
Treating Pain: New Guidelines for Using Controlled Substances

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Introduction

Adequate pain relief has become a central issue in the debate over assisted suicide and an important concern in providing high quality care for the dying. Inadequate treatment of pain is often blamed on a legal system that penalizes pain treatment while turning a blind eye to neglect of pain. In response, several states have acted to reduce the threat of disciplinary action against physicians who appropriately treat pain. Similarly, many professional and consumer organizations emphasize improved communication regarding pain between the physician and patient.

The purpose of this article is to provide an update on recent pain policy changes adopted by the State Board of Medical Examiners of South Carolina (SBMESC). First, we provide legal and regulatory background on the use of controlled substances for relief of chronic pain. Second, we describe the guidelines adopted by the SBMESC that authorize physicians to prescribe opioids for the treatment of pain (Table 1). Third, we detail recent changes that pertain to education of physicians and medical students about pain treatment. Combined, these changes are aimed at creating a better environment in South Carolina for the treatment of patients with pain.

Background

Why adopt guidelines?

Pain is often treated inadequately in a wide range of patient groups, including trauma and surgery, cancer, and terminally ill, as well as those living with a variety of chronic painful conditions. In addition to these direct effects on health and quality of life, unrelieved chronic pain may result in unscheduled hospital admissions, excessive use of emergency rooms, loss of employment, spouse, and family, and loss of life itself when chronic pain patients commit suicide.

Growing attention to end of life care issues has spawned a wave of research. One of the most comprehensive studies to date is the 1998 report issued by the Institute of Medicine, Approaching Death: Improving Care at the End of Life. A 12-member panel of experts was charged with (1) assessing clinical, behavioral, legal, economic, and other important aspects of care for terminally ill patients; (2) evaluating methods for assessing quality of care and functional status; (3) identifying factors that impede or promote quality care; and (4) making recommendations for improving such care and gaining consensus on what constitutes appropriate care (Table 1). Christine Cassell, M.D., the panel’s chair, concluded, “When medicine can no longer promise an extension of life, people should not fear that their dying will be marked by neglect, care inconsistent with their wishes or preventable pain and other distress. They should be able to expect the health care system to assure reliable, effective, and humane caregiving.”

In response to these and similar findings, the Federation of State Medical Boards in 1997 developed guidelines that emphasize the need to protect public safety by preventing drug abuse while encouraging effective pain management. The development of these guidelines was national in scope, and the Federation received testimony from a variety of organizations representing patient advocacy groups and the U.S. Drug Enforcement Administration. These guidelines served as a model for the Pain Guidelines adopted by the SBMESC, which are aimed at improving treatment and management of pain by South Carolina physicians.
Recent legislation

The U.S. Supreme Court’s 1997 decision on assisted suicide essentially returned its regulation to the states. The confluence of this decision and several other factors, including increasing longevity and increased awareness of end of life issues, has built momentum for change in the states. Over the past decade, for example, there has been a growing trend for states to adopt laws that address the prescribing of opioid analgesics for chronic pain. The first intractable pain treatment act was approved by the Texas legislature in 1989. The purposes of the act were to clarify legal ambiguities, bring Texas into conformity with the federal intractable pain regulation and “…assure that no Texan requiring narcotics for pain relief, for whatever reason, was denied them because of a physician’s real or perceived fear that the state regulatory agency would take disciplinary action against the physician for prescribing narcotics to relieve pain.” California followed suit in 1990 and Florida in 1994. Since 1989, twenty states have passed laws or regulations that address the prescribing of opioid analgesics for chronic pain.

Legislative involvement in establishing medical policy can be fraught with risks, however. Some of these new laws inadvertently impede pain management because they contain restrictive provisions. For example, some laws exclude pain patients who use drugs “non-therapeutically”, and a few impose additional requirements, such as special informed consent forms and mandated consultation with another physician. In addition, patient advocacy groups point out that changing laws and regulations may not be an efficient way to change public and professional knowledge and attitudes. Moreover, state medical boards – not the legislature – are accustomed to considering the balance between improving quality of medical care and protecting public health. For these reasons, laws and regulations should be used with caution and the potential risks and benefits of various methods should be weighed carefully.

In addition to laws and regulations, state medical boards also use guidelines to develop policy. A guideline is an official statement of the medical board’s attitude toward a particular issue. Although guidelines do not have legal force, they do help explain what activities the medical board considers to be within the boundaries of professional practice.

Guidelines have several potential benefits over statutes or regulations. First, guidelines alert licensees to unprofessional practices of concern to the board and give practitioners practical information about how to avoid these problems. Second, a policy statement issued by a state medical board is a more direct and flexible method than statutes in communicating policy and can more easily take into consideration the current and changing state of clinical medicine and science. Third, state medical boards are accustomed to considering the balance between improving quality of medical care and protecting public health. To date, twenty-six state medical boards have issued policy statements that clarify for physicians the parameters within which they may treat pain.

SBMESC Guidelines

The SBMESC’s guidelines address physicians’ concerns about regulatory scrutiny by clarifying the Board’s policy and explain how the Board distinguishes legitimate medical practice from unprofessional conduct. The guidelines define terms such as tolerance, physical dependence, addiction, and pseudoaddiction. They also emphasize
the need to protect public safety by preventing drug abuse while encouraging effective pain management.

Specifically, the guidelines suggest: (1) documentation of a complete history and physical examination; (2) development of a treatment plan with objectives that will be used to monitor progress and with documentation of a recognized medical indication for the use of a controlled substance; (3) obtaining informed consent and patient agreement to treatment; (4) periodic review for continuation or modification of therapy; (5) consultation, when appropriate; (6) documentation of the aforementioned treatment steps; and (7) compliance with both federal and state controlled substances laws and regulations.

The issue of whether to require use of a written informed consent remains controversial. It should be noted, however, that guideline #3 states: “the physician may [emphasis ours] employ the use of a written agreement . . .” Therefore, the use of a written informed consent for the prescription of controlled substances in the treatment of pain is not required in all instances in South Carolina.

We emphasize that guidelines are not absolute rules. Individual cases may reveal shortcomings of the guidelines and lead to their modification. In fact, the SBMESC’s guidelines allow a physician to deviate from the outlined requirements or recommendations for good cause. They should, nevertheless, be followed unless they conflict with stronger obligations or unless there are compelling reasons to make an exception. The important issue is not what is prescribed, but how well the patient’s care is managed and documented in legible form.

Other Legislative Approaches

Study groups

A number of states, including Virginia, Maryland, and Texas, have passed legislation to establish task forces or commissions to study the policy and societal issues raised by death and dying. Many of the task forces have focused on the themes associated with physician assisted suicide, including better pain management. The state of Virginia, for example, specifically provides for a subcommittee to study the legal and policy ramifications of inadequate pain management, including the ethical and legal issues of health insurance coverage and reimbursement.

Educational Efforts

Recently, a number of groups have held national meetings to raise public awareness of issues at the end of life and to discuss the barriers to effective pain management. For example, the American Society of Law, Medicine, and Ethics developed a model act aimed at affording legal protection from boards for physicians who prescribe opioids for chronic pain. The model act is the product of the Project on Legal Constraints on Access to Effective Pain Management, a major research effort to analyze state regulatory efforts and other legal issues that appeared to negatively influence access to effective pain relief. Following these workshops and seminars, a number of boards, such as Alabama and North Carolina, developed and disseminated guidelines for the prescription of controlled substances for pain. Similarly, the American Medical Association House of Delegates approved in 1996 a model intractable pain treatment act based on the Texas law. Moreover, several boards have gone beyond the development of guidelines by disseminating information about pain management and the board’s guidelines through the media, as well as by sponsoring physician and public
education programs about pain management. This trend in pain management policy is likely to continue in the light of current legal developments regarding physician-assisted suicide and the public’s interest in end of life care.

**Policy considerations**

As demonstrated above, legislators and policymakers have made a significant contribution to the discussion of issues at the end of life. Despite this recent attention, however, the American people remain woefully uninformed about many of these issues and the effect they may have on an important aspect of their lives. Therefore, one of the most important roles legislators and state medical boards can play is that of public educators. Legislators have the tools and resources available to raise their constituents’ level of consciousness and understanding of end of life issues.

Many commentators, for example, have proposed that legislatures require continuing medical education courses on palliative care as a condition for maintaining medical licensure. Others have called for using Medicaid funding to ensure an emphasis on proper pain management, especially as it relates to end of life care. A few have even suggested altering state licensure exams to include questions about the basics of pain management and drug prescriptions for palliative care. Using these outlets could help to catalyze improvement of the health care system and encourage the public to seriously consider issues at the end of life.

**Conclusion**

The SBMESC’s *Guidelines for the Use of Controlled Substances for the Treatment of Pain* aims to improve the treatment and management of pain by South Carolina physicians. These changes are part of a national effort to improve the regulatory environment in a way that will encourage adequate pain treatment. However, as the development of pain policy proceeds in South Carolina, we should take care not to oversimplify the complexity of chronic pain and its treatment. In fact, much more work needs to be done. In the future, the Board should work with other groups such as state medical societies and academic institutions to sponsor educational programs. Only a well-informed medical profession can fulfill the objectives of the policy.

*Note: The Institute of Human Values in Health Care web site (http://www.values.musc.edu) has published the pain-related laws, regulations, and medical board guidelines for each state, including the State Board of Medical Examiner of South Carolina’s Guidelines for the Use of Controlled Substances for the Treatment of Pain.*
References
1. State Board of Medical Examiners of South Carolina; Guidelines for the use of controlled substances for the treatment of pain. 1999.


5. Federation of State Medical Boards; Model guidelines for the use of controlled substances in the treatment of pain. April 1998.


7. For information about state laws as well as bills that have been introduced in the state legislatures, the National Conference of State Legislatures’ web site has links to each state’s web site at http://www.ncsl.org


10. Dubler N, Levine R, Johnson SH; Project on legal constraints on access to effective pain relief. A Project of the American Society of Law, Medicine & Ethics, 1996.

Table 1. The Institute of Medicine Recommendations for Improving Care at the End of Life.

1. Create and facilitate patient and family expectations for reliable, skillful and supportive care;
2. Ask health care professionals to commit themselves to improve care for dying patients and to using existing knowledge effectively to prevent and relieve pain and other symptoms;
3. Address deficiencies in the health care system through improved methods for measuring quality, tools for accountability by providers, revised financing systems to encourage better coordination of care and reformed drug prescribing laws; develop medical education to ensure practitioners have the relevant attitudes, knowledge and skills to provide excellent care for dying patients;
4. Develop medical education to ensure practitioners have the relevant attitudes, knowledge and skills to provide excellent care for dying patients;
5. Make palliative care a defined area of expertise, education and research; and Pursue public discussion about the modern experience of the dying, options available to dying patients and families and community obligations to those nearing death.
Table 2. SBMESC’s Guidelines for the Use of Controlled Substances for the Treatment of Pain

Note: The Board has adopted the following guidelines when evaluating the use of controlled substances for pain control. Nothing in this statement should be construed as advocating the imprudent use of controlled substances.

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

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

3. Informed Consent and Agreement for Treatment
The physician should discuss the risks and benefits of the use of controlled substances with the patient, persons designated by the patient or with the patient’s surrogate or guardian if the patient is incompetent. The patient should receive prescriptions from one physician and one pharmacy where possible. If the patient is determined to be at high risk for medication abuse or have a history of substance abuse, the physician may employ the use of a written agreement between physician and patient outlining patient responsibilities, including urine/serum medication levels screening when requested; number and frequency of all prescription refills; and reasons for which drug therapy may be discontinued (i.e., violation of agreement).

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

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

6. Medical Records
The physician should keep accurate and complete records to include, when indicated (1) the medical history and physical examination; (2) diagnostic, therapeutic and laboratory results; (3) evaluations and consultations; (4) treatment objectives; (5) discussion of risks and benefits; (6) treatments; (7) medications (including date, type, dosage and quantity prescribed); (8) instructions and agreements; and (9) periodic reviews. Records should remain current and be maintained in an accessible manner and readily available for review. Obviously the records for an acute episode such as emergency care visit will be less complex than a long term chronic illness.

7. Compliance with Controlled Substances Laws and Regulations
To prescribe, dispense or administer controlled substances, the physician must be licensed in the state and comply with applicable federal and state regulations. Physicians are referred to the Physicians Manual of the U.S. Drug Enforcement Administration and (any relevant documents issued by the state medical board) for specific rules governing controlled substances as well as applicable state regulations.

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

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

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

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

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

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

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

**Pseudoaddiction**: Pattern of drug-seeking behavior of pain patients who are receiving inadequate pain management that can be mistaken for addiction.
Substance Abuse: Substance abuse is the use of any substance(s) for non-therapeutic purposes or use of medication for purposes other than those for which it is prescribed. Tolerance: Tolerance is a physiologic state resulting from regular use of a drug in which an increased dosage is needed to produce the same effect, or a reduced effect is observed with a constant dose.