Balance and the sources of authority from which it is derived, and explains 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,
(3) presents the results of a criteria-based evaluation of federal and state policies that were current as of March 2006, and
(4) offers examples of language that can be used to achieve more balanced policies.

USING POLICY EVALUATION TO INFORM POLICY CHANGE

Interested parties can use the Evaluation Guide 2006 to learn about pain policies at the state or federal level and to guide their own evidence-based review of changes that may be needed to achieve more balanced policy. This document provides the results from a transparent evaluative framework, which can help shape an action plan to remove 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 have more effect on practice or care than others, PPSG did not believe there was enough information available at this time 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.

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1 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 IV for a description of the specific policies evaluated for this report).
In a state where significant impediments have been identified, it may be important to amend restrictive statutes or regulations as soon as possible. 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 pain management. In still other cases, it may be wise to initiate a broad-based study of the options to determine priorities prior to acting (Appendix C 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, it should be clear that policy improvement is a means to an end, and that policy must be disseminated and implemented to be useful (Connecticut Cancer Pain Initiative & American Cancer Society New England Division, 2003; Joranson, Gilson, & Nischik, 2002; Pain & Policy Studies Group, 2006).

This is a policy analysis, and not 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 this work.

AUDIENCE

The intended audience for the Evaluation Guide 2006 is individuals or organizations interested in improving pain, palliative care, or end-of-life care policy, including:

- state professional licensing boards
- state legislatures and attorneys general
- the Congress and federal agencies
- associations of healthcare professionals
- state or regional pain and palliative care initiatives
- national cancer, HIV/AIDS, and pain foundations.

SECTION II: Policy Research Terms

USE OF PAIN 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:

- **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.
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, or those that create prescription monitoring programs or pain advisory councils, or regulations that license healthcare facilities.

A “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, osteopaths, pharmacists, and nurses). Regulations of state agencies may not exceed the agency’s statutory authority (see Appendix D for further discussion).

“Guidelines” are 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.
UNRELIEVED PAIN CONTINUES TO BURDEN AMERICANS

Pain remains one of the most common physical complaints upon a person’s admission into the healthcare system (Foley, Back et al., 2005; Furrow, 2001; Kutner, Kassner et al., 2001; Lazarus & Neumann, 2001; Weiss, Emanuel et al., 2001). Pain is prevalent in cancer, especially near the end of life, and in other diseases and conditions such as HIV/AIDS and sickle-cell anemia. Unfortunately, pain often is not treated adequately. Inadequate pain management can impair all aspects of life and sometimes lead to a person’s wish for death (Institute of Medicine Committee on Care at the End of Life, 1997; Institute of Medicine National Cancer Policy Board, 2001). Sufficient pain relief can result in improved quality of living for people with chronic pain and can decrease suffering for people at the end of life.

International organizations have provided valuable guidance with regard to the policy implications of health care. 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), the World Health Organization (WHO), the World Health Assembly (WHA), and the Council of Europe have recognized pain relief as an important public health issue and, indeed, a universal human right.

There are many pharmacologic and non-pharmacologic treatments that are useful to relieve pain (Miaskowski, Cleary et al., 2005). Opioid analgesics in the class of morphine are effective for medical use (Federal Food, Drug, and Cosmetic Act, 21 USCS § 301 et seq.) and essential for the medical management of moderate or severe pain (World Health Organization, 1996). Opioids must be available in adequate amounts when and where patients need them, especially when pain is severe (World Health Organization, 1990). Physicians, osteopaths, pharmacists, and nurses (where allowed) must be able and confident to prescribe, administer and dispense opioids, according to individual patient needs (World Health Organization, 1996).

Many factors contribute to the continued prevalence of unrelieved pain in the U.S., including characteristics of the healthcare system and healthcare professionals. Most studies have focused on issues in the clinical domain, such as: (1) knowledge and attitudes of healthcare professionals about the legitimate use of opioids (Bonica, 1995; Hollen, Hollen et al., 2000; Lebovits, Florence et al., 1997; McMillan, Tittle et al., 2000), (2) patient and family perceptions about the use of opioids for pain relief (Breitbart, Passik et al., 1998; Drayer, Henderson et al., 1999; Institute of Medicine National Cancer Policy Board, 2001; Rhymes, 1996; Tolle, Tilden et al., 2000a; Ward, Goldberg et al., 1993), and (3) the inadequate clinical use of opioids used to treat moderate to severe pain (Furstenberg, Ahles et al., 1998; Joranson & Gilson, 2001; Morrison, Wallenstein et al., 2000). Restrictive drug-related public policies, as well as concerns about regulatory scrutiny when prescribing controlled substances, have also been recognized as significant impediments to pain relief (Cancer Pain Management Policy Review Group, 2001a; Gilson, Maurer, & Joranson, 2005; Institute of Medicine, 1997; Joranson & Gilson, 2001, 2003; Joranson, Gilson et al., 2000; Miaskowski, Cleary et al., 2005; National Association of Attorneys General, 2003a, 2003b; National Institutes of Health Consensus Development Program, 2002; Tucker, 2001).
Balancing Control and Availability

Because opioid analgesics also have a potential for abuse, their prescribing and dispensing, 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 (Gilson, Joranson et al., 2005; Joranson & Gilson, 2003).

To accomplish the desirable balance between availability and control, the international drug control authorities associated with the UN have asserted that efforts to prevent drug abuse and diversion should not interfere with the availability and medical use of controlled drugs (United Nations, 1977); indeed, the WHO (2000) has published evaluation guidelines to achieve balanced national opioids control policies (see Section V and Section VI for a detailed discussion of Balance and the imperative to create balanced healthcare policy). In addition, the UN ECOSOC has emphasized the importance of treating pain while taking into account the need to prevent drug diversion (United Nations Economic and Social Council, 2005a). Finally, the WHA (2005) urged Member States:

“...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).

The federal Controlled Substances Act (CSA) establishes the U.S. system of drug control that is also intended to accomplish availability through a set of laws and regulations (see Types of Policies in Section II) that governs drug importation, manufacture, and distribution. Licensed and registered professionals may prescribe, dispense, and administer controlled drugs for legitimate medical purposes in the course of professional practice2 (Code of Federal Regulations, Title 21 §1306.04(a); Controlled Substances Act, Title 21 §826(a)). To prevent diversion, the CSA establishes a closed system of licensing, security, record keeping, monitoring, and penalties (Drug Enforcement Administration, 2004). For example, Schedule II drugs require a written prescription and cannot be refilled; however, there are no statutory restrictions on dosages or quantities of drugs prescribed (Joranson & Gilson, 1994). Federal controlled substances law recognizes that many controlled substances are necessary for maintaining health and establishes a procedure for ensuring that these medications are adequately available to satisfy prescription demand. The CSA is not intended to interfere with medical practice or with the availability of controlled substances approved under the FFDCA for legitimate medical purposes (Controlled Substances Act, Title 21 §902; Joranson & Gilson, 1994; Noah, 2003). The CSA does, however, contain an archaic definition of “addiction,” but 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.

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2 The use of opioids to treat opioid addiction is not legitimate medical practice unless accomplished according to federal and state laws that regulate this practice.
STATE POLICIES MAY BE MORE RESTRICTIVE

In addition to federal requirements, the prescribing, dispensing, and administering of controlled substances is regulated by the states. States are responsible for regulating healthcare practice, including medical, osteopathic, and pharmacy practice. State policies tend not to be as balanced as international and federal policy (Gilson, Maurer, & Joranson, 2005); most state laws do not specifically recognize the public health importance of controlled drugs, as does federal law (Controlled Substances Act, Title 21 §801(1)). In addition, some state laws or other governmental policies restrict prescribing and dispensing of opioids to a greater extent than federal policy, and can interfere with medical decisions that should be based on individual needs of the patient and medical expertise, rather than government mandate.

Beginning in Wisconsin 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., 1989; Joranson & Dahl, 1989; Joranson, 1990a; Joranson & Gilson, 1996, 1997; Von Roenn, Cleeland et al., 1993). A succession of reports and articles on inadequate pain management has identified the possible influence of policy impediments at the state level (Cancer Pain Management Policy Review Group, 2001a, 2001b; Federation of State Medical Boards of the United States Inc., 1998, 2004; Fujimoto, 2001; Gilson, Maurer, & Joranson, 2005; Institute of Medicine Committee on Care at the End of Life, 1997; Merritt, Fox-Grage et al., 1998; Miaskowski, Cleary et al., 2005; National Conference of Commissioners on Uniform State Laws, 1990, 1994; National Institutes of Health Consensus Development Program, 2002; Rich, 2000; Tucker, 2001). The ACS (Cancer Pain Management Policy Review Group, 2001a), 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) and the World Health Organization (1990, 1998a, 2000) have called on all countries to identify and address regulatory barriers to cancer pain relief.

Regulatory impediments include unduly strict limitations on prescribing and dispensing, exclusion of substance abusers from receiving prescriptions for pain medications, and legal terminology that confuses physical dependence on opioids used in the course of pain therapy with opioid addiction, which is heavily stigmatized in the U.S. and is primarily associated with illegal activity (Cicero, Inciardi, & Munoz, 2005; Joranson & Gilson, 2005). Many of the restrictive provisions in state policies were enacted 20 or more years ago, and are likely based on outdated information about pain, opioids, and addiction.

STATE POLICIES ARE CHANGING

In the last two decades, efforts by a variety of individuals, state pain, cancer, and end-of-life care initiatives, patient groups, and state agencies have begun to reform state pain policy (Gilson, Joranson, et al., 2005; Gilson, Joranson, & Maurer, 2003; Gilson, Maurer, & Joranson, 2005). Figure 1 illustrates the growing number of state pain-specific policies, such as medical board guidelines and Intractable Pain Treatment Acts (IPTAs). Policy reform often produces more balanced state policies, but in some cases can also create additional restrictions and requirements that have the potential to impede pain management.

IPTAs are statutes intended to improve access to pain management by providing physicians immunity from regulatory sanctions for prescribing opioids to patients with intractable pain. However, many IPTAs also have imposed more requirements and restrictions on opioid prescribing for pain (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, in 2005 Rhode Island repealed a number of restrictive provisions from its IPTA, including removing the term and definition of “intractable pain;” the resulting law now governs the treatment of all types of pain. Instead of statutes, many states have chosen to develop guidelines or regulations containing language aimed at enhancing pain management.

From 1994 to 1998, and again between 2004 and 2005, state medical boards participated in pain management workshops sponsored by the PPSG and the Federation of State Medical Boards of the U.S. (the Federation) and began adopting guidelines and regulations to encourage better pain management and to address physicians’ fear of investigation (Gilson & Joranson, 2002; Gilson, Maurer, & Joranson, 2005; Joranson et al., 2002). To promote consistency in state medical policy, the Federation adopted in 1998 Model Guidelines for the Use of Controlled Substances for the Treatment of Pain (Model Guidelines). 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) (see Appendix A). 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 (Tucker, 1998, 2003). At this time, 28 states have adopted or adapted either the Model Guidelines or Model Policy (Figure 1). The trend to adopt state medical board policy statements on pain management has resulted in positive changes in state pain policies (Gilson, Joranson, & Maurer, 2003) and also in efforts to communicate them to practitioners and the public (Hoffmann & Tarzian, 2003) (Joranson, Gilson et al., 2002).

State-level advocacy initiatives 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 initiatives have as their goal to improve pain management practices in their state by, in part, evaluating the laws that impact patients’ access to adequate pain relief and develop a plan to remove any identified regulatory barriers (Maryland State Advisory Council on Pain Management, 2004; Michigan Department of Consumer and Industry Relations, 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, 2003). Improving pain, palliative care and end-of-life care policy has also been the focus of groups such as the American Alliance of Cancer Pain Initiatives (Dahl, Bennett et al., 2002), the American Cancer Society (ACS) (Cancer Pain Management Policy Review Group, 2001b; 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, 2004).

Improving state policy, like any other factor related to pain management, is not usually sufficient in and of itself to accomplish effective pain relief, but it is 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 little practical value. To be most effective, a new state policy should be disseminated widely and repeatedly to licensees and the public.

THE ROLE OF FEDERAL DRUG LAW ENFORCEMENT

Healthcare professionals and law enforcement share a responsibility to ensure that prescription pain medications are available to the patients who need them, while also protecting public health by preventing abuse and diversion of these drugs (Drug Enforcement Administration et al., 2001). A balanced approach can be accomplished only when health professionals who treat pain understand and avoid intentionally contributing to diversion, and when law enforcement understands and does not interfere with pain management when dealing with diversion (Drug Enforcement Administration et al., 2001). To this end, the pain and law enforcement communities have undertaken efforts to promote a balanced approach to pain management.

For example, in 2001 the PPSG collaborated with DEA’s Office of Diversion Control to create a joint statement, along with 21 healthcare organizations, entitled “Promoting Pain Relief and Preventing Abuse of Pain Medications: A Critical Balancing Act;” the statement has been endorsed by over 40 healthcare organizations and is available at http://www.painpolicy.wisc.edu/Consensus2.pdf. Following this successful collaboration, in 2002 the DEA began working with the PPSG, pain and addiction medicine experts, and regulatory personnel to author an extensive educational document for healthcare professionals and DEA investigators, entitled “Prescription Pain Medications: Frequently Asked Questions and Answers for Health Care Professionals and Law Enforcement Personnel” (FAQ). The FAQ was published in August 2004, and the DEA planned to make it available to all physicians and pharmacists in the country via the registration process, as well as to law enforcement and regulatory officials.

Soon after publication, however, DEA withdrew its support of the FAQ and issued an Interim Policy Statement (IPS) in the Federal Register on November 16, 2004. The IPS reversed the DEA’s previous policy that issuing several prescriptions on the same date with notations for later dispensing (i.e., a prescription series) was legal and took issue with several other statements in the FAQ, saying it contained “misstatements of law” (Federal Register, 2004, p. 67170). Despite extensive concern from around the country, the DEA issued another statement in the Federal Register re-affirming that issuing a prescription series was illegal. DEA requested comments and indicated that a final policy statement would be forthcoming. On September 6, 2006, a Final Policy Statement (FPS) was issued, along with a proposal that would allow “an individual practitioner [to] issue multiple prescriptions authorizing the patient to receive a total of up to a 90-day supply of a Schedule II controlled substance” (Federal Register, 2006, p. 52726), provided that certain conditions are met. The FPS can be found at www.deadiversion.usdoj.gov/fed_regs/notices/2006/fr09062.htm, and the proposed rule can be found at www.deadiversion.usdoj.gov/fed_regs/rules/2006/fr0906.htm.

THE IMPORTANCE OF NON-POLICY INITIATIVES

It should be recognized that there are many very important educational and organizational initiatives that address pain management as a healthcare priority which are not addressed in the PPSG evaluations because they are not federal or state policy initiatives. Examples include professional and public awareness presentations, the development of institutional standards, practice guidelines and cooperative efforts between state medical societies, pain initiatives, and hospice and palliative care groups.
OVERVIEW

This document presents the results of a systematic, criteria-based, evaluation of policies affecting pain management that have been adopted by the federal government, the 50 states, and the District of Columbia. The PPSG evaluated federal controlled substances statutes and regulations, as well as state statutes and regulations governing controlled substances, medical, osteopathic, and pharmacy practice, and regulation of healthcare facilities. We also evaluated other governmental policies where present, such as state medical board guidelines and official policy statements. The population studied for this research is the policies that are relevant to pain management and the use of controlled pain medications. Relevant federal policy includes the CSA, Controlled Substances Regulations (Code of Federal Regulations), Federal Food, Drug & Cosmetic Act (FFDCA), and Public Health laws. Relevant state policies consisted of the controlled substances and the professional practice statutes and regulations, as well as other policies containing language related to pain management.3

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. Governmental policies not available through Lexis were collected directly from the relevant state professional regulatory agencies. The websites of all medical, osteopathic, and pharmacy boards were accessed to determine if they contained official guidelines or policy statements that had been adopted by the board. If the policies were available electronically, they were downloaded; otherwise the medical, osteopathic, and pharmacy boards in each state were contacted to inquire about and, if necessary, obtain the policies.

Lexis also was used to perform a Boolean (i.e., 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 following terms were used to search the federal and state policies: “Pain,” “controlled substance,” “addict/addiction,” “dependence/dependent” (drug, substance, and physical), and “abuse” (drug, substance, narcotic, and opioid).

Data collection also was accomplished via (1) regular review of all medical, osteopathic, and pharmacy board newsletters that are available on the internet; (2) periodic updates from the National Association of State Controlled Substances Authorities; (3) regular review of newsletters such as the National Conference of State Legislatures’ “State Health Notes;” (4) various email list serves; and (5) personal contacts with those who are knowledgeable about policy trends.

Despite these comprehensive data-collection procedures, however, it is possible that relevant provisions were missed.4

SECTION IV:
Research Methodology

3 We did not consider a number of policies that could affect pain management but fall outside the scope of our evaluation, including reimbursement policies or provisions, advance directives or living wills policies or provisions, or policies such as nursing or physician assistants practice, controlled substances scheduling, worker's compensation, importation, or Internet prescribing. We also did not evaluate civil or administrative case law, or language from legislative notes. There are insufficient comparable authoritative sources that would support the valid application of the Central Principle of Balance and its evaluation criteria to these policies (see Section V and Section VIII). However, descriptive studies of these policies in relation to pain and prescribing controlled substances would be valuable.

4 Indeed, some relevant policy provisions were identified in 2006 that had been present in 2000 or 2003, but were overlooked in our previous evaluation, requiring us to change our evaluation results for some states.
POLICY EVALUATION

All relevant policies that were in force and available as of March 2006 were examined for this evaluation. A total of 543 policies were evaluated for this Evaluation Guide, including approximately 150 new or modified policies adopted between March 2003 and March 2006.

A Central Principle has been identified and defined (see Section V), from which 16 evaluation criteria were developed and defined (see Section VII). 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 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, three policy analysts at the PPSG applied the criteria to evaluate all the new or revised policies. Provisions were judged to satisfy the criteria only on the basis of explicitly-stated language (“black letter policy”), not by their implication or intent. For example, the overall intent of an IPTA 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”).

Provisions that met any of the criteria were identified by consensus among the policy analysts. These provisions are presented in the Federal and State Profiles section (see Section VIII). If a policy contained repetitive language, so that the same criterion could be satisfied multiple times, we identified only one provision 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 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 they represent different ideas. Once identified, the full text of all new and amended relevant provisions was added to the computerized database created for the first two Evaluation Guides (Joranson, Gilson et al., 2000; Pain & Policy Studies Group, 2003).

The Federal and State Profiles contain all relevant provisions extracted from each 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 and shading 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 further study.

The evaluation of provisions regulating controlled substances included only those relevant to Schedule II controlled substances because these are the only controlled medications approved and essential for 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 for Schedule II medications was considered. The evaluation of medical terminology relating to pain management was limited to terms such as “palliative care” and “intractable pain,” and addiction-related terminology such as “addiction,” “drug dependence,” “physical dependence,” “tolerance,” and “habitué.”

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5 For example, the Kansas “Pain Patient’s Quality of Care Act” was signed by the Governor on April 14, 2006. Because its adoption date fell outside of our time period, it was not included in this study.
6 One exception is Criterion #10, which addresses implicit policy language; see Section VII for the justification for this methodology.
METHODLOGY CHANGES

Several changes in methodology were made for the 2006 evaluation based on new information:

- advances in search technology enabled us to locate previously unidentified policy language
- the scope of data collection was broadened to include other areas of law containing relevant provisions that relate directly to the Central Principle of Balance
- based on feedback from the field, one criterion was reconsidered and modified.

Advances in search technology. In 2003, we used a web-based public access Lexis-Nexis Research program that did not have an extensive or sophisticated search capacity. For the 2006 data collection, Lexis-Nexis professional software was used. As a result, for this evaluation we were able to browse the table of contents for each state’s statutes and regulations, as well as more easily conduct Boolean (key-word) searches.

Additional policies and provisions. The 2006 policy evaluation has expanded to include:

- Policies that apply to osteopaths, when separate from policies governing physicians; professional practice for all osteopaths includes the use of controlled substances, as it does for physicians and pharmacists
- 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.

Change in the criteria. In our previous evaluations, we considered language satisfying Criterion #11 (The Belief That Opioids Hasten Death is Perpetuated) as potentially contributing to inadequate pain relief because it represented a prevalent misconception about the result of high-dose opioid treatment at the end of life. However, the language was found in policies designed 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. Following feedback from the field and further consideration, we determined that the policy attempts to lessen the impact of a clinical misconception about patient care by providing immunity, so the consequence of such a provision is not to inhibit the proper use of opioids but to protect the physician who uses opioids appropriately; this should improve (not impede) pain management. As a result, we now positively evaluate these provisions and have deleted Criterion #11 as it relates to language about hastening death.

The consequences of these modifications in methods are that some of the state policy profiles (see Section XIII) may be somewhat different from those in the previous Evaluation Guides.
Opioids 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. The Single Convention on Narcotic Drugs of 1961 is an international treaty to which most governments, including the U.S., are parties. This Convention establishes that governments are obligated to ensure the availability of narcotic drugs for medical and scientific purposes and to prevent diversion, illicit trafficking, and abuse.

The Central Principle, used for the Evaluation Guides from 2000 and 2003, is the same as for this evaluation. It was developed by the PPSG and 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 medical availability. 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 all 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 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 affect availability and medical use of opioids. Thus, the purpose of this guide is to evaluate policies affecting availability and not drug trafficking and abuse prevention.

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7 In addition, the Single Convention on Psychotropic Substances of 1971 established a similar imperative for balanced policy concerning psychotropic drug policy.
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 (see Table 1 and Table 2).

International authorities

The Single Convention on Narcotic Drugs of 1961 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” (United Nations, 1977, p. 13).

“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” (United Nations, 1977, p. 18-19).

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 morphine, codeine and other opioids as “essential drugs,” 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 decisions regarding the care of individual patients, the WHO (1996) recognized that:

“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).

The WHO (2000) prepared guidelines for evaluating national opioids control policy that are also 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” (p. 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).

The UN Economic and Social Council (2005b) addressed the demand for and supply of opioid analgesics for medical purposes, and:

“...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” (p. 1).

Urges all Governments to continue to contribute to maintaining a balance between the licit supply of and demand for opiate raw materials used for medical and scientific purposes...” (p. 2).

The UN Economic and Social Council (2005a) also addressed the treatment of pain using opioid analgesics, and:

“...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” (p. 2).

**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. 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, 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” (Controlled Substances Act, Title 21 § 801(1)).

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8 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.
Manufacturers are registered by the Department of Justice Drug Enforcement Administration (DEA), not only to maintain effective controls against diversion but also to:

“...produce an adequate and uninterrupted supply of these substances...” (Controlled Substances Act, Title 21 §823a(1)).

An administrative law judge for the DEA 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...” (Federal Register, 1988, 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 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” (Code of Federal Regulations, Title 21 §1306.07(c)).

In the Model Policy for the Use of Controlled Substances for the Treatment of Pain, the Federation (2004) reaffirmed 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” (p. 6).

The Federation (2004) also stated that:

“...principles of quality medical practice dictate that the people...have access to appropriate and effective pain relief...physicians [should] view pain management as a part of quality medical practice for all patients with pain...All physicians should become knowledgeable about assessing patients’ pain and effective methods of pain treatment, as well as statutory requirements for prescribing controlled substances...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” (p. 5).
In 2001, 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:

“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” (Drug Enforcement Administration, Last Acts et al., 2001).

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).
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 in part to statutes and regulations that impede the adequate availability and medical use of opioids.

The International Narcotics Control Board (INCB)\(^9\) observed that the medical need for opiates in the world was not being fully met. In cooperation with the WHO, the INCB (1989) 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” (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” (p. 15).

The WHO Expert Committee on Cancer Pain Relief and Active Supportive Care (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. More recently, the Council of Europe (2003), WHO HIV/AIDS (2004), the INCB (2005), and the UN ECOSOC (2005a) have all called for governments to identify and address regulatory barriers in the narcotics control policies.

The Institute of Medicine (IOM) (1997, 2001) concluded that there is evidence to support the contention that anti-diversion policies in the U.S. discourage the appropriate use of opioids in pain management. In addition, an expert panel of the National Institutes of Health (NIH) (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 (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.

\(^9\) The International Narcotics Control Board is an independent treaty-based body affiliated with the United Nations that monitors implementation of the Single Convention on Narcotic Drugs of 1961.

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

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The American Pain Society (APS) (Miaskowski, Cleary 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).

**Drug Control Policy Should Be Evaluated**

Several international and national authorities have called for studies to identify legal and regulatory impediments to the 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, asking them to:

“...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” (p. 17).

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 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).

The IOM Committee on Care at the End of Life (1997) recommended:

“...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).
The ACS (Cancer Pain Management Policy Review Group, 2001a) stated:

“...additional and sustained efforts are needed to ensure that new barriers are not erected and that adequate pain relief for cancer patients is assured” (p. 3).

An NIH expert panel (2002) recognized that:

“Regulatory barriers need to be revised to maximize convenience, benefit, and compliance...” (p. 15).
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 that identify provisions that may enhance pain management**

# 1 Controlled substances are recognized as necessary for public health
# 2 Pain management is recognized as part of general medical 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

**Criteria that identify provisions that may impede pain management**

# 9 Opioids are considered 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
  - 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
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 policies is to prevent the abuse of drugs (including the opioids) and also to recognize their important contribution to public health. Controlled substances policies 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, 1990b; Joranson & Gilson, 1994; National Conference of Commissioners on Uniform State Laws, 1994).

The INCB (1996) stated 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... for the implementation of those laws” (p. 16).

The WHO (2004) stated that:

“No health system in the world offers unlimited access to all medicines. Rational selection of essential medicines is one of the core principles of a national drug policy...It is a global concept which can be applied in any country, in both public and private sectors and at different levels of the health care system” (p. 3).

The Federal CSA stated that:

“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” (Controlled Substances Act, Title 21 §801(1)).

The National Conference of Commissioners on Uniform State Laws (1990) stated that:

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

**CRITERION #2. PAIN MANAGEMENT IS RECOGNIZED AS PART OF GENERAL MEDICAL PRACTICE**

In balanced policy, pain management is a fundamental part of medical practice. The Single Convention places the relief of pain and suffering within the purview of medicine and science (United Nations, 1977); the WHO has recommended that the health professions and all governments adopt an approach for the management of cancer pain that includes the use of opioid analgesics (1986, 2002), and has classified a number of opioid analgesics as Essential...
Drugs (1998b).

In the U.S., medical practice is regulated at the state level. Therefore, state medical practice acts should recognize that the diagnosis and treatment of pain, including the use of drugs, is a part of ordinary medical practice. The Federation’s Modern Medical Practice Act (MMPA) for the U.S. 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...” (Federation of State Medical Boards of the United States Inc., 2000, p. 2).

In addition, the Model Policy for the Use of Controlled Substances for the Treatment of Pain adopted by the House of Delegates of the Federation (2004) stated:

“...principles of quality medical practice dictate that the people of the State of [name of state] 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 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” (p. 5).

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

This criterion recognizes that a licensed practitioner’s 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 use of drugs with an abuse liability prohibit uses for other than legitimate medical purposes.

The Single Convention (United Nations, 1977), the INCB (1996), the WHO (1986, 1990, 1996), the U.S. CSA (Controlled Substances Act, Title 21 §801(1)), the Uniform Controlled Substances Act (National Conference of Commissioners on Uniform State Laws, 1994), the DEA (2004), and the FSMB (2004) regard the prescribing of opioids 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.

The DEA (2004)\(^{10}\) stated that:

“Controlled substances, particularly narcotic analgesics, may be used in the treatment of pain experienced by a patient with a terminal illness or intractable pain. These drugs have legitimate uses and the pharmacist should not hesitate to dispense them when a prescription indicates they are for a legitimate medical purpose” (p. 55)

\(^{10}\) The DEA’s Physician’s Manual has been removed as an authoritative source because it has not been published since 1990, is now out of print, and has been withdrawn from the DEA’s website. Where possible, we have used language from the DEA’s Pharmacist Manual to provide authoritative support.
The Model Policy adopted by the Federation (2004) stated:

“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 consider prescribing, ordering, dispensing or administering controlled substances for pain to be for a legitimate medical purpose if based on sound clinical judgment” (p. 5-6)

**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 the barriers to pain management by adopting positive statements about the importance of controlling pain. It should be noted that there may be unforeseen consequences in adopting policy statements about pain management: depending on the specific language ultimately agreed to, the result may be increased restrictions and increased practitioner hesitancy to treat pain. A number of bodies have adopted clear and positive policy statements, including the INCB and the WHO at the international level. In the U.S. a number of expert bodies have done so as well:

The American Pain Society (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 (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).

The DEA (2004) stated:

“It is the position of the DEA that controlled substances should be prescribed and dispensed when there is a legitimate medical need” (p. 55).

The Model Policy adopted by the House of Delegates of the Federation (2004) recommended that:

“The Board encourages physicians to view pain management as 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. Accordingly, this policy has been developed to encourage better pain management” (p. 5)
Inadequate use of opioids for pain management can stem from many factors. One well-recognized factor is practitioner 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 fear of 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); the fear 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 the fear of regulatory scrutiny exists, (2) clarify that a physician may prescribe opioids for pain without a risk of disciplinary sanction, and (3) most importantly, be implemented by the appropriate regulatory bodies.

In support of this criterion at the international level, the INCB has observed that the need for opioids is not being fully met; in cooperation with the WHO, the INCB studied the reasons for inadequate availability of opioids for pain relief in the world.

An INCB survey (1996) of impediments to opioid availability reported that:

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

The INCB (1989) determined 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:

“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 the prescribing or dispensing of opiates” (p. 15).

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” (p. 15-16).
The WHO Expert Committee on Cancer Pain Relief and Active Supportive Care (1990) stated 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).

In the U.S., the Federation (2004) Model Policy clearly stated that:

“...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 pain management...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” (pp. 5-6).

The American Medical Association House of Delegates (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)

**Criterion #6. Prescription Amount Alone Is Recognized as Insufficient to Determine Legitimacy of Prescribing**

This criterion addresses another source of concern about regulatory policy: that duration or amount of drug therapy will be used to judge the propriety of prescribing. Outdated views about the “appropriate” use of opioids held that dosing and duration should be limited so as to prevent harm from “excessive” doses or the inevitable onset of “habituation” or “addiction,” and that such use of drugs could not be justified in some patient populations. Policies that maintain this outdated concept 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.

Neither international nor U.S. federal controlled substances policy limits the dose, amount or duration of prescribing. However, some state regulatory policies continue to base unprofessional conduct on the number of doses or the duration of treatment. On the other hand, 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.
In the U.S., this view was recognized by the Food and Drug Administration (FDA):

“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” (Federal Register, 1972, p. 16503).

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).

The Federation’s (2004) Model Policy stated:

“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...” (p. 6).

By 2004, the DEA continued to support this view:

“The quantity of drug prescribed and frequency of prescriptions filled are not alone indications of fraud or improper prescribing especially if the patient is being treated with opioids for pain management” (DEA, 2004, p. 82).

**CRITERION #7. PHYSICAL DEPENDENCE OR ANALGESIC TOLERANCE ARE NOT CONFUSED WITH “ADDICTION”**

According to the INCB survey (1996), the impediment to improving availability and use of opioids most frequently identified by government narcotic control agencies was concern about addiction. The use of terms like “addiction,” 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 chronic pain (Gilson & Joranson, 2002; Joranson & Gilson, 2003; Maurer, Gilson, & Joranson, in press; National Conference of Commissioners on Uniform State Laws, 1990, 1994). Policies that continue to use such archaic terminology, which is inconsistent with current medical and scientific knowledge, is 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 either be removed or be defined according to the prevailing medical standard for defining “addiction” (Savage, Joranson 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 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” (Lee, 1941, p. 217).
A 1952 statement from the WHO, the expert body consulted in the development of international drug control policy, confused the critically important distinction between physical and psychological dependence:

“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).

In 1969 WHO replaced the term “addiction” with the term “drug dependence.” “Drug dependence” was correctly defined as psychological dependence, with neither physical dependence nor tolerance sufficient to define “drug dependence” (or “addiction”):

“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” (World Health Organization, 1969, p. 6).

The WHO (1996) also clarified correctly that cancer patients who are physically dependent, the manifestation of which would be a withdrawal syndrome if the opioid medication were stopped abruptly, are not considered to be “drug dependent”:

“Psychological dependence, or ‘drug dependence,’ is a behavioral pattern characterized by craving for the drug and an overwhelming preoccupation with obtaining it. Undue anxiety about psychological dependence has caused physicians and patients to use inadequate doses of opioids. Wide clinical experience has shown that psychological dependence does not occur in cancer patients as a result of receiving opioids for relief of pain. This is true of both children and adults” (p. 19).

“Studies have shown that, while physical dependence and tolerance do occur in patients who take opioids over a long period, psychological dependence is extremely rare. Consequently, the risk of such dependence should not be a factor in deciding whether to use opioids to treat the cancer patient with pain” (p. 41).

“Physical dependence, which may develop when opioids are used to treat chronic pain, should not be confused with psychological dependence” (p. 58).
The WHO Expert Committee on Cancer Pain Relief and Active Supportive Care (1990) evaluated studies that differentiate the risk of psychological dependence (addiction) from medically prescribed opioids, emphasizing that:

"...drug use alone is not the major factor in the development of psychological dependence..." (p. 37).

Expert national medical and regulatory authorities agreed:

"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).

"Physicians should recognize that tolerance and physical dependence are normal consequences of sustained use of opioid analgesics and are not the same as addiction” (Federation of State Medical Boards of the United States Inc., 2004, p. 5).

"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" (American Pain Society, 2005, p. 55).

Weissman and Haddox (1989) have defined the term “pseudoaddiction.” This term characterizes a situation in which the pattern of drug-seeking behavior by a pain patient who is receiving inadequate pain management is mistaken by healthcare providers for addictive behavior. The inappropriate perception of pain patients as drug-seekers or addicts may result in denial of the opioid prescriptions they need for pain management.

In 2001, three U.S. national organizations 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 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).
The American Academy of Pain Medicine, the American Pain Society, and the American Society of Addiction Medicine recognized the following definitions and recommend their use.

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.

2. **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.

3. **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.”

The Federation (2004) included these jointly-prepared definitions of Addiction, Physical Dependence, and Tolerance, with slight but non-substantive changes, in their Model Policy.

**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 while adhering to state medical board policy, or encouraging multidisciplinary collaboration when treating pain. In addition, this criterion is used to identify policy language that recognizes that a physician’s failure to treat a patient’s pain can be grounds for professional discipline: If pain management is part of quality medical practice, then it follows that inadequate pain management may be substandard practice (Furrow, 2001; Martino, 1998). Policies that extend beyond addressing practitioners’ concerns about regulatory scrutiny (identified by Criterion #5), and attempt to provide additional immunity from criminal prosecution, also are recognized as meeting this criterion.

**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. 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 require a report on the program's effectiveness and how it impacts patient care. Finally, many state laws establish policy 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 CONSIDERED A TREATMENT OF LAST RESORT**

Balanced policies should be consistent with the Central Principle of Balance, which recognizes the appropriate use of opioid analgesics to be part of medical practice. Today, we know that opioids can be used effectively to relieve chronic pain (Burckhardt CS, Goldenberg D, Crofford L, et al., 2005; Miaskowski C, Cleary J, Bumey R, et al., 2005; Simon LS, Lipman AG, Caudill-Slosberg M, et al., 2002). However, mistaken beliefs about opioids based on inaccurate or outdated information have led to exaggerated fears of these drugs and consequently to their underuse for relief of pain. Moreover, a regulatory policy can discourage the medical use of opioids to treat pain even though the purpose of the policy is to encourage pain management by addressing physicians’ concerns about regulatory scrutiny. Some state policies assert that opioids be used only under certain circumstances and only after other methods of treatment have failed (Joranson & Gilson, 1997). Although there is no question that non-pharmacologic and non-opioid treatments are valuable, the decision about when to use a particular treatment including opioids should be medical, not governmental. State legislators and regulators should avoid promoting a fixed 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, usually in 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). This statement suggests that use of opioid analgesics is outside the “generally accepted course of medical practice,” which is the reason physicians need immunity for prescribing. Physicians may, therefore, 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 may reflect the situation in the late 1980s and early 1990s in some states; 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 consequence of such a policy could be that a particular prescribing practice involving controlled substances, which is viewed to be outside the IPTA, would be considered a violation of federal and state controlled substances law or regulatory policy. However, IPTAs were probably not intended to formalize the use of opioids for pain as being outside medical practice unless specifically meeting the IPTA standards. Nevertheless, the resulting IPTA language is complex 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. It is unlawful to prescribe opioids for the purpose ofmaintaining addiction (unless a separate registration for this activity is obtained pursuant to federal and state law). However, it remains a legitimate medical purpose to prescribe opioids to a patient who is an addict if the purpose of prescribing is to relieve pain (DEA, 2004), although such prescribing may require additional expertise and patient monitoring. As explained in Criterion #7, the incorrect use of addiction-related terms still exists in some policies and has the potential to define pain patients as addicts or to exclude addicts from pain treatment. According to definitions used in some policies, addiction or drug dependence could be established solely by the presence of physical dependence.

When archaic or confusing policy terminology is applied in practice, it has the potential to stigmatize pain patients and restrict prescribing practices, leading to inadequate pain management. For example, some states still impose restrictions on prescribing to those who “habitually use” controlled substances, although “habitual” is an archaic term discarded by WHO more than 30 years ago (see Criterion #12, Category A). In addition, some states require the practitioner to report “addicts” to a government agency; if physical dependence or analgesic tolerance is interpreted as “addiction,” pain patients could be reported even if they are not psychologically dependent (see Criterion #14).

CRITERION #12. MEDICAL DECISIONS ARE RESTRICTED

Patient care decisions should be based on medical expertise and individual patient characteristics. In a balanced policy on medical use of opioids, it should be professionals with medical training who make treatment decisions, not the government. Medical practitioners, due to their training and experience, are in a better position than the government to evaluate a patient’s needs, make diagnoses, and decide treatment, including the eligibility of patients to receive opioids, choice of medication, and the dose and duration of prescribing.

The WHO (1996) stated:

“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).

The ACS (Cancer Pain Management Policy Review Group, 2001a) declared:

“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” (p. 4).

The American Pain Society (2005) recognized that:

“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” (p. 6)
Four categories of policy provisions have the potential to restrict medical decisions:

**Category A: Restrictions based on patient characteristics.** Some state statutes and regulations limit the physician from prescribing controlled substances to certain patient populations (Joranson & Gilson, 2002). For example, some state policies prohibit or regulate prescribing to the class of “addicts.” These provisions may pre-date federal policy, which only prohibits physicians from prescribing narcotic drugs for the purpose of maintaining narcotic addiction, but not to persons who may be addicts (see also Criterion #2 and Criterion #3). Such state policies have the potential to interfere with the treatment of pain in persons with an addictive disease, for example an addict who has cancer or HIV/AIDS and who needs an opioid analgesic for pain. Efforts in some states to correct this problem have resulted in additional and complex language that may have a net effect of being more, rather than less, restrictive. A provision that meets this negative 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 stigmatize patients with pain who are using controlled substances and subsequently become tolerant or physically dependent.

**Category B: Mandated consultation.** There is no question that physicians should seek consultation when needed. However, some state policies, such as IPTAs, require the physician to obtain a consultation from a specialist for each intractable pain patient as a means to qualify for immunity from discipline for prescribing opioids to that patient. Such a requirement may be inappropriate if the practitioner is knowledgeable, it appears to excessively regulate pain management and the class of patients who have chronic pain, and it does not allow for the possibility that the patient may need immediate treatment. Although 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, as well the possibility of increased cost for the patient. Also, when a state policy requires a consultation, what is the consequence to a physician who prescribes an opioid in the course of treating a patient with pain but does not obtain a consultation?

**Category C: Restrictions regarding quantity prescribed or dispensed.** This criterion is the converse of Criterion #6. Federal law does not limit the quantity of drug prescribed or dispensed and avoids using quantity or duration to determine the legitimacy of the physician’s treatment of the patient. Some state policies limit the amount of controlled substances that can be prescribed or dispensed at one time, apparently intending to prevent abuse, diversion, and addiction. Such policies may have been adopted when the prevailing wisdom held that the development of addiction was primarily related to the dose and duration of prescribing. However, the quantity specified in a government policy may not be sufficient to meet the individual needs of patients under all legitimately-occurring circumstances, and can result in inadequate treatment of pain.

The Model Policy adopted by the Federation (2004) stated:

> “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…” (p. 6).
Category D: Undue prescription limitations. Some statutes and regulations place additional unduly strict limits on prescribing or dispensing controlled substances for pain management; these conflict with current medical and scientific understanding and are unnecessarily more restrictive than federal controlled substances policy. For example, some states recommend drug holidays as a routine part of prescribing, or appear to disallow off-label prescribing, which is recognized as a legitimate medical practice under federal policy.

In 1975, the FDA 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” (Federal Register, 1975, p. 15394).

The FDA 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” (Food and Drug Administration, 1982, p. 5).

“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).

Finally, in providing guidance to physicians for interpreting product labeling, the Physician’s Desk Reference (Thomson Healthcare, 2001) stated:

“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” (Federal Register, 1983, p. 26733).

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. While 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, slow mail delivery, or other extenuating circumstances exist. Exceeding a prescription’s validity period necessitates issuance of a new prescription and
a likely return visit to the physician. For this evaluation, validity periods of less than two weeks (14 days) are considered potentially restrictive.

**CRITERION #14. PRACTITIONERS ARE SUBJECT TO UNDUE PRESCRIPTION REQUIREMENTS**

Several states have enacted Prescription Monitoring Programs (PMPs) that require the physician to use government-issued prescription forms only when prescribing controlled substances in certain schedules (see Table 3). Several recent studies have shown that, after implementation of such programs, the prescribing of those drugs being monitored declined substantially and appear to have caused an increase in the prescribing of drugs in lower (less restricted) schedules that may have been less appropriate clinically for the patient’s condition (Ross-Degnon, Simoni-Wastila et al., 2004; Simoni-Wastila, Ross-Degnon et al., 2004; Simoni-Wastila & Tompkins, 2001; Wagner, Soumerai et al., 2003; Wastila & Bishop, 1996).

A number of publications have examined the purpose of PMPs and their effects on diversion, medical practice and patient care (Alliance of States with Prescription Monitoring Programs, 1999; Drug Enforcement Administration & National Alliance for Model State Drug Laws, 2000; Joranson, Carrow et al., 2002; United States General Accounting Office, 2002, 2004). Representatives of PMPs indicate that such 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. Their purpose is to provide law enforcement and prescribers and dispensers with information on “doctor shoppers,” “scammers,” and dishonest physicians. Special government-required prescription forms also are said to have the advantage of reducing forgeries. Reduction in prescribing resulting from implementation of a PMP has been interpreted by enforcement authorities to indicate only a reduction in over-prescribing.

Some experts have expressed concern that government forms required by PMPs 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, 2001c; Fishman et al., 2004). Some physicians claim they do not obtain the government prescription forms because of the burden of ordering, re-ordering and maintaining security. In some states, over half of all licensed physicians do not have the prescription forms necessary to prescribe the selected controlled substances so that a physician many not be able to prescribe an opioid for severe pain when necessary.

All states with PMPs currently utilize Electronic Data Transfer (EDT) systems in conjunction with their program (Brushwood, 2003), either alone or in combination with a government-required or security form. 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 certain schedules of drugs, and that EDT alone is less intrusive to physicians’ prescribing and can help to identify errant prescribers and doctor shoppers (American Alliance of Cancer Pain Initiatives, 2002; 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.

These recent PMP developments support the requirements of the National All Schedules Prescription Electronic Reporting Act (NASPER) (Public Health and Welfare, Title 42 § 280g-3), which was signed into federal law in 2005 and provides formula grants to states for creating a PMP that covers prescribing of Schedules II-IV medications. States can still adopt PMPs that do
not meet NASPER Act requirements, but they would not receive federal government funding to do so. NASPER provides a mandate for the Secretary of Health and Human Services to evaluate the safety and efficacy of each program created under the Act, but the outcome measures are left undefined.

This negative criterion is satisfied when a state’s PMP law requires the physician to use a government-issued prescription form for Schedule II controlled substances only because of the stigmatization of this important class of medications and because research has shown that the use of government issued special forms can impede appropriate prescribing. PMPs that utilize EDT technology, either with a regular prescription form or with a security form to monitor all schedules of controlled substances, did not satisfy this criterion at this time due to a lack of published studies examining their effect on prescribing.

The WHO Expert Committee on Cancer Pain Relief and Active Supportive Care (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 (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 (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)

This criterion also applies to special requirements that healthcare professionals must follow only for patients receiving prescriptions for Schedule II controlled substances. Examples include requirements that pharmacists verify the need for dose increases before dispensing a prescription, and that practitioners report the names of patients receiving Schedule II medications to a government agency. When practitioners are required to report “addicts” to a government agency, this could affect pain patients in states where physical dependence or analgesic tolerance are confused 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 that have the potential to impede pain management, but were not sufficiently specific to be assigned an individual criterion. For example, a state’s law permits pharmacists to refuse to fill a prescription if potential harm, even if such a determination is based solely on the quantity of medication prescribed. In another state, the Department of Justice can assign a physician to examine the records of any patient prescribed a Schedule II or III controlled substance, or who is a “habitual user.” If implemented, such a requirement could subject both physicians and patients to undue scrutiny and seriously disrupt legitimate prescribing 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. The test we used to identify ambiguous provisions was whether the language would be clear to a person, professional or lay, who only reads the words of the provision to understand its meaning.

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 distributing 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 standard determines the legitimacy of a particular prescribing practice and who sets that standard.

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. A prevalent example of this category is presence of provisions that seem to suggest that a physician cannot prescribe opioids as a treatment of first choice, regardless of pain severity or other clinical considerations that would justify their appropriate initial use (see rationale for this in Criterion #9). Such provisions typically occur in intractable pain treatment policies, which have been created to provide immunity to physicians who prescribe controlled substances for “intractable pain.” “Intractable pain” is typically 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. As a result, the policy provides immunity for prescribing opioids to patients with a history of failed treatments, but would exclude opioid treatment for patients who present initially with severe pain, such as those with sickle-cell anemia.

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 provisions found in other parts of those policies, 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, 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; this establishes a seemingly contradictory treatment standard. In addition, there are many instances where statutory language does not conform to the regulatory language created to implement the statute.
SECTION VIII:
Results - Profiles of Federal and State Pain Profiles
STATUTES

- Controlled Substances Act
  Title 21. Food and Drugs

- Public Health and Welfare
  Title 42. The 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
# Provisions that may ENHANCE pain management

<table>
<thead>
<tr>
<th>Criteria</th>
<th>1</th>
<th>2</th>
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<td><strong>Controlled substances are necessary for public health</strong></td>
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<td>Pain management is part of medical practice</td>
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<td>Opioids are part of professional practice</td>
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<td>Encourages pain management</td>
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<td>Addresses fear of regulatory scrutiny</td>
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<td>Prescription amount alone does not determine legitimacy</td>
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<td>Physical dependence or analgesic tolerance are not confused with &quot;addiction&quot;</td>
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### STATUTES

- Controlled Substances Act: ●
- Public Health and Welfare: ●

### REGULATIONS

- Food and Drugs: ●
- Public Health: ●
- Public Welfare: ●

### OTHER GOVERNMENTAL POLICIES

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

- Veteran’s Benefits: ●

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*Note: A dot indicates that one or more provisions were identified. ¹ No provisions were found in this policy, ² No policy found*
### Provisions that may IMPEDE pain management

<table>
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<tr>
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<td>Opioids are a last resort</td>
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<td>Implies opioids are not part of professional practice</td>
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<td>Physical dependence or analgesic tolerance confused with “addiction”</td>
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<td>Medical decisions are restricted</td>
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<td>Length of prescription validity is restricted</td>
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<td>Undue prescription requirements</td>
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</table>

#### STATUTES

- Controlled Substances Act
- Public Health and Welfare

#### REGULATIONS

- Food and Drugs
- Public Health
- Public Welfare

#### OTHER GOVERNMENTAL POLICIES

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

- Veteran’s Benefits

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Note: A dot indicates that one or more provisions were identified. ¹ No provisions were found in this policy. ² No policy found.
Controlled Substances Act

21 USC § 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.

21 USC § 801a

§ 801a. Congressional findings and declarations: psychotropic substances

The Congress makes the following findings and declarations:

(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.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.
PHYSICAL DEPENDENCE OR ANALGESIC TOLERANCE CONFUSED WITH “ADDICTION”

CRITERION 11: 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.

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.

STATUTES

Public Health and Welfare

For complete reference to this policy, see “Citations for Policies Evaluated” at the beginning of this State Profile.

42 USCS § 201

§ 201. Definitions

(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.

42 USCS § 280g-3

§ 280g-3. Controlled substance monitoring program

(i) 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;

(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;

42 USCS § 14402

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

(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.

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.
CODE OF FEDERAL REGULATIONS

Food and Drugs

For complete reference to this policy, see “Citations for Policies Evaluated” at the beginning of this State Profile.

21 CFR 1306.07

§ 1306.07 Administering or dispensing of narcotic drugs.

(c) This section is not intended to impose any limitations on a physician or authorized hospital staff to administer or dispense narcotic drugs in a hospital to maintain or detoxify a person as an incidental adjunct to medical or surgical treatment of conditions other than addiction, or 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.

(-) CRITERION 16:
Provisions that are ambiguous

CATEGORY B:
Unclear intent leading to possible misinterpretation

COMMENT: Does this imply that opioids are a last resort?

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.
§ 1306.11 Requirement of prescription.

(a) A pharmacist may dispense directly a controlled substance listed in Schedule II, which is a prescription drug as determined under the Federal Food, Drug, and Cosmetic Act, only pursuant to a written prescription signed by the practitioner, except as provided in paragraph (d) of this section. A prescription for a Schedule II controlled substance may be transmitted by the practitioner or the practitioner's agent to a pharmacy via facsimile equipment, provided that the original written, signed prescription is presented to the pharmacist for review prior to the actual dispensing of the controlled substance, except as noted in paragraph (e), (f), or (g) of this section. The original prescription shall be maintained in accordance with § 1304.04(h) of this chapter.

(b) An individual practitioner may administer or dispense directly a controlled substance listed in Schedule II in the course of his professional practice without a prescription, subject to § 1306.07.

(c) An institutional practitioner may administer or dispense directly (but not prescribe) a controlled substance listed in Schedule II only pursuant to a written prescription signed by the prescribing individual practitioner or to an order for medication made by an individual practitioner which is dispensed for immediate administration to the ultimate user.

(d) In the case of an emergency situation, as defined by the Secretary in § 290.10 of this title, a pharmacist may dispense a controlled substance listed in Schedule II upon receiving oral authorization of a prescribing individual practitioner,... prepared in accordance with § 1306.05 written for a Schedule II narcotic substance to be compounded for the direct administration to a patient by parenteral, intravenous, intramuscular, subcutaneous or intraspinal infusion may be transmitted by the practitioner or the practitioner's agent to the pharmacy by facsimile. The facsimile serves as the original written prescription for purposes of this paragraph (e) and it shall be maintained in accordance with § 1304.04(h) of this chapter.

(e) A prescription prepared in accordance with § 1306.05 written for Schedule II substance for a resident of a Long Term Care Facility may be transmitted by the practitioner or the practitioner's agent to the dispensing pharmacy by facsimile. The facsimile serves as the original written prescription for purposes of this paragraph (f) and it shall be maintained in accordance with § 1304.04(h).

(f) A prescription prepared in accordance with § 1306.05 written for Schedule II narcotic substance for a patient enrolled in a hospice care program certified and/or paid for by Medicare under Title XVIII or a hospice program which is licensed by the state may be transmitted by the practitioner or the practitioner's agent to the dispensing pharmacy by facsimile. The practitioner or the practitioner's agent will note on the prescription that the patient is a hospice patient. The facsimile serves as the original written prescription for purposes of this paragraph (g) and it shall be maintained in accordance with § 1304.04(h).

§ 1306.13 Partial filling of prescriptions.

(a) The partial filling of a prescription for a controlled substance listed in Schedule II is permissible, if the pharmacist is unable to supply the full quantity called for in a written or emergency oral prescription and he makes a notation of the quantity supplied on the face of the written prescription (or written record of the emergency oral prescription). The remaining portion of the prescription may be filled within 72 hours of the first partial filling; however, if the remaining portion is not or cannot be filled within the 72-hour period, the pharmacist shall so notify the prescribing individual practitioner. No further quantity may be supplied beyond 72 hours without a new prescription.
(+) 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: Establishes a mechanism (Minimum Data Set) 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 (Minimum Data Set) 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 (Minimum Data Set) 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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Other provisions that may enhance pain management

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Regulatory or policy issues

COMMENT: Establishes a mechanism (Minimum Data Set) 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.)

Note: Underlining and/or shading was added to identify policy language meeting the corresponding criterion.
§ 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;

(+) 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.
Veteran’s Benefits

38 USCS § 7327

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

(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.

(+) 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.