

Special Article

Pain Management, Controlled Substances, and State Medical Board Policy: A Decade of Change

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Abstract

Physicians' concerns about regulatory scrutiny and the possibility of unwarranted investigation by regulatory agencies negatively affect their prescribing of opioid analgesics to treat pain. Indeed, some state medical boards have rejected prescribing practices that are considered acceptable by today's standards. This article describes a ten-year program of research, education, and policy development implemented by the Pain & Policy Studies Group aimed at updating and clarifying state medical board policies on the use of opioid analgesics to treat pain, including cancer and chronic noncancer pain. Following surveys of medical board members and educational workshops, state medical board policies began an initial period of change, drawing on guidelines from other states, particularly in California. The next phase of policy development was marked by the introduction of Model Guidelines by the Federation of State Medical Boards of the U.S. The Model Guidelines address professional standards for the appropriate prescribing of opioid analgesics for pain management, as well as physicians' fears of regulatory scrutiny. Although most state medical boards have adopted regulations, guidelines, or policy statements relating to controlled substances and pain management, to date ten boards have adopted the Model Guidelines, while ten more have adopted the Model Guidelines in part. Further actions are recommended so that state medical boards can address inadequate pain management and physician concerns about regulatory scrutiny. J Pain Symptom Manage 2002;23:138-147. © U.S. Cancer Pain Relief Committee, 2002.

Key Words

Medical boards, pain policy, chronic pain, cancer pain, opioids

Introduction

There are many safe and effective treatments for pain, both pharmacologic and non-phar-

macologic. Clinical practice guidelines, as well as other authoritative sources, emphasize that opioid analgesics are essential for the treatment of moderate to severe pain, especially acute pain^{1,2} and cancer pain.²⁻⁴ In addition, there is a growing consensus that opioids can be appropriate for certain patients with chronic non-cancer pain if there is proper evaluation and monitoring of pain relief and functional out-

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comes.⁵⁻⁷ Despite the availability of such treatments, inadequate management of pain has been found in patients with a variety of diagnoses and conditions⁸⁻¹² and in a variety of health-care settings.¹³⁻¹⁹

It is well-documented that many factors, or barriers contribute to inadequate treatment of pain; among these are physicians' fears of being investigated for prescribing opioids.²⁰⁻²⁴ Studies have demonstrated that physicians underprescribe opioid analgesics out of fear of state board disciplinary action, even though prescribing opioids for pain management is legitimate if done in the course of professional practice. Apprehension on the part of physicians seems warranted by evidence from a 1991 survey indicating that some members of state medical boards, the organizations that license and discipline physicians, appear to have attitudes and beliefs that conflict with the use of opioids for treatment of pain.²⁵ These attitudes may be reflected in the policies issued by a state medical board, as well as in a board's enforcement procedures. Indeed, some board policies have contained statements and recommendations that discourage the use of opioid analgesics for pain management.

There is a need for state medical boards to adopt policies that encourage adequate pain management and dispel physicians' fears of being disciplined, in keeping with accepted medical practice. Adoption and dissemination of such policies can play an important role in modifying physicians' knowledge, beliefs, and practices concerning the treatment of pain with opioid analgesics. It is important to note that national organizations such as the American Medical Association²⁶ and the Federation of State Medical Boards in the United States (FSMB)²⁷ have advocated a non-legislative approach to promoting the use of controlled substances for pain management, which is the focus of this paper. In addition, some state statutes may hinder appropriate pain management by containing additional restrictions or requirements on prescribing opioid analgesics,²⁸⁻²⁹ superseding the authority of state medical boards to regulate medical practice.²⁷

Over the last decade, a program of research, education and policy evaluation was undertaken by the Pain Policy Studies Group (PPSG) with state medical boards and national pain associations to address physicians concerns about

regulatory scrutiny. The program was developed in several stages, beginning with a national survey of state medical board members and followed by educational workshops for board members, evaluation of medical board policies, and technical assistance to develop model state medical-regulatory guidelines for the use of controlled substances in pain management. Taken together, these efforts demonstrate that regulatory agencies are making efforts to recognize the importance of pain management with opioids, for cancer and non-cancer conditions.

Physician Concern About Regulatory Scrutiny

A 1990 survey of oncologists studied the reasons for inadequate cancer pain management and found that 18% rated excessive regulation of analgesics as one of the top four barriers.³⁰ Indeed, oncologists in several states had been investigated and prosecuted for prescribing opioids to cancer patients (who were by then deceased). Eventually the charges were dismissed, but these events reached the news media, including being described in a cancer journal.³¹

A 1991 survey of Wisconsin physicians found that more than half would at least occasionally reduce dose, quantity or refills, or prescribe a drug in a lower schedule due to fear of regulatory scrutiny.³² These physicians' concerns about investigation were least when opioids were prescribed for acute pain, but increased if prescribing was for chronic cancer pain; concern was greatest if prescribing was for chronic pain not related to cancer, or for patients with a history of drug abuse.

In that same year, 40% of surveyed physician-members of the American Pain Society (APS) said that concerns about regulatory scrutiny, rather than medical reasons, led them to avoid prescribing opioids for chronic non-cancer pain patients.³³ In a national survey of physicians, some respondents reported that regulatory pressure restricted their use of opioids for patients with chronic non-cancer pain.²³ Indeed, the use of opioid analgesics for chronic non-cancer pain has been controversial^{16,34,35} and actively discouraged by some in both the pain and regulatory communities. More recently, clinicians, researchers, and regulators have be-

gun to reexamine the use of opioids for chronic non-cancer pain, including treatment efficacy, potential of adverse pharmacologic effects, and abuse and addiction liability, concluding that there is a role for opioids in carefully-selected patient populations.^{5-7,36,37}

Research and Education with State Medical Boards

In response to these findings, in 1991 the PPSG surveyed all the members of state medical boards to assess whether board members' knowledge and attitudes could pose a threat to physicians who prescribe opioids for management of chronic cancer and non-cancer pain.²⁵ With the cooperation of the FSMB, a confidential pre-tested questionnaire was mailed to all 627 state medical board members in the U.S. A 50% response rate was achieved. Respondents represented 49 states, with a mean of six respondents per state. Physicians, public members, and other health-care practitioners were surveyed; 79% of the respondents were physicians and 15% were public members.

To directly address the validity of physicians' fears of regulatory scrutiny, board members were asked their opinions about the legality and medical acceptability of prescribing opioids for more than several months to patients with different diagnoses, including a patient with chronic cancer pain and a patient with chronic non-cancer pain. The respondent could indicate whether the prescribing practice was: (1) lawful and generally acceptable medical practice, (2) lawful but generally not acceptable and should be discouraged, (3) probably a violation of state medical laws or regulations and should be investigated, (4) probably a violation of federal or state controlled substances laws and should be investigated, or (5) that the respondent did not know the legality of extended opioid prescribing. It is important to note that, while federal drug enforcement policy recognizes that the use of opioids for pain including for patients with chronic disorders is lawful, it remains the province of the states to determine what constitutes legitimate medical practice.^{21,38,39}

While most respondents agreed that the prescribing of opioids for the cancer patient was legal and generally acceptable medical practice, only 12% were confident in the legality of pre-

scribing for the patient with chronic non-cancer pain; the majority of respondents (77%) would discourage this practice or even investigate it as a violation of law. It is of interest that the median year in which the physician-board members received their medical training was 1961, before pain treatment became a clinical science, before pain relief had become a public health priority, and well before the growing recognition that opioids could be used for patients with chronic non-cancer pain. There were also deficiencies in board members' knowledge about the extent to which cancer pain can be relieved, appropriate pharmacologic treatments for moderate to severe cancer pain, and the meaning and incidence of addiction when opioids are used to manage pain. Public members were more likely to indicate that they did not know the answers to survey items.

The survey results showed a clear need to update medical board members' knowledge about pain management and public policy. The findings were published in the FSMB journal, the *Federation Bulletin*,²⁵ in order to further a working relationship aimed at education, policy evaluation, and future research with the medical boards. The PPSG initiated a series of seminars for board members, believing that they would want to know about recent developments in pain management, and that they would respond to other physicians' concerns about being investigated for prescribing to treat chronic pain.

The PPSG and the FSMB cosponsored a series of 11 workshops on "Pain Management in a Regulated Environment" between 1994 and 1998. The faculty for all workshops was consistent, and included experts in pharmacology, pain medicine, addiction medicine, and public policy. Workshop content included the extent of the pain problem, the reasons for inadequate management of pain including exaggerated fear of addiction and concerns about regulatory scrutiny, methods for the assessment and treatment of pain, a review of recent advances in the understanding of pain physiology and opioid pharmacology, and the status of federal and state controlled substances and professional practice law, regulations, and medical board guidelines about the use of controlled substances for pain management.⁴⁰

A total of 297 representatives of state medical boards signed up to participate in any one of the 11 one-day workshops; the participants

represented 40 states and approximately 25% of the total board member population.⁴⁰ Participants in the workshops included both physician and public members, as well as some investigators, attorneys, and administrative staff. All participants completed a pre-test, post-test, and follow-up survey to evaluate changes in knowledge and attitudes as a result of their involvement in the workshops.⁴⁰

Evaluation of State Medical Board Policy

In the next phase of the program, the quality of state medical board policies was evaluated to better understand the potential for these policies to pose a threat to physicians who prescribe controlled substances for pain management. Medical board policies and guidelines express the attitude of the board regarding controlled substances and pain management. By 1990, few medical boards had adopted policies relevant to controlled substances and the treatment of pain; most of these early policies were eventually superceded by new policies.²⁸ By 2000, more than half of the state medical boards had adopted pain guidelines (see Fig. 1). The full text for the medical board policy in each state can be found at: <http://www.medsch.wisc.edu/painpolicy/matrix.htm>.

A team analysis approach⁴¹ with three researchers was used to evaluate guidelines and policy statements that had been adopted in 24 states between 1989 and 1997, the most recent year for which policies were available when this study was begun (see Table 1). Each policy was rated according to several criteria, including

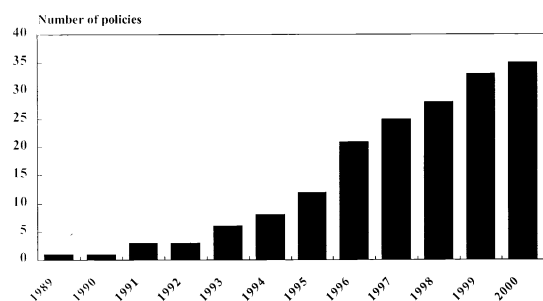


Fig. 1. The cumulative trend in the number of pain management or controlled substances policies adopted by state medical boards in the United States from 1989 to 2000.

whether the guidelines: (1) contained a stated purpose to address concerns about regulatory scrutiny, encourage pain management, and encourage physicians to become knowledgeable about pain management; (2) recognized the medical use of opioids for pain, including chronic non-cancer pain; and (3) recognized that certain restrictions or requirements could interfere with prescribing opioids for pain management.

The raters' evaluations of the items found in each policy were compared to determine the extent of discrepancy, i.e., when raters had different responses. There was an initial agreement of 86% among raters, suggesting high "reproducibility" (p. 17).⁴² For each discrepancy, the reasons were determined and a consensus was achieved and recorded. Percentages were calculated to represent the extent that each item was present in each policy.

Stated Purpose of the Policy

Fifty-four percent of the 24 policies (13 states) recognized physicians' concerns about regulatory scrutiny but only 33% (8 states) actually addressed the concerns by providing guidelines or principles the board uses to distinguish legitimate from questionable prescribing practices. Thirty-eight percent of the guidelines (9 states) included statements that encouraged pain management; 46% (11 states) provided physicians with sources of information about pain management, such as the Agency for Health Care Policy and Research clinical practice guidelines or the consensus statement by the APS and the American Academy of Pain Medicine (AAPM).

Recognition of Medical Uses for Opioids

Thirty-eight percent of the guidelines (9 states) recognized the appropriateness of using opioids for cancer pain; 46% (11 states) recognized that opioids may be used for chronic non-cancer

Table 1
Twenty-Four States Represented in Content
Evaluation of Medical Board Policies

Alaska	Massachusetts	Rhode Island
Arizona	Minnesota	Tennessee
California	Montana	Texas
Colorado	New Mexico	Utah
Florida	North Carolina	Vermont
Georgia	Ohio	Washington
Idaho	Oklahoma	West Virginia
Maryland	Oregon	Wyoming

pain. For example, a medical board policy statement from North Carolina stated that:

It should be understood that the Board recognizes opioids can be an appropriate treatment for chronic pain (p. 2).⁴³

Twenty-one percent of the guidelines (5 states) stated the principle that pain management, including the use of opioid analgesics, should be considered a part of quality medical practice. For example, Washington's policy contains a statement that directly addresses this issue:

Under generally accepted standards of medical practice, opioids may be prescribed for the treatment of acute or chronic pain including chronic pain associated with cancer and other non-cancer conditions (p. 1).⁴⁴

Additional Requirements and Restrictions

Several state medical boards had policies that created potential barriers to pain management because they placed additional and apparently inflexible restrictions on a physician's ability to make an independent medical decision about the use of opioid analgesics that should be based on the physician's expertise and the individual characteristics of the patient. These restrictions fell into two groups: Those that require in *every* case that opioids be used only after other treatments, and those that require consultation with an expert in *every* case involving a patient with a history of substance abuse. Two states (8%) required that other treatments be attempted before opioids are used for chronic non-cancer pain. For example, an Ohio medical board policy statement indicates that treatment of chronic pain with opioid analgesics can begin only when:

There is documentation that pain cannot be adequately controlled by other treatment methods such as, but not limited to behavior modification, non-narcotic medications, physical therapy, TENS, manipulation, and other forms of recognized treatment (pp. 4–5).⁴⁵

While trials of non-opioid treatments are certainly reasonable, it is unclear how many treatments a physician should require of the patient in order to avoid possible discipline, or what should be done in the case of a patient's need for immediate pain relief. Such requirements may delay pain management, increase

the costs of treatment, and marginalize opioids as a treatment of last resort.

Nine guidelines (47%) appeared to mandate consultation with another physician when the patient has a history of substance abuse:

The management of pain in patients with a history of substance abuse requires extra care, monitoring, documentation and consultation with addiction medicine specialists...(p. 1).⁴⁶

Assessment of patients for a history of substance abuse is very important, but requiring a consultation in every case may not be necessary, especially when the physician is well-trained or an expert. However, the failure to meet this requirement could result in a disciplinary proceeding.

The evaluation of state medical board policies showed that there was a lack of clear and consistent purpose, and considerable variation in policy content across states.⁴⁷ Only some policies encouraged better pain management, addressed physicians' concerns about regulatory scrutiny, or clarified the board's view of the role of opioids in pain management.²⁸ The analysis was presented to the FSMB, which used it to inform a process that was begun to study and improve the content and consistency of state medical board pain policies.

The Development of Model Guidelines for State Medical Boards

In 1997, the FSMB convened a task force of pain, policy, and regulatory experts to develop "Model Guidelines for the Use of Controlled Substances for the Treatment of Pain,"³⁷ which could be given to all state medical boards for their consideration. A draft was prepared, taking advantage of the PPSG's policy evaluation and incorporating exemplary language from several state medical boards' policies.⁴⁸ The FSMB sponsored a public forum to receive comments on the draft from a variety of medical and pain organizations, state medical boards, and patient advocacy groups.⁴⁸ A representative of the U.S. Drug Enforcement Administration (DEA) presented a written statement which said in part:

The guidelines will help physicians comply with acceptable pain management standards and will help DEA and other regulators de-

termine whether such treatment is appropriate under the circumstances. Perhaps most importantly, the guidelines will help ensure patient access to needed controlled substances for pain management (p. 4).⁴⁹

The Model Guidelines contain language that clearly recognizes the medical uses of controlled substances for pain, encourages physicians to provide adequate pain management for all patients, recognizes and addresses fear of regulatory scrutiny, and encourages physicians to update their knowledge about pain management (see Table 2). In addition, the Model Guidelines present guidelines for prescribing controlled substances that are based on the general principles of good medical practice, which include having a bona fide physician-patient relationship, physical examination, diagnosis, treatment plan, informed consent, periodic monitoring, documentation, consultation as needed, and adherence to federal and state laws concerning controlled substances. The Model Guidelines recognize that opioids can be appropriate for pain control even when a person has a history of substance abuse, and recommend the use of a written agreement outlining patient responsibilities and monitoring of medication use. Up-to-date definitions are provided for key terms that are commonly misused, including addiction, tolerance and physical dependence. A relatively new concept, "pseudoaddiction,"⁵⁰ is defined in order to draw attention to the importance of distinguishing between patients who request more

pain medications because their pain is inadequately managed, and persons who seek drugs for other than legitimate purposes.

The Model Guidelines do not contain unwarranted additional requirements or restrictions. Indeed, they are explicitly flexible:

Each case of prescribing for pain will be evaluated on an individual basis. The board will not take disciplinary action against a physician for failing to adhere strictly to the provisions of these guidelines, if good cause is shown for such deviation. The physicians conduct will be evaluated to a great extent by the treatment outcome, taking into account whether the drug used is medically and/or pharmacologically recognized to be appropriate for the diagnosis, the patient's individual needs—including any improvement in functioning—and recognizing that some types of pain cannot be completely relieved. (p. 2)³⁷

The Model Guidelines were unanimously adopted by the Federation's House of Delegates on May 2, 1998. Subsequently, they were endorsed by the APS and the AAPM.⁴⁸ The Model Guidelines represent an emerging consensus among groups representing the perspectives of pain management, regulation, and drug law enforcement about the medical use of controlled substances for the treatment of pain. The intention of the FSMB is that the Model Guidelines be considered and acted upon by all state medical boards.²⁷ The Model

Table 2
Selected Provisions of the Model Guidelines

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- "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." (p. 1)
 - "The Board encourages physicians to view effective pain management as a part of quality medical practice for all patients with pain, acute or chronic, and it is especially important for patients who experience pain as a result of terminal illness." (p. 1)
 - "Inadequate pain control may result from physicians' lack of knowledge about pain management or an inadequate understanding of addiction. Fears of investigation or sanction by federal, state, and local regulatory agencies may also result in inappropriate or inadequate treatment of chronic pain patients." (p. 1)
 - "Physicians should not fear disciplinary action from the Board or other state regulatory or enforcement agency for prescribing, dispensing, or administering controlled substance, including opioid analgesics, for a legitimate medical purpose and in the usual course of professional practice." (p. 2)
 - "The Board will judge the validity of prescribing based on the physician's treatment of the patient and on available documentation, rather than on the quantity and chronicity of prescribing." (p. 2)
 - "All physicians should become knowledgeable about effective methods of pain treatment. . . Physicians are referred to the U.S. Agency for Health Care [Policy] and Research Clinical Practice Guidelines for a sound approach to the management of acute and cancer-related pain. The medical management of pain should be based on current knowledge and research and includes the use of both pharmacologic and non-pharmacologic modalities." (p. 1)
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Source: Federation of State Medical Boards of the United States, Inc. *Model Guidelines for the Use of Controlled Substances for the Treatment of Pain*. Euless, TX; May 1998.

Guidelines are available on the FSMB Web site at <http://www.fsmb.org>. The Model Guidelines, endorsements of the Model Guidelines, as well as all state medical board policies and state laws governing the use of controlled substances for pain management, are available on the PPSG Web site at <http://www.medsch.wisc.edu/painpolicy/matrix.htm>.

Discussion

That physicians fear they will be investigated for writing excessive opioid prescriptions has been described as an “unwritten doctrine” (p. 257).⁵¹ Although opioid analgesics have been regarded as the mainstay of treatment for pain related to surgery and trauma for many years, national encouragement of their use for cancer pain did not occur until more recently.¹⁻⁴ There is a growing consensus supporting the use of opioids in chronic non-cancer pain.^{5,37} These changes, along with the advent of new information about pain physiology, opioid pharmacology, and revised conceptions of addiction and dependence, represent new knowledge that needs to be incorporated into medical education and practice.⁵² It is essential that state medical policies adapt to these changes.

The Model Guidelines provide a carefully considered policy framework that can be used by state medical boards to accomplish this goal. However, many state medical boards have yet to adopt the new guidelines, as recommended by the FSMB.²⁷ Since May of 1998, ten state medical boards have adopted policies that are substantially the same as the Model Guidelines: Alabama, Florida, Kansas, Minnesota, Nebraska, Nevada, Pennsylvania, South Carolina, South Dakota, and Utah. In addition, another ten state medical boards have issued policies that use the Model Guidelines in part: Arizona, Kentucky, Louisiana, Maine, Missouri, New Hampshire, New York, Oklahoma, Tennessee, and West Virginia. Most of the medical boards from these states had at least one member participate in the workshops on “Pain Management in a Regulated Environment.” Apparently, the workshops provided not only a rationale but an impetus for medical boards to develop policy to encourage pain management and to allay physicians’ fears about regulatory scrutiny. Identifying all the catalysts for policy

development by state medical boards will require further study.

Conclusions and Recommendations

Successful elimination of physician fear of regulatory scrutiny will depend in part on achieving more balanced controlled substances policies in each state (i.e., policies that aim not only to prevent drug abuse but also acknowledge the important medical uses of controlled substances, in particular the opioid analgesics).^{29,53} The purpose is not to advocate the use of opioids for all pain, but to encourage effective pain management, including the use of opioids when appropriate.

We recommend that all state medical boards adopt guidelines or policy statements (rather than statutes) on the use of controlled substances for pain management, and ensure that investigation and discipline of physicians is consistent with board policy and does not interfere with pain management. New state board guidelines should be based on the FSMB Model Guidelines. They should be disseminated to all licensed physicians, and publicized through the boards’ Web sites, newsletters, and press releases. In addition, we urge that medical boards cooperate with state boards of pharmacy and nursing to coordinate and establish policies that reflect a consensus of health-care professionals, as has been done in Washington, North Carolina, West Virginia, and Kansas. Alternatively, physicians could work with their medical society to develop pain management policies, which could then be endorsed by the state medical board.

We encourage state medical societies to organize educational programs for physicians that address pain management, regulatory requirements, medical board policies, and concerns about regulatory scrutiny. Medical boards can participate in such efforts, communicating directly with physicians and addressing their perceptions of risk.

Despite dissemination of guidelines to licensees, practitioners often remain unaware of new policies in their state.^{48,54} Overcoming this communication gap requires attention to effective communication strategies. The North Carolina medical board has made great effort to communicate its pain guidelines, and has sponsored educational programs about pain

and end-of-life care for both the public and professionals. Most medical boards have little in the way of educational resources and will need support. One strategy has been employed by the Alabama Board of Medical Examiners through joint sponsorship of educational events with the state medical society. Approximately 75% of medical boards have sponsored Web sites and newsletters; these can be used to inform licensed practitioners of the board's policy to encourage pain management.

If the collective efforts of the pain management and regulatory communities do not make significant progress to eliminate fears of regulatory scrutiny, frustration with physicians who do not provide adequate pain management will mount and may lead to policies that penalize *inadequate* pain management. Such policies have already been discussed by the Institute of Medicine and state medical boards.^{22,52} Indeed, the Oregon Board of Medical Examiners disciplined a physician for inadequate pain management.⁵⁵ In lieu of license revocation, the Oregon Board required the physician to participate in an intensive educational curriculum about pain management.

We believe that education, not discipline, should be the cornerstone of efforts to improve pain management. However, it is axiomatic that if pain management is to be an expected part of quality medical practice, then substandard pain management practice must be subject to review and corrective action as in any other area of medical practice.

The trends in state medical board policies reported here are a reflection of increasing concern about inadequate pain management. Making real improvements in pain management will require the proactive efforts of many organizations. The contribution of state medical boards and other regulatory agencies is a welcome addition.

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