Interpreting Changes in State Laws and Regulations Governing the Use of Controlled Substances to Treat Pain

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Unrelieved pain is a prevalent condition affecting a variety of patient populations, and can decrease a person’s functioning and quality of life. Inadequate pain relief can result from numerous factors, such as the knowledge and beliefs of practitioners and the public about the appropriate use of opioid analgesics to treat pain. Frequent, but often overlooked, barriers to pain management also include characteristics of the legal and regulatory environment, typically evidenced in state drug control and professional practice policies. Such policies can contain language that, if implemented into practice, would restrict clinical decision-making and hinder the availability of opioids for patient pain relief. National and international authorities, including the National Institutes of Health and the World Health Organization, have recognized the potential impact of policies governing pain management and have called for their improvement. The Pain & Policy Studies Group developed a research program to longitudinally evaluate and quantify the quality of US state drug control and regulatory policy. This article describes the current status of state policy governing the use of controlled substances for pain relief in the US, as well as how policy content has changed over time and the implications for policy change in today’s healthcare environment. Adv Pain Manage 2007;1(2):60–6.

Pain is one of the most common physical complaints following an individual’s admission into the healthcare system [1–6]. Moderate to severe pain is frequently reported to be experienced throughout hospitalization, during treatment, and following discharge. Unrelieved pain has been found to occur in numerous healthcare settings and to affect a variety of patient populations [7–16]. Individuals with chronic cancer or non-cancer conditions often experience pain that is debilitating and negatively impacts their quality of life [14,17–20].

There are many useful pharmacological and non-pharmacological treatments for pain, and opioid analgesics such as morphine can play an important role in relieving severe pain, especially when the pain results from cancer [20,21]. Using opioids to treat non-cancer pain remains somewhat controversial [22]; however, practitioners should evaluate patients’ pain during the initial evaluation and monitor their pain and functioning during treatment to determine whether opioids are, and remain, an effective therapeutic option [23]. Given these considerations, opioid therapy to improve pain relief and patient function remains a legitimate medical practice and has become a greater healthcare priority. As a result, there has been increased focus on the diverse factors that can interfere with the medical use of opioids for pain management and can negatively impact patients’ access to effective pain relief. Most studies have focused on issues in the clinical domain, such as the knowledge and attitudes of healthcare professionals about the legitimate use of opioids [7,18,24–27], and patient and family perceptions about the use of opioids for pain relief [28–33]. However, restrictive federal and state policy can also inhibit the appropriate use of opioid medications, which can limit medical decision-making, create undue prescribing burdens, and impede patient care.

As opioids have a potential for abuse, healthcare professionals and their patients are governed by both federal and state policies that regulate the prescribing and dispensing of “controlled substances” (see Table 1 for definitions of these types of policies). In addition to controlled substances policy, state regulatory policies (e.g. policies created by medical, pharmacy, or nursing boards) authorize professional practice, including the medical use of opioid analgesics. Regulatory policies also define unprofessional conduct, prohibit unauthorized distribution of controlled substances, and establish parameters for patient care decisions affecting pain management, palliative care, and end-of-life care.

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Table 1. Types of state policies affecting pain management.

- "Laws" that have binding legal force and include:
  - Statutes adopted by a state legislative body.
  - Regulations adopted by an agency of the executive branch of state government (e.g. medical, osteopathic, pharmacy, and nursing board) pursuant to statutory authority.

The most common laws affecting pain management are statutes and regulations governing the prescribing of controlled substances; statutes such as an Intractable Pain Treatment Act and Pain Relief Acts; statutes creating and regulations implementing prescription monitoring programs or pain advisory councils; regulations issued by healthcare licensing boards governing professional and unprofessional conduct for practitioners regulated by the agency; and regulations that license healthcare facilities.

- "Guidelines" do not have binding legal force, but are officially adopted policies issued by a government agency to express the agency's position about a particular issue. Many state medical, osteopathic, pharmacy, or nursing boards have issued guidelines regarding the medical use of opioid analgesics for the treatment of pain. Such guidelines can help healthcare practitioners to better understand their licensing board's standards of practice regarding the treatment of pain.

Consequently, healthcare professionals' choice to treat pain with opioids can be influenced by what their state policies say about this practice. Unfortunately, some of these policies contain restrictions that have the potential to interfere with the medical use of controlled substances for the treatment of pain, referred to as "regulatory barriers", or fail to recognize pain relief as part of quality healthcare practice [34]. Furthermore, there can be a perception among healthcare practitioners that drug control or regulatory policies restrict professional practice, even when they do not, and this perception can make practitioners reluctant to prescribe these medications [35].

Recently, both international and national legal and healthcare organizations have expressed concern about the possible detrimental effects of regulatory barriers. International organizations such as the International Narcotics Control Board [36] and the World Health Organization [21,37] have called on all countries to identify and address regulatory barriers to cancer pain relief. In the last few years in the US, the American Cancer Society (ACS) [17], the Institute of Medicine [38], and the National Institutes of Health (NIH) [39] have called for studies to improve pain management, and to identify the legal and regulatory impediments to using opioids for pain relief. As recently as 2004, the NIH's National Consensus Project on Quality Palliative Care identified that palliative care programs need to be knowledgeable about the legal and regulatory issues surrounding the appropriate prescribing of opioids and other controlled substances [40].

To address this long-standing imperative, the authors created a research program to longitudinally evaluate and quantify the quality of state drug control and regulatory policy, identifying language that if implemented into healthcare practice would either improve or obstruct the availability of controlled substances for patient pain relief. This article describes the current status of state policy governing the use of controlled substances for pain relief, as well as how the content of such policy has changed over time and the implications for policy change in today's healthcare environment.

Evaluation of state policy

The University of Wisconsin Pain & Policy Studies Group (PPSG) developed a research program to improve US drug control and healthcare regulatory policies related to pain management, palliative care, and end-of-life care. To realize this objective, thePPSG created a criteria-based methodology to evaluate federal and state policies, resulting in a series of policy reports entitled "Achieving Balance in Federal and State Pain Policy: A Guide to Evaluation" (Evaluation Guide) [41–43] and "Achieving Balance in State Pain Policy: A Progress Report Card" (Progress Report Card) [44,45]. Grants from the ACS and the Susan G Komen for the Cure, as well as a partnership with the Lance Armstrong Foundation, supported the most recent policy evaluation reports (Evaluation Guide 2006 [43] and Progress Report Card 2006 [45]). The Evaluation Guide and Progress Report Card were conceived as tools that advocates from government and non-government organizations, as well as healthcare practitioners, can use to inform the identification and removal of regulatory barriers. Policy change activities guided by these tools will achieve more positive and consistent state policies regulating the use of controlled substances for pain relief.

The most recent Evaluation Guide was issued in July 2006 and evaluates all statutes and regulations governing the prescribing, dispensing, and administering of Schedule II controlled substances and medical, osteopathy, and pharmacy practice. Other healthcare regulatory policies (e.g. guidelines and policy statements) were obtained from each state's medical and pharmacy boards. Table 2 contains examples of state policies evaluated. Evaluation results are expressed as a policy profile for the federal government and for each state and the District of Columbia. Both the
Table 2. Examples of evaluated state policies.

<table>
<thead>
<tr>
<th>State</th>
<th>Policy type</th>
<th>Policy reference</th>
</tr>
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<tbody>
<tr>
<td>Arizona</td>
<td>Osteopathic Board Guidelines</td>
<td>Guidelines: The Prescribing of Controlled Substances for the Treatment of Pain Management</td>
</tr>
<tr>
<td>California</td>
<td>Pharmacy Board Policy Statement</td>
<td>Dispensing Controlled Substances for Pain</td>
</tr>
<tr>
<td>Colorado</td>
<td>Law</td>
<td>Controlled Substances Act – 18-18-308: Prescriptions</td>
</tr>
<tr>
<td>Florida</td>
<td>Osteopathic Board Regulation</td>
<td>64815-14.005 Standards for the Use of Controlled Substances for Treatment of Pain</td>
</tr>
<tr>
<td>Florida</td>
<td>Pharmacy Board Regulation</td>
<td>64816-27.831 Standards of Practice for the Dispensing of Controlled Substances for Treatment of Pain</td>
</tr>
<tr>
<td>Kansas</td>
<td>Medical Board Guideline</td>
<td>Guidelines for the Use of Controlled Substances for the Treatment of Pain</td>
</tr>
<tr>
<td>Iowa</td>
<td>Medical Board Regulation</td>
<td>653 IAC 13.2: Standards of Practice – Prescribing or Administering Controlled Substances for the Treatment of Patients with Chronic, Nonmalignant or Intractable Pain</td>
</tr>
<tr>
<td>Minnesota</td>
<td>Joint Board Guideline (Medical, Pharmacy, and Nursing Boards)</td>
<td>Joint Statement on Pain Management</td>
</tr>
<tr>
<td>New Mexico</td>
<td>Law</td>
<td>N.M. Stat Ann. 24-2D-1 to 24-2D-6: Pain Relief Act</td>
</tr>
<tr>
<td>Wisconsin</td>
<td>Law</td>
<td>961.001: Uniform Controlled Substance Act Declaration of Intent, 961.38 Prescriptions</td>
</tr>
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Evaluation Guide 2006 and the Progress Report Card 2006 are accessible on the PPSG website [43,45]. This article reviews selected findings about state policy that were included in these reports.

The central principle of Balance
Valid and credible principles must underlie a policy evaluation methodology [46]. A central principle of drug regulation and medical ethics, called Balance, was used as the basis for this evaluation of policies. The principle stems from a long-standing national and international recognition that efforts to control abuse and diversion must not impede the legitimate use of medications (i.e. for pain management) and, by extension, that drug regulatory policy should conform to current medical and scientific understanding. Ultimately, balanced state policies will avoid creating barriers to appropriate healthcare practice and patient care, and will encourage effective pain management, including acknowledging the use of controlled substances as an essential component of quality medical practice. It is important to note that Balance supports both public health and safety – the principle prohibits medication use outside the established system of control, and authorizes licensed healthcare practitioners’ use of opioid analgesics only for legitimate medical purposes in the course of professional practice. However, the reports described in this article evaluate only aspects of policies affecting medication availability and not their drug control and abuse prevention properties.

A number of governmental, regulatory, and healthcare organizations have recommended that controlled substances policy and medical practice policy should be balanced (see Table 3 for a list of international and national organizations). To this end, the Federation of State Medical Boards of the US (the Federation) has worked with the PPSG to develop model policies for state medical boards to adopt; the model policies encourage effective pain management and address physicians’ concerns about regulatory scrutiny [47–49], which reports have shown are prevalent and can hinder medication availability for patient pain relief [50–53]. In order to promote consistency in medical regulatory policy, in 1998 the Federation adopted a policy template for boards to use when creating policies in their states, entitled “Model Guidelines for the Use of Controlled Substances for the Treatment of Pain” [54]. 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” [55]. The revision is very 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 [56]. Twenty-eight states have now adopted or adapted the Federation’s model policies.
Table 3. Organizations calling for balanced regulatory policy.

- World Health Organization
- International Narcotics Control Board
- Institute of Medicine
- National Cancer Institute
- American Medical Association
- American Pain Society
- American Cancer Society
- American Academy of Pain Medicine
- Alliance of State Pain Initiatives
- Federation of State Medical Boards
- National Association of Attorneys General
- National Association of State Controlled Substances Authorities
- Drug Enforcement Administration

Evaluation criteria

Sixteen evaluation criteria were derived from the principle of Balance, with each criterion falling into one of two categories:

- Positive provisions – policy language that can enhance pain relief.
- Negative provisions – restrictive or ambiguous language that can impede pain relief.

A complete list and description of each criterion, as well as the clinical and policy justifications for their relevance, can be found in Section VI of the Evaluation Guide 2006 [43].

Results from the Evaluation Guide 2006

The 2006 state policy evaluation identified numerous occurrences of restrictive or ambiguous language related to the use of Schedule II controlled substances, which have the potential to interfere in the management of moderate to severe pain. Older state laws and regulations typically contain these types of provisions, which do not conform to current standards of professional practice. Examples of such provisions include:

- Equating addiction with physical dependence or tolerance (found in 16 states).
- Requiring or suggesting that opioids be used only after other treatments have failed (found in 16 states).
- Requiring that physicians always consult with specialists when prescribing controlled substances, regardless of clinical skill (found in 10 states).
- Restricting prescribing of pain medication to patients with pain who also have an addictive disease or a history of substance abuse (found in nine states).

- Restricting the amount of pain medication that can be prescribed or dispensed at one time (found in nine states).
- Restricting the amount of time that a prescription is valid to <2 weeks (found in five states).

The evaluation also identified policies that promote effective pain management and could increase access to patient care; these policies are generally found in more recent regulatory policies of state agencies, rather than in legislative statutes. For example, state policies:

- Recognize the medical use of opioids as part of legitimate professional practice (found in all 50 states and the District of Columbia).
- Recognize pain management as part of legitimate professional practice (found in 45 states).
- Address physicians' concerns about regulatory scrutiny (found in 39 states).
- Do not equate addiction with physical dependence or tolerance (found in 36 states).
- Recognize that the amount of medication alone is insufficient to determine prescription legitimacy (found in 31 states).

Without such language, a state's drug control and regulatory policy is unbalanced, as it focuses disproportionately on the abuse potential of opioids. A summary of the policy evaluation findings for each state appears in Section VIII of the Evaluation Guide 2006 [43].

The policy evaluations led to state advocates becoming interested in improving pain policy, and identified the need for a method to compare states on the quality of their policy and to measure policy change across time. The criteria-based, policy evaluation results for each state were converted to grades for the years 2000, 2003, and 2006. The states' policy grades, and the method to calculate the grades, are described in the Progress Report Card 2006 and are available on the PPSG website [45]. Grades range from A to F, with higher grades representing more balanced policy and lower grades associated with potential barriers to healthcare practice and patient pain relief. A letter grade serves to simplify a state's complex policy and regulatory environment.

Results from the Progress Report Card 2006

Table 4 contains the number of states at each grade level for each study year. In 2006, 16% of states scored the average grade of C, whereas 82% scored above C. Only one state (Georgia) was below the average with a D+, and represented the least balanced policies. Michigan and Virginia achieved the highest grade (A), and therefore, have the most balanced
policies in the country; given a sufficient number of positive provisions, to achieve an A grade a state must have no restrictive or ambiguous policy language. No state received a grade of D or F. California, New York, and Texas, three states representing approximately a quarter of the US population, each earned an average grade of C. These grades result from the state policies containing numerous instances of both positive and negative provisions.

In addition, results showed that while the quality of policies varies greatly among states, it has improved over time. Although 35 states changed their policies between years 2003–6, the changes were sufficient in 19 states to improve their grade. Rhode Island demonstrated the most improvement, increasing from a D+ to a B, primarily by repealing numerous unduly restrictive requirements or ambiguities from state legislation. No states' grade decreased between years 2000–6. The source of this positive policy change largely continues to be state healthcare regulatory boards (i.e. medical, osteopathic, and pharmacy) that adopted policies encouraging pain relief, palliative care, or end-of-life care.

Discussion
Since the year 2000, when the PPSG began evaluating state policies, there has been a notable improvement in the extent that the policies encourage effective pain management and the appropriate use of opioid analgesics. Advocates in many states have successfully used the Evaluation Guide and Progress Report Card to identify policy language in need of change and have promoted its repeal, or have adopted positive regulatory policy.

While unrelieved pain is being recognized as a significant public health problem, it is occurring at the same time as the increasing crisis of pain medication abuse and diversion. Efforts to prevent prescription medication abuse can have the undesirable and unintended consequence of restricting access for legitimate medical purposes. It remains important to effectively address the risks for pain medication abuse and diversion without impeding patient care. Recent policies issued by state medical boards promote such a perspective, conforming to the principle of Balance [48]. The policies support pain management practices that monitor whether the medication is being used for the reason it is prescribed, as well as gauging treatment effectiveness by improvements in patient functioning. This approach to prescribing controlled substances for pain helps accomplish the dual objective of enhancing public health (through effective patient pain relief) and protecting public safety (through minimizing the possibility of medication abuse or diversion) [23].

Although some policy improvement resulted from efforts to repeal state legislative barriers, the primary reason for positive change over time occurred because medical, osteopathy, and pharmacy regulatory boards adopted policies about pain management. In the past 6 years, 17 state regulatory boards adopted policies based on the Federation's models designed to encourage better treatment of pain and to address practitioners' fear of investigation and discipline [45]. A further five states developed board policies for which neither of the Federation's models were the source [45]. In addition, four states approved joint policy statements relating to the use of controlled substances for pain relief; these are collaborative efforts by several regulatory boards, such as medicine, osteopathy, pharmacy, and nursing, which emphasize the importance of multidisciplinary pain treatment and communicate positive messages to a variety of healthcare licensees [45]. Furthermore, some medical boards have created programs to share their pain management policy with their licensees, and have developed sections on their websites that provide information to licensees about the use of controlled substances to treat pain [57]. The frequency of policy creation and educational initiatives demonstrates that many regulatory boards are serious about confronting unrelieved pain.

Despite the significant positive policy adoption in recent years, state advocates now face the challenge of eliminating many outdated negative provisions from statutes, some of which were adopted >30 years ago. Although states can endorse stricter laws than federal policy, undue restrictions are not a necessary part of drug control or professional practice laws. Since the year 2000, there has been a 60% increase in positive provisions, compared with only a 13% reduction in negative provisions during the same period [45]. As a result, the repeal of negative provisions from statutes seems to be receiving less attention than efforts of professional licensing boards to adopt positive policies. A particular challenge remains for states that have a considerable number of both positive and negative provisions. There must be
efforts in these states to reduce the number of restrictive or ambiguous provisions in legislation in order for grade improvement to occur.

The issue of state drug control and professional practice policies is becoming a more frequent part of the dialogue when conceptualizing what can be done to improve pain management for people with chronic cancer or non-cancer conditions. For example, statutorily mandated advisory councils are multidisciplinary committees (typically composed of legislative, regulatory, and healthcare appointees) created to enhance pain management at the state level. Historically, such committees have focused on educational initiatives for healthcare professionals or the general public, but in recent years they have additionally begun to examine the quality of policies in their states and to design strategies to repeal barriers. Furthermore, activities of state pain initiatives are expanding to address barriers present in healthcare laws and regulations. This evolving approach clearly connects the dots among state policy, professional practice, and patient care.

Similar to any single factor, positive policy change is not usually sufficient in itself to enhance pain management. However, improving state policy is a necessary complement to the many ongoing state-level efforts designed to educate healthcare professionals about the appropriate use of pain medications and to inform the general public about the availability of pain treatment options. Most importantly, improving state policy will remove restrictions and can enhance appropriate access to pain medications for people who experience moderate to severe pain during the course of their illness and beyond. State policy barriers must not stand in the way of patients achieving effective pain relief and an improved functioning and quality of life.

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References


