State Pain Policies

Including State Statutes, Regulations, and Medical Board Guidelines
and Selected Articles About Pain Policy

APRIL, 1998

Pain & Policy Studies Group
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PAIN & POLICY STUDIES GROUP

WHO Collaborating Center
for Policy and Communications
in Cancer Care

April, 1998

Dear Colleague:

This compilation of state policies relating to pain management is being provided to you by the University of Wisconsin Pain and Policy Studies Group (PPSG) with grant support from the Robert Wood Johnson Foundation.

The management of pain at the end of life and also for people with chronic diseases and conditions has become an important focus of public and professional discussion in the United States. States have begun to enact new pain-related policies, including statutes, regulations and guidelines.

The PPSG is studying this unprecedented growth trend in state pain policy, in cooperation with pain medicine and legal experts, national organizations and government agencies. We need to understand the reasons for inadequate pain management, know what impediments exist in current policies, and what new policies could make a difference.

While we are studying these issues, it is important for policy makers, regulators, health professionals, patients and the public to have access to existing policies. This compilation contains the current pain-related statutes, regulations and medical board guidelines for each state. Every effort has been made to ensure that the policies in the binder are the same as the originals. Questions about interpretation or application of these policies should be directed to the relevant state agency.

Appendix A addresses what state legislatures can do to improve pain management and discusses whether we need state intractable pain treatment acts or legislative leadership to study a more comprehensive approach. Appendix B contains articles which identify the principles which can be used to identify impediments and guide the development of pain-related controlled substances and medical policy, a report on workshops that have been held for state medical boards, as well as a review of state medical board guidelines[1]. Terminology is discussed in Appendix C.

The information in this compilation and other publications relevant to the US and other countries, are available on the PPSG website: (http://www.biostat.wisc.edu/painpolicy/domestic.htm).

We welcome comments on this compilation.

Sincerely,

David E. Joranson, Senior Scientist
Director

[1]At this writing, the PPSG is planning six more workshops on pain management issues for state medical boards, and the Federation of State Medical Boards of the United States is developing a model guideline for state medical boards.

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Reg. = Regulation
Guide. = Medical Board Guideline
State. = Statement

ALABAMA

Alabama Administrative Code

540-X-4-.08. Alabama Board of Medical Examiners Pain Control Policy.

(1) The Alabama Board of Medical Examiners has for some time been considering the subject of quality medical practice and how a basic component of a quality practice dictates that patients who suffer pain and other distressing symptoms should be adequately relieved so their quality of life is as optimum as possible. The Board has conducted several pain management seminars throughout the state in an effort to inform Alabama physicians of this policy. This policy statement is another effort of the Alabama Board to keep the Alabama physicians informed of their policies.

(2) The Board recognizes that opiates (narcotics) and other controlled substances are indispensable for the treatment of pain: and, are useful for relieving and controlling other distressing symptoms that patients suffer. It is the policy of the Board that these drugs be prescribed for the treatment of these symptoms in appropriate and adequate doses after an appropriate diagnosis is made.

(3) The Board believes the standard of practice for the use of these drugs should focus on their use for the targeted symptom diagnosed after a careful history, physical examination and appropriate laboratory studies have been done. The Board does recognize that complaints of pain and other related symptoms most times are subjective, and the appropriateness and adequacy of drugs and dosages will vary. The standard will be determined largely by the treatment outcome taking into consideration that the drug used is pharmacologically recognized to be appropriate for the diagnosis as determined by a consensus of recognized medical experts. The quantity of the prescribing will be judged on the basis of diagnosis and treatment of the targeted symptoms.

(4) The Board further recognizes that controlled substances are subject to abuse and when practitioners are prescribing controlled substances they should be diligent in preventing them from being diverted from legitimate to illegitimate use.

(5) The Alabama Board of Medical Examiners hopes this statement will clarify its position on the appropriate use of opiates and other controlled substances for the treatment of pain related distressing symptoms.

March 15, 1995.
Effective Date: April 21, 1995

ALASKA

Alaska State Medical Board
Source: Letter to Alaska Physicians dated June 22, 1993

WALTER J. HICKEL, GOVERNOR

DEPARTMENT OF COMMERCE AND ECONOMIC DEVELOPMENT

DIVISION OF OCCUPATIONAL LICENSING

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June 22, 1993

Dear Alaskan Physicians:

On October 8, 1992, the Alaska State Medical board heard complaints from patients and physicians that licensees were unsomfortable about prescribing narcotic analgesics. Discomfort arose from a fear that such prescribing might lead to disciplinary action from state or federal regulatory agencies.

Patients with documented diagnoses related stories of enduring pain due to underprescribing by practitioners. The board is sensitive to such issues. It recognized the impropriety of withholding necessary treatment in the form of narcotic analgesics at the expense of patient suffering. The board is providing the attached summary published by the Minnesota Board of Medical Examiners as a guideline for Alaska physicians as it pertains to prescribing practices.

The members of the Alaska State medical Board continue to be aware of uncertainty on the part of physicians regarding the medical board's intervention in the prescriptive use of DEA controlled substances. This memorandum is intended to clarify the responsibility of the Alaska State Medical Board when a complaint is received. Complaints come to board attention by way of patients, family members, friends, nurses, insurance companies, pharmacies, and other physicians.

When a complaint is filed, an investigation is mandatory. In the majority of cases, the complaints can be handled in an expeditious manner in the absence of apparent illegal or negligent medical practice. The case is then closed without further action.

When the DEA contacts the State Medical Board regarding a potential problem, a routine review often closed the case. The DEA performs computerized monitoring which may identify significant over-prescription of a given drug. A routine review of patient records, conducted by the board investigator in cooperation with the involved physician often results in case closure. On occasion, a board member may be requested to participate in the record review and recommendation process. When injudicious prescribing is recognized, the priorities of the State Medical board are those of patient protection, physician education, and rehabilitation.

The DEA publishes a booklet for physicians outlining the Controlled Substances Act. Copies of this publication, JUS-437, may be obtained from the DEA's Seattle Division Office, 220 West Mercer, Suite 301, Seattle Washington 98119; telephone (206) 442-5590. For further concerns of inquiries, contact the Executive Secretary, Caroline Stuart, telephone (907) 561-2878.

Attachment

STATE MEDICAL LICENSING BOARD

State of Alaska
Division of Occupational Licensing
3601 C Street, Suite 722
Anchorage, Alaska 99503

GUIDELINES FOR PRESCRIBING CONTROLLED SUBSTANCES

1. Perform a work up sufficient to support a diagnosis, including all necessary tests.

2. Document a treatment plan that includes the use of non-addictive modalities, and make referrals to specialists within the profession when indicated.

3. Document by history or clinical trial that non-addictive modalities are not appropriate or are ineffective.

4. Identify drug seeking patients. Review your records. If the patient is new, discuss drug and chemical use and family chemical history with the patient. If drug abuse is suspected, consider obtaining a chemical dependency evaluation or contacting local pharmacies.

5. Obtain informed consent of the patient before using a drug with the potential to cause dependency. Drug companies, the AMA, and other outlets provide printed material in layman's terms that can be used for patient education.

6. Monitor the patient. It is important to follow the patient for the primary condition that necessitates the drug, and for side effects of the drug, as well as the results of the drug. Drug holidays to evaluate for symptom recurrence or withdrawal are important.

7. Control the supply of the drug. Keep detailed records of the type, dose, and amount of the drug prescribed. Monitor, record, and control refills. Require the patient to return to obtain refill authorization at least part of the time. Records of cumulative dosage and average daily dosage are valuable.

8. Maintain contact with the patient's family as an objective source of information on the patient's response and compliance to the therapy.

9. Create an adequate record of care.

ARIZONA

Arizona State Board of Medical Examiners.
Source: Bomex Basics Num. 31, Nov. 1997, p. 4.
Approved Sept. 24, 1997.

GUIDELINES FOR PRESCRIBING CONTROLLED SUBSTANCES

The use of opioids for the treatment of chronic pain was recently addressed in a consensus statement from the American Academy of Pain Medicine and the American Pain Society. It states, in part,

> Pain is one of the most common reasons people consult a physician, yet it frequently is inadequately treated, leading to enormous social cost in the form of lost productivity, needless suffering, and excessive healthcare expenditures. Impediments to the use of opioids include [physician] concerns about [patient] addiction, respiratory depression and other side effects, tolerance, diversion, and fear of regulatory action.

The following guidelines have been developed to assist physicians in the proper management of patients with chronic pain while complying with statutory requirements for prescribing controlled substances, in order to address physician's concerns about regulating the prescribing of controlled substances.

I. Statutory ability to develop guidelines

Pursuant to Arizona Revised Statutes §32-1403(A)(3), the Board may develop and recommend standards governing the profession in Arizona. In developing these guidelines, the Board reviewed 18 guidelines developed by other states and agencies[1]. The purpose of these guidelines is to inform the public as to the standards the Board will use in reviewing prescribing cases.

II. Guidelines for Patient Care when prescribing controlled substances for chronic pain

A) Pain Assessment

Pain assessment should occur during initial evaluation, after each new report of pain, at appropriate intervals after each pharmacological intervention, and at regular intervals during treatment. Unless a patient is terminally ill and death is imminent (in which case the diagnosis is usually

evident and diagnostic evaluations may be of little value and discomforting to the patient), the evaluation should include:

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

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

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

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

B) Treatment Plan

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

i. Pain relief;
ii. Improved physical functioning;
iii. Proposed diagnostic evaluations (i.e., blood tests, radiologic, psychological and social studies such as CAT and bone scans, MRI and neurophysiologic examinations such as electromyography); and
iv. Analysis of inclusion and exclusion criteria for opioid management: Inclusion criteria includes a clear diagnosis consistent with symptoms, all reasonable alternative therapies have been explored; the patient is reliable and communicates well, there has been informed consent or a treatment agreement signed; Potential exclusion criteria include a history of chemical dependency, major psychiatric disorder, chaotic social situation, or a planned pregnancy.

C) Informed Consent

The physician should advise the patient, guardian, or designated surrogate of the risks and benefits of the use of controlled substances. The patient should be counseled on the importance of regular visits, the

impact of recreational drug use, the number of physicians and pharmacies used for prescriptions, taking medications as prescribed, etc.

D) Ongoing Assessment

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

E) Consultation

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

F) Documentation

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

Specific to chronic pain patients, the documentation should include:

i. The medical history and physical examination;
ii. Related evaluations and consultations, treatment plan and objectives;
iii. Evidence of discussion regarding informed consent;
iv. Prescribed medications and treatments;
v. Periodic reviews of treatments and patient response; and
vi. Any physician-patient agreements or contracts.

III. Compliance with Laws and Regulations

To prescribe controlled substances, physicians must comply with all applicable laws, including but not limited to the following:

A) Possess a valid current license to practice medicine in the State of Arizona;
B) Possess a valid and current controlled substances Drug Enforcement Administration registration for the schedules being prescribed;
C) If drugs are dispensed from the office, comply with Arizona Revised Statutes §32-1491 et. seq., and ACC R4-16-201 through R4-16-205.
D) If controlled substances are provided for detoxification, comply with 22 CFR 1306.07(a).

[1] Statutes were reviewed from the Alabama, Delaware and Texas Medical Boards; Policies were reviewed from the California, Colorado, Florida, Idaho, Minnesota, New Mexico, North Carolina, Ohio, Oregon, Rhode Island, Tennessee, and Vermont Medical Boards, as well as the Agency on Health Care Policy and Research, American Academy of Pain Management and American Pain Society, and the Arizona Pain Society/American Society of Anesthesiologist Task Force.

ARKANSAS

Regulations of the Arkansas State Medical Board

The Treatment of pain with dangerous drugs and controlled substances is a legitimate medical purpose when done in the usual course of medical practice. If the provisions as set out below in this Resolution are met, and if all drug treatment is properly documented, the Board will consider such practices as prescribing in a therapeutic manner, and prescribing and practicing medicine in a manner consistent with public health and welfare.

However, a physician who prescribes controlled substances or dangerous drugs (e.g. regulated drugs which commonly produce habituation) on a long-term basis (more than six (6) months) for a patient with intractable pain will be considered exhibiting gross negligence or ignorant malpractice unless he has complied with the following:

a. The physician will maintain a complete medical history and physical examination of the patient, to include an assessment of the pain, physical and psychological function, substance abuse history, assessment of underlying and co-existing diseases.

b. The physician will develop a treatment plan which would state the objectives by which treatment success can be evaluated, such as pain relief and/or improved physical or psychosocial function, and indicate if any further diagnostic evaluations or other treatments are planned.

c. The physician will obtain informed consent of the patient by discussing the risks and benefits of the use of controlled substances or dangerous drugs with the patient, his guardian or authorized representatives. The informed consent of the patient should be in writing and should be kept in the patient's file.

d. The physician should periodically review the course of schedule drug treatment of the patient and any new information about the etiology of the pain. If the patient has not improved, the physician should assess the appropriateness of continued prescribing of scheduled medications or dangerous drugs, or trial of other modalities.

e. The physician should be willing to refer the patient as necessary for additional evaluation and treatment in order to achieve treatment objectives. Physicians should give special attention to those intractable pain patients who are at risk for misusing their medications including those living arrangements that pose a risk for medication misuse or diversion.

f. The physician should keep accurate and complete records according to the items listed above, to include the medical history, physical examination, other evaluations and consultations, treatment plan objective, informed consent, treatment, medications given, agreements with the patient and periodic reviews.

g. The physician should be licensed appropriately in Arkansas and have a valid controlled substance registration and comply with the Federal and State regulations for the issuing of controlled substances and prescriptions, more especially the regulations as set forth in 21 Code of Federal Regulations Section 1300, et sequence.

Adopted March 13, 1997. (Amendment)

CALIFORNIA

Business and Professions Code
Section 2241.5 Intractable Pain Treatment Act

Section 2241.5. (a) Notwithstanding any other provision of law, a physician and surgeon may prescribe or administer controlled substances to a person in the course of the physician and surgeon's treatment of that person for a diagnosed condition causing intractable pain.

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

(c) No physician and surgeon shall be subject to disciplinary action by the board for prescribing or administering controlled substances in the course of treatment of a person for intractable pain.

(d) This section shall not apply to those persons being treated by the physician and surgeon for chemical dependency because of their use of drugs or controlled substances.

(e) This section shall not authorize a physician and surgeon to prescribe or administer controlled substances to a person the physician and surgeon knows to be using drugs or substances for nontherapeutic purposes.

(f) This section shall not affect the power of the board to deny, revoke, or suspend the license of any physician and surgeon who does any of the following:

(1) Prescribes or administers a controlled substance or treatment that is nontherapeutic in nature or nontherapeutic in the manner the controlled substance or treatment is administered or prescribed or is for a nontherapeutic purpose in a nontherapeutic manner.

(2) Fails to keep complete and accurate records of purchases and disposals of substances listed in the California Controlled Substances Act, or of controlled substances scheduled in, or pursuant to, the federal Comprehensive Drug Abuse Prevention and Control Act of 1970. A physician and surgeon shall keep records of his or her purchases and disposals of these drugs, including the date of purchase, the date and records of the sale or disposal of the drugs by the physician and surgeon, the name and address of the person receiving the drugs, and the reason for the disposal of or the dispensing of the drugs to the person and shall otherwise comply with all state recordkeeping requirements for controlled substances.

(3) Writes false or fictitious prescriptions for controlled substances listed in the California Controlled Substances Act or scheduled in the federal Comprehensive Drug Abuse Prevention and Control Act of 1970.

(4) Prescribes, administers, or dispenses in a manner not consistent with public health and welfare controlled substances listed in the California Controlled Substance Act or scheduled in the federal Comprehensive Drug Abuse Prevention and Control Act of 1970.

(5) Prescribes, administers, or dispenses in violation of either Chapter 4 (commencing with Section 11150) or Chapter 5 (commencing with Section 11210) of Division 10 of the Health and Safety Code or this chapter.

(g) Nothing in this section shall be construed to prohibit the governing body of a hospital from taking disciplinary actions against a physician and surgeon, as authorized pursuant to Sections 809.05, 809.4, and 809.5.

(Added by Stats.1990, c.1588 (S.B.1802), § 1.)

CALIFORNIA

California Medical Board
Source: Action Report. Vol. 51, pp. 1, 8-9, Oct. 1994.
Adopted May 6, 1994.

Text of "Guideline for Prescribing Controlled Substances for Intractable Pain"

PREAMBLE

On May 6, 1994, the Medical Board of California formally adopted a policy statement entitled "Prescribing controlled substances for pain." *(Action Report,* July 1994) The statement outlines the Board's proactive approach to improving appropriate prescribing for effective pain management in California, while preventing drug diversion and abuse. The policy statement is the product of a year of research, hearings and discussions. California physicians are encouraged to consult the policy statement and these guidelines.

The Medical Board recognizes that inappropriate prescribing of controlled substances including the opioids can lead to drug abuse and diversion. Inappropriate prescribing can also lead to ineffective management of pain, unnecessary suffering of patients and increased health care costs. The Board recognizes that some physicians do not treat pain properly due to lack of knowledge or concern about pain. Fear of discipline by the Board may also be an impediment to medically appropriate prescribing for pain. This Guideline is intended to encourage effective pain management in California, and help physicians reach a level of comfort about appropriate prescribing by clarifying the principles of professional practice that are endorsed by the Board.

"A HIGH PRIORITY"

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

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

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

Intractable pain is defined by law in California as: "a pain state in which the cause of the pain cannot be removed or otherwise treated and which in the generally accepted course of medical practice no relief or cure of the cause of the pain is possible or none has been found after reasonable efforts including, but not limited to, evaluation by the attending physician and surgeon and one or more physicians and surgeons specializing in the treatment of the area, system, or organ of the body perceived as the source of the pain." (Section 2241.5(b) California Business and Professions Code)

Physicians who prescribe opioids for intractable pain should not fear disciplinary action from any enforcement or regulatory agency in California if they follow California law (section 2241.5 (c)), which reads, "No physician and surgeon shall be subject to disciplinary action by the board for prescribing or administering controlled substances in the course of treatment of a person for intractable pain." Also, physicians should use sound clinical judgment, and care for their patients according to the following principles of responsible professional practice:

GUIDELINES

NEW, EASY GUIDELINES ON PRESCRIBING

Adopted unanimously by the Medical Board on July 29, 1994.

"No physician and surgeon shall be subject to disciplinary action by the board for prescribing or administering controlled substances in the course of treatment of a person for intractable pain."
-Business and Professions Code §2241.5(c)

1. HISTORY/PHYSICAL EXAMINATION

A medical history and physical examination must be accomplished. This includes an assessment of the pain, physical and psychological function, substance abuse history, assessment of underlying or coexisting diseases or conditions, and should also include the presence of a recognized medical indication for the use of a controlled substance. Prescribing controlled substances for intractable pain in California, as noted in the definition in the text of the Report, also requires evaluation by one or more specialists.

2. TREATMENT PLAN, OBJECTIVES

The treatment plan should state objectives by which treatment success can be evaluated, such as pain relief and/or improved physical and psychosocial function, and indicate if any further diagnostic evaluations or other treatments are planned. The physician should tailor drug therapy to the individual medical needs of each patient. Several treatment modalities or a rehabilitation program may be necessary if the pain has differing etiologies or is associated with physical and psychosocial impairment.

3. INFORMED CONSENT

The physician should discuss the risks and benefits of the use of controlled substances with the

patient or guardian.

4. PERIODIC REVIEW

The physician should periodically review the course of opioid treatment of the patient and any new information about the etiology of the pain. Continuation or modification of opioid therapy depends on the physician's evaluation of progress toward treatment objectives. If the patient has not improved, the physician should assess the appropriateness of continued opioid treatment or trial of other modalities.

5. CONSULTATION

The physician should be willing to refer the patient as necessary for additional evaluation and treatment in order to achieve treatment objectives. In addition, physicians should give special attention to those pain patients who are at risk for misusing their medications including those whose living arrangements pose a risk for medication misuse or diversion. The management of pain in patients with a history of substance abuse requires extra care, monitoring, documentation and consultation with addiction medicine specialists, and may entail the use of agreements between the provider and the patient that specify the rules for medication use and consequences for misuse.

6. RECORDS

The physician should keep accurate and complete records according to items 1-5 above, including the medical history and physical examination, other evaluations and consultations, treatment plan objectives, informed consent, treatments, medications, agreements with the patient, and periodic reviews.

7. COMPLIANCE WITH CONTROLLED SUBSTANCES LAWS AND REGULATIONS

To prescribe controlled substances, the physician must be appropriately licensed in California, have a valid controlled substances registration and comply with federal and state regulations for issuing controlled substances prescriptions. Physicians are referred to the Physicians Manual of the U.S. Drug Enforcement Administration and the Medical Board's Guidebook to Laws Governing the Practice of Medicine by Physicians and Surgeons for specific rules governing issuance of controlled substances prescriptions.

POSTSCRIPT

Under federal and state law, it is unlawful for a physician to prescribe controlled substances to a patient for other than a legitimate medical purpose (for example, prescribing solely for the maintenance of opioid addiction), or outside of professional practice (for example, prescribing without a medical examination of the patient). It is lawful to prescribe opioid analgesics in the course of professional practice for the treatment of intractable pain according to federal regulations and California Business and Professions Code Section 2241.5, the California Intractable Pain Treatment Act (CIPTA). However, the CIPTA does not apply to those persons being treated by the physician and surgeon for chemical dependency because of their use of drugs or controlled substances (Section 2241.5(d)), and does not authorize a physician or surgeon to prescribe or administer controlled substances to a person the practitioner knows to be using drugs or substances for nontherapeutic purposes (Section 2241.5(e)).

THE MISSION OF THE MEDICAL BOARD OF CALIFORNIA

The mission of the Medical Board of California is to protect consumers through proper licensing of physicians and surgeons and certain allied health professions and through the vigorous, objective enforcement of the Medical Practice Act.

CALIFORNIA

Medical Board of California
Action Report, July 1994, pp. 4-5.

A Statement by the Medical Board:

On May 6 the Medical Board formally adopted the following statement on "Prescribing Controlled Substances For Pain Management." It is the first formal statement of its kind in the nation made by a licensing board.

This statement was adopted after a year of testimony at hearings held by the Board's Task Force on Appropriate Prescribing and a day-long "Summit," sponsored by Governor Wilson, involving scores of experts from around the country.

At the Board's July 28-29 meeting the members will consider formal adoption of a set of guidelines based on this policy statement. The guidelines, once adopted, will be published in the October Action Report and other publications read by physicians.

INTRODUCTION

The 1993 report of the Medical Board to the Governor signalled a new beginning in the history of medical regulation in California. An important part of this initiative is implementation of the recommendations made by the Board's Task Force on Appropriate Prescribing, chaired by Jacqueline Trestrail, M.D.

The Task Force was established to look into "malprescribing," one of the fastest growing categories of physician discipline. The Board continues to be concerned that controlled substances are subject to abuse by individuals who seek them for their mood altering and other psychological effects, rather than for legitimate medical purposes.

The Board is also concerned about effective pain management and the appropriate medical use of controlled substances. During the Task Force's public meetings, the members heard testimony that some physicians avoid prescribing controlled substances, including the "triplicate" drugs, for patients with intractable pain for fear of discipline by the Board. The Task Force recommended that the Board take a pro-active approach to emphasize to all California physicians that it supports prescribing of opioid analgesics (narcotics) and other controlled substances when medically indicated for the treatment of pain, including intractable pain. After careful review of this matter, the Board concurs with the following statement.

This statement is consistent with good medical practice, protection of public health and consumer interests, with international treaties, federal and California law, including the California Intractable Pain Treatment Act.

THE PAIN PROBLEM

The Board recognizes that pain, whether due to trauma, surgery, cancer and other diseases, is often undertreated. Minorities, women, children, the elderly and people with HIV/AIDS are at particular risk for under treatment of their pain. Unrelieved pain has a harsh and sometimes disastrous impact on the quality of life of people and their families.

While some progress is being made to improve pain and symptom management, the Board is concerned that a number of factors continue to interfere with effective pain management. These include the low priority of pain management in our health care system, incomplete integration of current knowledge into medical education and clinical practice, lack of knowledge among consumers about pain management, exaggerated fears of opioid side effects and addiction, and fear of legal consequences when controlled substances are used.

PAIN MANAGEMENT SHOULD BE A HIGH PRIORITY IN CALIFORNIA

Principles of quality medical practice dictate that citizens of California who suffer from pain should be able to obtain the relief that is currently available. The Board believes that the appropriate application of current knowledge and treatments would greatly improve the quality of life for many California citizens, and could also reduce the morbidity and the costs that are associated with uncontrolled pain.

In addition to making this statement, the Board will take a number of steps to help make effective pain management a reality in California. The Board has provided information to all state physicians about new clinical practice guidelines for pain management that have been prepared by a panel of experts supported by the Agency for Health Care Policy and Research. The Board also co-sponsored and participated in the March 18, 1994 Pain Management and Appropriate Prescribing Summit in conjunction with the Department of Consumer Affairs on removing impediments to appropriate prescribing of controlled substances for effective pain management. Further, the Board will develop guidelines to help physicians avoid investigation if they appropriately prescribe controlled substances for pain management.

Prescribing Controlled Substances for Pain

THE APPROPRIATE ROLE OF OPIOID ANALGESICS

There are numerous drug and non-drug treatments that are used for the management of pain and other symptoms. The proper treatment of any patient's pain depends upon a careful diagnosis of the etiology of the pain, selection of appropriate and cost-effective treatments, and ongoing evaluation of the results of treatment. Opioid analgesics and other controlled substances are useful for the treatment of pain, and are considered the cornerstone of treatment of acute pain due to trauma, surgery and chronic pain due to progressive diseases such as cancer. Large doses may be necessary to control pain if it is severe. Extended therapy may be necessary if the pain is chronic.

The Board recognizes that opioid analgesics can also be useful in the treatment of patients with intractable non-malignant pain especially where efforts to remove the cause of pain or to treat it with other modalities have failed. The pain of such patients may have a number of different etiologies and may require several treatment modalities. In addition, the extent to which pain is associated with physical and psychosocial impairment varies greatly. Therefore, the selection of a patient for a trial of opioid therapy should be based upon a careful assessment of the pain

as well as the disability experienced by the patient. Continuation of opioid therapy should be based on the physician's evaluation of the results of treatment, including the degree of pain relief, changes in physical and psychological functioning, and appropriate utilization of health care resources. Physicians should not hesitate to obtain consultation from legitimate practitioners who specialize in pain management.

The Board recommends that physicians pay particular attention to those patients who misuse their prescriptions, particularly when the patient or family have a history of substance abuse that could complicate pain management. The management of pain in such patients requires extra care and monitoring, as well as consultation with medical specialists whose area of expertise is substance abuse or pain management.

The Board believes that addiction should be placed into proper perspective. Physical dependence and tolerance are normal physiologic consequences of extended opioid therapy and are not the same as addiction. Addiction is a behavioral syndrome characterized by psychological dependence and aberrant drug-related behaviors. Addicts compulsively use drugs for non-medical purposes despite harmful effects; a person who is addicted may also be physically dependent or tolerant. Patients with chronic pain should not be considered addicts or habitues merely because they are being treated with opioids.

PAIN MANAGEMENT, CONTROLLED SUBSTANCES AND THE LAW

The laws and regulations of the federal government and the State of California impose special requirements for the prescribing of controlled substances, including requirements as to the form of the prescription document, so as to prevent harm to the public health that is caused when prescription drugs are diverted to non-medical uses. For example, it is illegal to prescribe controlled substances solely to maintain narcotic addiction. However, federal and California law clearly recognize that it is a legitimate medical practice for physicians to prescribe controlled substances for the treatment of pain, including intractable pain.

The Medical Board will work with the Drug Enforcement Administration, the Bureau of Narcotic Enforcement, the Office of the Attorney General, the Board of Pharmacy and its own investigators in an attempt to develop policy and guidelines based on the physician's diagnosis and treatment program rather than amounts of drugs prescribed.

Concerns about regulatory scrutiny should not make physicians who follow appropriate guidelines reluctant to prescribe or administer controlled substances, including Schedule II drugs, for patients with a legitimate medical need for them. A physician is not subject to Board action when prescribing in the regular course of his or her profession to one under the physician's treatment for a pathology or condition and where the prescription is issued after a good faith examination and where there is medical indication for the drug. Good faith prescribing requires an equally good faith history, physical examination and documentation.

The Medical Board may identify a pattern of controlled substance use that merits further examination. A private, courteous and professional inquiry can usually determine whether the physician is in good faith appropriately prescribing for patients, or whether an investigation is necessary. The Board will judge the validity of prescribing based on the physician's diagnosis and treatment of the patient and whether the drugs prescribed by the physician are appropriate for that condition, and will not act on the basis of predetermined numerical limits on dosages or length of drug therapy.

The Board hopes to replace practitioners' perception of inappropriate regulatory scrutiny with recognition of the Board's commitment to enhance the quality of life of patients by improving pain management while, at the same time, preventing the diversion and abuse of controlled substances.

COLORADO

Colorado State Statutes
Title 18: Criminal Code
Article 18: Uniform Controlled Substances Act
Part 3: Regulation of Manufacture, Distribution, and Dispensing of Controlled Substances

Section 18-18-308

(1) As used in this section, "medical treatment" includes dispensing or administering a narcotic drug for pain, including intractable pain.

(2) A person may dispense a controlled substance only as provided in this section.

(3) Except when dispensed directly by a practitioner, other than a pharmacy, to an ultimate user, a substance included in schedule II may not be dispensed without the written prescription of a practitioner.

(4) Except when dispensed directly by a practitioner, other than a pharmacy, to an ultimate user, a substance included in schedule III, IV, or V may not be dispensed without a written or oral prescription order of a practitioner. The prescription order must not be filled or refilled more than six months after the date thereof or be refilled more than five times.

(5) A practitioner may dispense or deliver a controlled substance to or for an individual or animal only for medical treatment or authorized research in the ordinary course of that practitioner's profession.

(6) No civil or criminal liability or administrative sanction may be imposed on a pharmacist for action taken in reliance on a reasonable belief that an order purporting to be a prescription was issued by a practitioner in the usual course of professional treatment or in authorized research.

Source: L. 92: Entire article R&RE, p. 353, § 1, effective July 1. L.96 amended, p. 1427, § 17, effective July 1.

COLORADO

HOUSE BILL 97-1188

An Act

BY REPRESENTATIVES Dean, Faatz, Morrison, Bacon, Clarke, Epps, Keller, Kreutz, Lamborn, Leyba, Mace, Paschall, Tucker, Tupa, Udall, and Veiga; also SENATORS Wattenberg, Bishop, Chlouber, Hernandez, J. Johnson, Linkhart, Martinez, Pascoe, Phillips, Rupert, and Wham.

CONCERNING THE PROHIBITION OF DISCIPLINING A PHYSICIAN SOLELY FOR THE PRESCRIPTION OF MEDICATIONS TO TREAT INTRACTABLE PAIN.

Be it enacted by the General Assembly of the State of Colorado:

SECTION 1. 12-36-117, Colorado Revised Statutes, 1991 Repl. Vol., as amended, is amended BY THE ADDITION OF A NEW SUBSECTION to read:

12-36-117. Unprofessional conduct. (1.5) (a) A physician shall not be subject to disciplinary action by the Board solely for prescribing controlled substances for the relief of intractable pain.

(b) For the purposes of this subsection (1.5), "intractable pain" means a pain state in which the cause of the pain cannot be removed and which in the generally accepted course of medical practice no relief or cure of the cause of the pain is possible or none has been found after reasonable efforts including, but not limited to, evaluation by the attending physician and one or more physicians specializing in the treatment of the area, system, or organ of the body perceived as the source of the pain.

SECTION 2. Effective date - applicability. This act shall take effect at 12:01 a.m. on the day following the expiration of the ninety-day period after final adjournment of the general assembly that is allowed for submitting a referendum petition pursuant to article V, section 1 (3) of the state constitution; except that, if a referendum petition is filed against this act or an item, section, or part of this act within such period, then the act, item, section, or part, if approved by the people shall take effect of the date of the official declaration of the vote thereon by proclamation of the governor. This act shall apply to disciplinary actions originating on or after the effective date of this act.

Approved April 21, 1997.
Effective August 6, 1997.

COLORADO

Colorado State Board of Medical Examiners
Source: The Examiner, Vol. 5, num. 2, Aug. 1996.
Adopted May 16, 1996

GUIDELINES FOR PRESCRIBING CONTROLLED SUBSTANCES FOR INTRACTABLE PAIN

ADOPTED 05/16/96

COLORADO BOARD OF MEDICAL EXAMINERS

INTRODUCTION

The Colorado Board of Medical Examiners (CBME) strongly urges physicians to view effective pain management as a high priority in all patients. Minorities, women, children, the elderly, and people with HIV/AIDS are at particular risk for under treatment of their pain.

Pain should be assessed and treated promptly, effectively, and for as long as pain persists. The medical management of pain should be based on up-to-date knowledge about pain, pain assessment, and pain treatment. Pain treatment may involve the use of several drug and non-drug treatment modalities, often in combination. For some types of pain, the use of drugs is emphasized and should be pursued vigorously; for other types, the use of drugs is better de-emphasized in favor of other therapeutic modalities. Physicians should have sufficient knowledge or consultation to make such judgements for their patients.

The Board recognizes that inappropriate prescribing of controlled substances, including opiates, can lead to drug abuse and diversion. Inappropriate prescribing can also lead to ineffective management of pain, unnecessary suffering of patients, and increased health care costs. Concerns about regulatory scrutiny should not make physicians who follow appropriate guidelines reluctant to prescribe or administer substances for patients with a legitimate medical need for them.

Drugs, particularly the opioid analgesics, are considered the cornerstone of treatment for pain associated with trauma, surgery, medical procedures, and cancer. Large doses may be necessary to control pain if it is severe, and extended therapy may be necessary if the pain is chronic. The CBME firmly believes that physicians have a duty to provide maximal comfort levels and alleviate suffering in their dying patients in a skillful and compassionate manner. The Board is concerned that fear on the part of physicians may result in ineffective pain control and unnecessary suffering in terminal patients. Physicians are referred to the U.S. Agency for Health Care Policy and Research Clinical Practice Guidelines, which reflect a sound yet flexible approach to the management of these types of pain.

The prescribing of opioid analgesics for patients with intractable non-cancer pain may also be

beneficial. Intractable pain is defined as pain in which the cause cannot be removed or otherwise treated and no relief or cure has been found after reasonable efforts, including evaluation by one or more physicians specializing in the treatment of the area of the body perceived as the source of the pain. Physicians who prescribe opiates for intractable pain should not fear disciplinary action from any enforcement or regulatory agency in Colorado if they use sound clinical judgment and care for their patients according to the following principles of responsible professional practice.

GUIDELINES FOR PRESCRIBING CONTROLLED SUBSTANCES FOR CHRONIC NON-MALIGNANT PAIN

Guidelines do not have the legal status of laws and regulations, but guidelines can explain what activities the Medical Board considers to be within the boundaries of professional practice. Guidelines alert licensees to unprofessional practices of concern to the Board and give physicians practical information about how to avoid these problems.

1. HISTORY/PHYSICAL EXAMINATION/ASSESSMENT

A medical history and physical examination documenting the presence of a recognized medical indication for the use of a controlled substance must be performed. This includes an assessment of the pain, physical and psychological function, substance abuse history, and assessment of underlying or coexisting diseases or conditions. A statement of alternative strategies used for managing the pain and why these modalities are inappropriate or ineffective, as well as a summary of the evaluations performed by one or more specialists, should be included.

2. TREATMENT PLAN/OBJECTIVES

The treatment plan should state objectives by which treatment success can be evaluated. This may include: and ongoing assessment of the patient's functional status, including the ability to engage in work or other gainful activities; patient consumption of health care resources; positive answers to specific questions about the pain intensity and its interference with activities of daily living; quality of family life and social activities; and physical activity of the patient as observed by the physician. The plan should indicate if any further diagnostic evaluations or other treatments are planned. The physician should tailor drug therapy to the individual medical needs of each patient. Several treatment modalities or a rehabilitation program may be necessary if the pain has differing etiologies or is associated with physical and psychosocial impairment.

3. INFORMED CONSENT

The physician should discuss the risks and benefits of the use of controlled substances with the patient or guardian. A written consent is strongly advised when using drugs with a high dependence/tolerance potential.

4. PERIODIC REVIEW

The physician should periodically review the course of treatment of the patient and any new information about the etiology of progress toward treatment objectives. If the patient has not

stabilized, the physician should assess the appropriateness of continued treatment with controlled substances.

The physician is responsible for monitoring the dosage of controlled substances to ensure that it does not escalate over time without maintenance of the patient's function. Monitoring also includes ongoing assessment of patient compliance with the controlled prescribing practice of the physician. Utilization of a single prescribing physician and a single pharmacy is advised.

5. CONSULTATION

The physician should be willing to refer the patient as necessary for additional evaluation and treatment in order to achieve treatment objectives. In addition, physicians should give special attention to those pain patients who are at risk for misusing their medications, including those whose living arrangements pose a risk for medication misuse or diversion. The management of pain in patients with a history of substance abuse requires extra care, monitoring, documentation, and ongoing consultation with an addiction medicine specialist.

6. RECORDS

The physician should keep accurate and complete records according to items 1-5 above. The physician should keep detailed records of each drug dosage, amount, and number of refills. Again, the use of a single prescribing physician and a single pharmacy is advised.

A written contract is recommended, which includes: contingencies for management of pain exacerbations; substance abuse; loss of prescriptions; misuse of medications; and noncompliance with treatment.

7. COMPLIANCE WITH CONTROLLED SUBSTANCES LAWS AND REGULATIONS

To prescribe controlled substances, the physician must be appropriately licensed in Colorado, have a valid controlled substances registration, and comply with federal and state regulations for issuing controlled substances prescription.

Under federal and state law, it is unlawful for a physician to prescribe controlled substances to a patient for other than a legitimate medical purpose (i.e., prescribing opiates for the treatment of opioid addiction without a specialized license), or outside of professional practice (i.e., prescribing without a medical examination of the patient). The law does not allow the physician to prescribe or administer controlled substances to a person the physician knows to be using drugs or substances for non-therapeutic purposes.

It is lawful to prescribe opioid analgesics in the course of professional practice for the treatment of intractable pain.

8. ADDICTION VERSUS PHYSICAL DEPENDENCE

Addiction should be placed into proper perspective. Physical dependence and tolerance are normal physiologic consequences of extended opioid therapy and are not the same as addiction. Addiction is a behavioral syndrome characterized by psychological dependence and aberrant drug-related behaviors. Addicts compulsively use drugs for non-medical purposes despite harmful effects; a person who is addicted may also be physically dependent or tolerant. Patients with chronic pain should not be considered addicts merely because they are being treated with opiates.

CONCLUSION

The Board hopes to replace practitioners' perception of inappropriate regulatory scrutiny with recognition of the Board's commitment to enhance the quality of life of patients by improving pain management while, at the same time, preventing the diversion and abuse of controlled substances.

The Colorado Board of Medical Examiners wishes to acknowledge the work of the State Boards of California, Ohio, Oregon, Texas and Washington, upon which these guidelines are based.

FLORIDA

Florida Statutes.
Chapter 458: Medical Practice

Section 458.326. Intractable pain; authorized treatment.
(1) For the purposes of this section, the term "intractable pain" means pain for which, in the generally accepted course of medical practice, the cause cannot be removed and otherwise treated.
(2) Intractable pain must be diagnosed by a physician licensed under this chapter and qualified by experience to render such diagnosis.
(3) Notwithstanding any other provision of law, a physician may prescribe or administer any controlled substance under Schedules II-V, as provided for in s. 893.03, to a person for the treatment of intractable pain, provided the physician does so in accordance with that level of care, skill, and treatment recognized by a reasonably prudent physician under similar conditions and circumstances.
(4) Nothing in this section shall be construed to condone, authorize, or approve mercy killing or euthanasia, and no treatment authorized by this section may be used for such purpose.

Added by Laws 1994, c. 94-96, § 3, effective April 8, 1994.

FLORIDA

Florida Board of Medicine, Board of Osteopathic Medicine, Agency for Health Care Administration
Source: Provided by the Florida Board of Medicine to the PPSG
Adopted: October 25, 1996

FLORIDA GENERIC CLINICAL PRACTICE GUIDELINE
MANAGEMENT OF PAIN
USING DANGEROUS DRUGS AND CONTROLLED SUBSTANCES

PART I
PREFACE

The State of Florida recognizes that pain, including intractable pain, is often undertreated. Unrelieved pain can have harsh and sometimes disastrous influence on the quality of life for patients and their families.

PAIN MANAGEMENT SHOULD BE A HIGH PRIORITY IN FLORIDA

Principles of quality medical practice dictate that citizens of Florida who suffer from pain should seek relief with treatment that is currently available. The appropriate application of current knowledge and treatments can greatly improve the quality of life for many Florida citizens and reduce the morbidity and costs associated with untreated pain.

In addition to promoting competent patient care, these guidelines are intended to help physicians avoid investigation if controlled substances are appropriately prescribed for short or long-term pain management.

PRESCRIBING DANGEROUS DRUGS AND CONTROLLED SUBSTANCES FOR PAIN

The proper treatment for any patient's pain depends upon a careful diagnosis of the etiology of the pain, selection of appropriate and cost effective treatments and the ongoing evaluations of the results of treatment. Patients with chronic pain may demand more time of the practitioner because of the complexity of their problem.

Opioid analgesics and other dangerous and controlled substances are useful for pain treatment. They are the cornerstone of treatment for acute pain due to trauma or surgery and of chronic pain due to progressive diseases, such as cancer. Other than that specified in the Physician's Desk Reference (PDR), large doses, if documented, may be necessary to control severe pain. Extended therapy may also be needed to alleviate chronic pain. Published formularies, relating to commercial financial incentives, should not be a deterrent to achieving optimal pain relief.

Opioid analgesics may also be useful in treating patients with intractable nonmalignant pain especially when efforts to remove or treat the pain with other modalities have failed. Such intractable pain may have a number of different etiologies and might require several treatment methods. In addition, the extent to which pain is associated with physical and psychosocial

impairment varies greatly. Therefore, when patients are selected for therapy trials using dangerous drugs and opioid therapy, care should be used to assess the pain as well as the patient's disability. The duration of drug therapy should depend on the physician's evaluation of the results of treatment, including the degree of pain relief, the changes in physical and psychological functioning and the appropriate utilization of health care resources.

Addiction in relation to these substances should be placed in proper perspective. Physical dependence and tolerance are normal physiological consequences of extended opioid therapy and are not the same as addiction. Addiction is a behavioral syndrome characterized by psychological dependence and aberrant, drug-related behaviors. Addicts use drugs in a compulsive manner and not for medical purposes. An addict may also be physically dependent or tolerant. Patients with chronic pain should not be considered addicts merely because they are being treated with opioids. Physicians need to be cognizant of the fact that patients with a history of drug abuse may be particularly problematic to the management of pain.

PAIN MANAGEMENT, CONTROLLED SUBSTANCES AND THE LAW

Federal government laws and regulations and those of the State of Florida impose special requirements for dangerous drugs and controlled substances prescription. These regulations are aimed at preventing harm to the consumer from dangerous prescription drugs which are diverted to nonmedical uses. It is legitimate medical practice for physicians to prescribe controlled substances for the treatment of pain, including intractable pain.

The Agency for Health Administration supports the examination of prescriptions for analgesics and opioids for the treatment of pain. This examination must be based on the documented diagnosis and treatment rather than on the drug dosage or on the number of prescriptions written.

Concerns about regulatory scrutiny should not cause physicians to be reluctant to prescribe or administer dangerous and controlled substances, including Schedules II-V drugs as provided for in Florida Statutes s. 893.03, for patients with legitimate medical needs. Physicians need not fear administrative action when prescribing dangerous drugs and controlled substances to patients in their care for a pathology or condition when the prescription is issued after a good faith examination and there is medical indication for the prescription.

The regulatory boards may identify a pattern of dangerous and controlled substance use which merits further examination, but private, courteous and professional inquiry can usually determine whether the physician is appropriately prescribing for patients in good faith or whether an investigation is warranted. The Florida Board of Medicine and the Florida Board of Osteopathic Medicine must judge the prescription validity relative to the physician's documented diagnosis and treatment and if the prescribed drugs are appropriate for the patient's condition. Predetermined limits should not be placed on dosages or length of drug therapy.

It is the goal of the Agency for Health Care Administration to change practitioner perception of regulatory scrutiny and recognize the commitment of regulatory boards to improving pain management in order to enhance the quality of lives of pain-affected patients in Florida. Federal and State laws and regulatory policies should not hamper the appropriate use of dangerous drugs and controlled substances for the relief of pain.

DEFINITIONS

INTRACTABLE PAIN - A pain state in which the cause of the pain cannot be removed or otherwise treated and which, in the generally accepted course of medical practice, no relief or cure of the cause of the pain is possible or none has been found after reasonable efforts.

NONTHERAPEUTIC USE - A medical use or purpose that is not legitimate in nature or in manner.

ABUSER OF NARCOTIC DRUGS, CONTROLLED SUBSTANCES AND DANGEROUS DRUGS - An individual who takes a drug or drugs for other than legitimate medical purposes.

1. The treatment of pain, including intractable pain, with dangerous drugs and controlled substances has a legitimate medical purpose when performed in the usual course of medical practice.

2. Physicians duly authorized to practice under their respective practice act and to prescribe controlled substances and dangerous drugs in Florida, shall not be subject to disciplinary action by their respective licensure board for prescribing, ordering, administering or dispensing dangerous drugs or controlled substances for the treatment and relief of pain, including intractable pain, in the usual course of professional practice for a legitimate medical purpose in compliance with applicable state and federal law.

3. The prescribing, ordering, administering or dispensing of dangerous drugs or controlled substances for pain will be considered to be for a legitimate medical purpose if based upon scientific knowledge of the treatment of pain, including intractable pain, and are not in contravention of applicable state and federal law, and if prescribed, ordered, administered or dispensed in compliance with the following guidelines where appropriate and as is necessary to meet the individual needs of the patient.

A physician will be considered in compliance if:

a. The medication is prescribed after a documented patient history and physical examination by the physician prescribing or providing the medication, which includes: an assessment and consideration of the physical and psychological impact of the pain, any patient history or potential for substance abuse, for coexisting diseases and conditions and the prescience of a recognized medical indication for the use of a dangerous drug or controlled substance.

b. If medications are prescribed pursuant to a written treatment plan tailored for the individual needs of the patient and if treatment progress and success can be evaluated with stated objectives such as pain relief and improved physical and psychosocial function. Such a written treatment plan will consider pertinent medical history and physical examination as well as the need for further testing, consultations, referrals or the use of other treatment modalities.

c. The physician should discuss with the patient, significant other(s) or legal guardian, if appropriate, the risks, i.e. narcotic bowel syndrome (information attached),

addiction and other side effects in comparison to the benefits from the use of dangerous and controlled substances.

d. The patient will be subject to documented periodic review of the care by the physician at reasonable intervals and in view of the individual circumstances of the patient in regard to progress toward reaching the stated objectives. The review will take into consideration the course of medications prescribed, ordered, administered or dispensed, as well as any new information about the etiology of the pain.

e. Complete and accurate records of the care provided are kept as set forth in a-d, above. When controlled substances are prescribed, records are made which include names, quantities prescribed, dosages and number of authorized refills. This record takes into account that pain-affected patients with a history of substance abuse, or patients who live in an environment that may pose a risk for medication misuse or diversion, may require special consideration. Management of these patients may warrant closer monitoring by the physician managing the pain and require consultation with appropriate health care professionals.

4. A physician's decision not to adhere strictly to the provisions of number 3. above, will not if "good faith or cause" is shown, constitute grounds for board disciplinary action. Each case of prescribing for pain will be evaluated on an individual basis. The physician's conduct will be evaluated to a great extent by the treatment outcome, taking into account: 1/ whether the drug used is medically or pharmacologically recognized to be appropriate for the diagnosis, 2/ the patient's individual needs, including any improvement in functioning, and 3/ recognizing that some types of pain cannot be completely relieved.

5. If the provisions set out in numbers 1-4, above, are met, and if all drug treatment is properly documented, the board will consider such practices as prescribing in a therapeutic manner, and as prescribing and practicing in a manner consistent with public health and welfare.

6. Quantity of pharmaceutical and chronicity of the prescription will be evaluated on the basis of the documented appropriate diagnosis and treatment of the recognized medical indication. Documented persistence of the recognized medical indication, and properly documented follow-up evaluations with appropriate continuing care as set out in these guidelines, will also be evaluated.

7. A physician may use any number of treatment modalities for the treatment of pain, including intractable pain, which are consistent with legitimate medical purposes.

GEORGIA

Georgia Composite State Board of Medical Examiners
Source: Article provided by the Georgia Composite State Medical Board Examiners to the PPSG

GEORGIA COMPOSITE STATE BOARD OF MEDICAL EXAMINERS

To All Doctors Licensed to Practice Medicine in Georgia:

If you don't have time to read this article now, we request that you read it later.

Management of Prescribing with Emphasis on
Addictive or Dependence-Producing Drugs

The Georgia Board of Medical Examiners is charged by law to protect the citizens of the State from harmful physician management. A significant number of physicians who are asked to appear before the Board are required to do so because of their lack of information about the management and responsibilities involved in prescribing controlled substances. Frequently, the inadvertent offender is a physician with a warm heart and a desire to relieve pain and misery, who is always pressed for time and finds himself prescribing controlled drugs on demand over prolonged periods without adequate documentation. These are often for chronic ailments such as headache, arthritis, old injuries, chronic orthopedic problems, backache and anxiety. (Terminal cancer pain management is not a consideration here.) The purpose of the Board of Medical Examiners in presenting the following information is to help licensed physicians in Georgia consider and reevaluate their prescribing practice of controlled substances. Practicing physicians who become new Board members have often mentioned the abrupt education they received in their own prescribing patterns. Moreover, there have been many requests to the Board from physicians for detailed information on prescribing in certain specific situations.

It's not what you prescribe, but how well you manage the patient's care and document that care in legible form, that's important.

The prescribing matters that come before the Board are almost always related to the prescription of controlled substances. We feel that a majority of instances where physicians have been disciplined by the Board for prescribing practices could have been avoided completely if they followed the steps that are being outlined here.

To prevent any misunderstanding, it's necessary to state what the Board does not have.

It does not have a list of "bad" or "disallowed" drugs. All formulary drugs are good if prescribed and administered when properly indicated. Conversely, all drugs are ineffective, dangerous, or even lethal when used inappropriately.

It does not have some magic formula for determining the dosage and duration of administration

for any drug. These are aspects of prescribing that must be determined within the confines of the individual clinical case, and continued under proper monitoring. What's good for one patient may be insufficient or fatal for another.

What the Board does have is the expectation that physicians will create a record that shows:

-Proper indication for the use of drug or other therapy
-Monitoring of the patient where necessary
-The patient's response to therapy on follow-up visits
-All rationale for continuing or modifying the therapy

STEP ONE
First and foremost, before you prescribe anything, start with a diagnosis which is supported by history and physical findings, and by the results of any appropriate tests. Too many times a doctor is asked why he or she prescribed a particular drug, and the response is, "Because the patient has arthritis." Then the doctor is asked, "How did you determined that?", and the answer is "Because that's what the patient complained of". Nothing in the record or in the doctor's recollection supports the diagnosis except the patient's assertion. Do a workup sufficient to support a diagnosis, including all necessary tests.

STEP TWO
Create a treatment plan which includes the use of appropriate non-addictive modalities, and make referrals to appropriate specialists, such as neurologists, orthopedists, psychiatrists, etc. The results of the referral should be included in the patient's chart.

STEP THREE
Before beginning a regimen of controlled drugs, make a determination through trial or through a documented history that non-addictive modalities aren't appropriate or they don't work. A finding of intolerance or allergy to Non Steroidal Anti Inflammatory Drugs is one thing, but the assertion of the patient that, "Gosh, doc, nothing seems to work like that Percodan stuff!" is quite another. Too many of the doctors the Board has seen have started a treatment program with powerful controlled substances without ever considering other forms of treatment.

STEP FOUR
Make sure you are not dealing with a drug-seeking patient. If you know the patient, review the prescription records in the patient's chart and discuss the patient's chemical history before prescribing a controlled drug. If the patient is new or otherwise unknown to you, at a minimum obtain an oral drug history, and discuss chemical use and family chemical history with the patient.

STEP FIVE
It's a good idea to obtain the informed consent of the patient before using a drug that has the potential to cause dependency problems. Take the time to explain the relative risks and benefits of the drug and record in the chart the fact that this was done. When embarking on what appears to be the long term use of a potentially addictive substance, it may be wise to hold a family conference and explain the relative risks of dependency or addiction and what that may mean to the patient and to the patient's family.

Refusal of the patient to permit a family conference may be significant information.

STEP SIX

Maintain regular monitoring of the patient, including frequent physical monitoring. If the regimen is for prolonged drug use, it is very important to monitor the patient for the root condition which necessitates the drug, and for the side effects of the drug itself. This is true no matter what type of controlled substance is used or what schedule it belongs to. Also, remember that with certain conditions, drug holidays are appropriate. This allows you to check to see whether the original symptoms recur when the drug is not given - indicating a continuing legitimate need for the drug or whether withdrawal symptoms occur - indicating drug dependence.

STEP SEVEN

Make sure YOU are in control of the supply of the drug. To do this, at a minimum you must keep detailed records of the type, dose, and amount of the drug prescribed. You must also monitor, record and personally control all refills. Do not authorize your office personnel to refill prescriptions without consulting you. One good way to accomplish this is to require the patient to return to obtain refill authorization, at least part of the time. Records of cumulative dosage and average daily dosage are especially valuable. A thumbnail sketch of three cases will illustrate our point here. In the first case, a physician prescribed Tussionex to a patient for approximately five years for a cumulative dosage of nineteen and one half gallons. In the second case, a physician prescribed Tylenol 3's to a patient for slightly more than a year at the average rate of 30 per day! The third case is very similar, except it was Tylenol 4's at the rate of 20 per day. Some quick observations:

-No physician who was aware of that kind of prescribing would have continued with it.
-Few, if any patients could have been consuming that much Tylenol with codeine. In all likelihood, they were selling it.

Another important part of controlling the supply of drugs is to check on whether the patient is obtaining drugs from other physicians. Checking with pharmacies and pharmacy chains may tell whether a patient is obtaining extra drugs or is doctor shopping. It is a felony in Georgia for a patient to fail to disclose to his physician that he has received controlled substances of a similar therapeutic use from another practitioner at the same time. If you are aware of this occurring, contact your local police, the State Drugs and Narcotics Agency or the Board of Medical Examiners.

STEP EIGHT

Maintaining regular contact with the patient's family is a valuable source of information on the patient's response to the therapy regimen, and may be much more accurate and objective than feedback from the patient alone.

The family is a much better source of information on behavioral changes, especially dysfunctional behavior, than is the patient. Dysfunctional changes may be observable when the patient is taking the drug, or when the drug is withdrawn. These changes, at either time, may be symptoms of the dependency or addiction.

The family is also a good source of information on whether the patient is obtaining drugs from other sources, or is self-medicating with other drugs or alcohol.

STEP NINE

To reiterate, one of the most frequent problems faced by a physician when he or she comes before the Board or other outside review bodies is inadequate records. It's entirely possible that the doctor did everything correctly in managing a case, but without records which reflect all the steps that went into the process, the job of demonstrating it to any outside reviewer becomes many times more difficult. Luckily, this is a problem which is solvable.

IDAHO

Idaho State Board of Medical Examiners
Source: State Pamphlet entitled, "Guidelines Prescribing Opioids for Chronic Pain", Mar. 1997.

Guidelines
Prescribing Opioids for Chronic Pain

Idaho State Board of Medicine
P.O. Box 83720
Boise, ID 83720-0058

The prescription of opioid medications, (narcotics), often poses a difficult problem for the practitioner. The Board of Medicine remains concerned about the potential for abuse of narcotics by those patients who use these medications for their mood altering or psychological effects. At the same time the Board recognizes that effective pain management is one of the most important benefits that modern medicine can provide.

Physicians should not hesitate to treat aggressively the pain of acute trauma, surgery, or malignancy with narcotics. However, the use of narcotics for the treatment of chronic nonmalignant pain is more problematic. Some patients may divert drugs for illicit use. On the other hand, there exists a subset of patients with chronic pain for which regular use of narcotics is appropriate. In this group narcotics can provide safe and effective pain relief with little risk of addiction or abuse.

Addiction is a behavioral syndrome characterized by psychological dependence and aberrant drug-related behaviors, including drug seeking behavior. Addicts compulsively use drugs for their psychological effects in spite of the attendant harm that may accompany their use. Addiction does not invariably occur with continued use of narcotics and differs fundamentally from tolerance and physical dependence which are normal physiological consequences of chronic opioid therapy.

Candidates for chronic opioid therapy need to be selected very carefully. Most important, a cause for the chronic pain must be carefully sought. In all cases treatment of the root problem should be attempted before consideration of chronic opioid therapy. Non-opioid medication alternatives should be utilized whenever possible. Consultation with an appropriately qualified specialist should precede institution of routine opioid therapy. The practitioner needs to be aware that daily use of narcotics may, in fact, aggravate some chronic pain conditions.

When the patient is started on routine opioid treatment, the patient must be accountable and must understand that the prescriptions will be carefully monitored. Aberrant drug seeking

behaviors should not be tolerated. The doctor and patient must commit to regular office visits to monitor for effectiveness of the treatment regimen and to screen for behaviors that may suggest drug abuse. Legible and thoughtful documentation is mandatory.

The Board recommends that physicians pay particular attention to those patients who misuse their prescriptions, particularly when the patient or family has a history of substance abuse that could complicate pain management. The management of chronic nonmalignant pain requires extra care and monitoring; as well as consultation with medical specialists, whose area of expertise is substance abuse or pain management.

It is illegal to prescribe controlled substances solely to maintain narcotic addiction. However, under appropriate circumstances, physicians should not be reluctant to prescribe or administer controlled substances for patients with legitimate medical needs.

From time to time the Board may identify a pattern of controlled substance use that merits further investigation. The Board will judge the appropriateness of prescribing on the basis of the diagnosis and treatment of the patient documented in the patient record, not upon an arbitrary perception of excessive prescribing.

Narcotic medications and other controlled substances are an important part of the modern pharmacopoeia. A problem arises when they are prescribed, administered, or dispensed by a physician without documented medical need.

Iowa Administrative Code
653: Medical Examiners Board
Chapter 13: Standards of Practice and Professional Ethics

653--13.2(148,150,150A,272C) Standards of practice--prescribing or administering controlled substances for the treatment of patients with chronic, nonmalignant or intractable pain. This rule establishes standards of practice for the management of chronic, nonmalignant or intractable pain. The purpose of the rule is to assist physicians who prescribe and administer drugs to provide relief and eliminate suffering in patients with intractable pain as defined in this rule.

13.2(1) Definitions. As used in this subrule:

"American Academy of Pain Medicine" or "AAPM" means the American Medical Association-recognized specialty society of physicians who practice pain medicine in the United States. The mission of the AAPM is to enhance pain medicine practice by promoting a climate conducive to the effective and efficient practice of pain medicine.

"American Pain Society" or "APS" means the national chapter of the International Association for the Study of Pain, an organization composed of physicians, nurses, psychologists, scientists and other professionals who have an interest in the study and treatment of pain. The mission of the APS is to serve people in pain by advancing research, education, treatment and professional practice.

"Chronic, nonmalignant or intractable pain" means persistent or episodic pain of a duration or intensity that adversely affects the functioning or well-being of a patient. It is pain that cannot be removed or otherwise treated in the generally accepted course of medical practice subsequent to an evaluation by the attending physician and at least one other physician specializing in the treatment of the area, system, or organ perceived to be the source of the pain for any of the following reasons: (1) no relief or cure for the cause of pain is possible; (2) no relief or cure for the cause of pain has been found; or (3) relief or cure for the cause of pain through other medical procedures would adversely affect the well-being of the patient.

"U.S. Agency for Health Care Policy and Research" or "AHCPR" means the agency within the U.S. Department of Health and Human Services which is responsible for establishing Clinical Practical Guidelines on various aspects of medical practice.

13.2(2) General provisions. Various controlled drugs, particularly opioid analgesics, can be safely and effectively utilized to control pain in certain patients. However, inappropriate prescribing of controlled substances can lead to, or accelerate, drug abuse and diversion. Therefore, the medical management of pain shall be based on a thorough knowledge of pain assessment, pain treatment, and concern for the patient.

a. Treatment of acute pain and intractable pain associated with malignancy. Physicians may refer to the Clinical Practice Guidelines published by the U.S. AHCPR for counsel on the proper treatment of acute pain associated with trauma, surgery, and certain medical procedures, and chronic pain associated with cancer. The AHCPR Clinical Practice Guidelines provide a sound, compassionate, and flexible approach to the management of pain in these patients.

b. Treatment of chronic, nonmalignant pain. The basic premise underlying this rule is that various drugs, particularly opioid analgesics, may be useful for treating patients with chronic, nonmalignant pain in a safe, effective, and efficient manner when other efforts to remove or treat the pain have failed. The board strongly recommends that physicians who have

reservations about the use of drugs in the treatment of chronic, nonmalignant pain consult: The Use of Opioids for the Treatment of Chronic Pain: A Consensus Statement from the American Academy of Pain Medicine and the American Pain Society (1997). Copies of the statement are available from the AAPM, the APS, and the office of the board at 1209 East Court Avenue, Des Moines, Iowa 50319.

13.2(3) Effective chronic, nonmalignant pain management. To ensure that pain is properly and promptly assessed and treated, a physician who prescribes or administers controlled substances to a patient for the treatment of intractable pain shall exercise sound clinical judgement by establishing an effective pain management plan in accordance with the following:

a. Physical examination. A physical examination that includes a comprehensive medical history shall be conducted prior to the initiation of treatment. The examination shall also include an assessment of the pain, physical and psychological function, substance abuse history and any underlying or coexisting conditions. The physician shall seek corroboration of the assessment from an evaluation conducted by another physician who specializes in pain medicine or the treatment of the area, system, or organ perceived to be the source of the pain. Interdisciplinary evaluation is strongly encouraged.

b. Treatment plan. The physician shall establish a comprehensive treatment plan that tailors drug therapy to the individual needs of the patient. To ensure proper evaluation of the success of the treatment, the plan shall clearly state the objectives of the treatment, for example, pain relief, or improved physical or psychosocial functioning. The treatment plan shall also indicate if any further diagnostic evaluations or treatments are planned and their purposes. The treatment plan shall also identify any treatment modalities and rehabilitation programs necessary to manage pain of differing etiologies or physical/psychosocial impairments.

c. Informed consent. The physician shall discuss the risks and benefits of controlled substances with the patient or person representing the patient.

d. Periodic review. The physician shall periodically review the course of drug treatment of the patient and the etiology of the pain. Modification or continuation of drug therapy by the physician shall be dependent upon evaluation of the patient's progress toward the objectives established in the treatment plan. The physician shall consider the appropriateness of continuing drug therapy and the use of alternative treatment modalities if periodic reviews indicate the patient's condition is not improving in accordance with the treatment plan.

e. Consultation/referral. The physician shall refer the patient for further evaluation and treatment to another physician, if necessary, to meet the treatment plan objectives.

f. Records. The physician shall keep accurate, timely, and complete records that detail compliance with this subrule, including physical examination, treatment plan, informed consent, periodic review, consultation, and any other relevant information about the patient's condition and treatment.

g. Physician-patient agreements. Physicians treating patients at risk for substance abuse shall consider establishing physician-patient agreements that specify the rules for medication use and the consequences for misuse. In preparing agreements, a physician shall evaluate the case of each patient on its own merits, taking into account the nature of the risks to the patient and the potential benefits of treatment.

13.2(4) Restrictions and limitations. No aspect of this rule shall be construed to interfere with:

a. Federal and state laws and regulations governing the proper prescribing and

administering of controlled substances;

b. Treatment of patients suffering from chronic malignant pain, such as patients cared for in a hospice or other long-term care facility setting; or

c. Delivery of medical services to a patient as a result of trauma or a medical emergency.

Adoption Date: 05/02/97
Effective Date: 06/25/97

LOUISIANA

Title 46 Professional and Occupational Standards
Part XLV. Medical Professions,
Subpart 3. Practice

RULE

Department of Health and Hospitals
Board of Medical Examiners

Noncancer-Related Chronic or Intractable Pain
Medications (LAC 46:XLV.6915-6923)

Chapter 69. Prescription, Dispensation and Administration of Medications
Subchapter B. Medications Used in the Treatment of Noncancer-Related Chronic or Intractable Pain

§6915. Scope of Subchapter

The rules of this Subchapter govern physician prescription, dispensation, administration or other use of controlled substances employed in the treatment of noncancer-related chronic or intractable pain.

§6917. Definitions

As used in this Subchapter, unless the content clearly states otherwise, the following terms and phrases shall have the meanings specified:

Addiction--a compulsive disorder in which an individual becomes preoccupied with obtaining and using a substance, despite adverse social, psychological and/or physical consequences, the continued use of which results in a decreased quality of life.

Board--the Louisiana State Board of Medical Examiners.

Chronic Pain--pain which persists beyond the usual course of a disease, beyond the expected time for healing from bodily trauma, or pain associated with a long-term incurable or intractable medical illness or disease.

Controlled Substance--any substance defined, enumerated or included in federal or state statute or regulations 21 CFR §§1308.11-15 or R.S. 40:964, or any substance which may hereafter be designated as a controlled substance by amendment or supplementation of such regulations and statute.

Diversion--the conveyance of a controlled substance to a person other than the person to whom the drug was prescribed or dispensed by a physician.

Drug Abuse--a maladaptive or inappropriate use or overuse of a medication.

Intractable Pain--a chronic pain state in which the cause of the pain cannot be eliminated or successfully treated without the use of controlled substance therapy and, which in the generally accepted course of medical practice, no cure of the cause of pain is possible or no cure has been achieved after reasonable efforts towards such cure have been attempted and documented in the patient's medical record.

Noncancer-Related Pain--that pain which is not directly related to symptomatic cancer.

Physician--physicians and surgeons licensed by the board.

Protracted Basis--utilization of any controlled substance for the treatment of noncancer-related chronic or intractable pain, for a period in excess of 12 weeks during any 12-month period.

§6919. General Conditions/Prohibitions

The treatment of noncancer-related chronic or intractable pain with controlled substances constitutes legitimate medical therapy when provided in the usual course of professional medical practice and when fully documented in the patient's medical record. A physician duly authorized to practice medicine in Louisiana and to prescribe controlled substances in this state shall not, however, prescribe, dispense, administer, supply, sell, give or otherwise use for the purpose of treating such pain, any controlled substance unless done in strict compliance with applicable state and federal laws and the rules enumerated in this Subchapter.

§6921. Use of Controlled Substances, Limitations

A. Requisite Prior Conditions. In utilizing any controlled substance for the treatment of noncancer-related chronic or intractable pain on a protracted basis, a physician shall comply with the following rules:

1. Evaluation of the Patient. Evaluation of the patient shall initially include a full history, including complete medical, pain, alcohol and substance abuse histories, an assessment of the impact of pain on the patient's physical and psychological functions, a review of previous diagnostic studies, previously utilized therapies, an assessment of coexisting illnesses, diseases or conditions and a complete physical examination.

2. Medical Diagnosis. A medical diagnosis shall be established and fully documented in the patient's medical record, which indicates not only the presence of noncancer-related chronic or intractable pain, but also the nature of the underlying disease and pain mechanism if such are determinable.

3. Treatment Plan. An individualized treatment plan shall be formulated and documented in the patient's medical record, which includes medical justification for controlled substance therapy. Such plan shall include documentation that other medically reasonable alternative treatments for relief of the patient's noncancer-related chronic or intractable pain have been offered or attempted without adequate or reasonable success. Such plan shall specify the intended role of controlled substance therapy within the overall plan, which therapy shall be tailored to the individual medical needs of each patient.

4. Patient Information. A physician shall ensure that the patient and/or his guardian is informed of the benefits and risks of protracted controlled substance therapy.

B. Controlled Substance Therapy. Upon completion and satisfaction of the conditions prescribed in Subsection A of this Section, and upon a physician's judgment that the prescription, dispensation or administration of a controlled substance is medically warranted, a physician shall adhere to the following rules:

1 . Assessment of Treatment Efficacy and Monitoring. Patients shall be seen by the physician at appropriate regular and frequent intervals, of not more than 12 weeks, to assess the efficacy of treatment, assure that controlled substance therapy remains indicated, and evaluate the patient's progress toward treatment objectives and any adverse drug effects. During each visit, attention shall be given to the possibility of decreased function or quality of life as a result of controlled substance usage, as well as indications of possible addiction, drug abuse or diversion.

2. Drug Screen. If a physician reasonably believes that the patient is suffering from addiction or drug abuse or that he is diverting controlled substances, the physician shall obtain a drug screen on the patient. It is within the physician's discretion to decide the nature of the screen and which type of drug(s) to be screened.

3. Responsibility for Treatment. A physician shall take primary responsibility for the controlled substance therapy employed by him in the treatment of a patient's noncancer-related chronic or intractable pain.

4. Consultation. Consultation with specialists may be warranted depending on the expertise of a physician and the complexity of the presenting problem. If the patient is maintained on controlled substance therapy on a protracted basis, the physician should either consult with one or more specialists for additional evaluation and/or treatment in order to achieve treatment objectives, or he should document in the patient's medical record the reason he has not obtained such consultation. It is within the discretion of the physician to decide the level and type of consultation which is believed to be medically warranted.

5. Medications Employed. A physician shall document in the patient's medical record the medical necessity for the use of more than one type or schedule of controlled substance employed in the management of a patient's noncancer-related chronic or intractable pain.

6. Treatment Records. A physician shall document and maintain in the patient's medical record, accurate and complete records of all history, physical and other examinations and evaluations, consultations, laboratory and diagnostic reports, treatment plans and objectives, controlled substance and other medication therapy, informed consents, periodic assessments and reviews and the results of all other attempts at analgesia which he has employed alternative to controlled substance therapy.

7. Documentation of Controlled Substance Therapy. At a minimum, a physician shall document in the patient's medical record the date, quantity, dosage, route, frequency of administration, the number of controlled substance refills authorized, as well as the frequency of visits to obtain refills.

C. Termination of Controlled Substance Therapy. Evidence or behavioral indications of addiction, drug abuse or diversion of controlled substances, shall be followed by tapering and discontinuation of controlled substance therapy and referral to an addiction medicine specialist, a pain management specialist, a psychiatrist, or other substance abuse specialist, or by an immediate referral to an addiction medicine specialist, a pain management specialist, a psychiatrist or other substance abuse specialist for treatment. Such therapy shall be reinitiated only after referral to, and written concurrence of the medical necessity of continued controlled substance therapy by an addiction medicine specialist, a pain management specialist, a psychiatrist or other substance abuse specialist based upon his physical examination of the patient and a review of the referring, physician's medical record of the patient.

§6923. Effect of Violation

Any violation of or failure of compliance with the provisions of this Subchapter, §§6915-6923, shall be deemed a violation of R.S. 37:1285(A)(6) and (14), providing cause for the board to suspend or revoke, refuse to issue, or impose probationary or other restrictions on any license held or applied for by a physician to practice medicine in the state of Louisiana culpable of such violation.

Delmar Rorison
Executive Director

MARYLAND

Maryland Board of Physician Quality Assurance
Source: Maryland BPQA Newsletter, Vol. 4, num. 1, pp. 1-3, Mar. 1996.

PRESCRIBING CONTROLLED DRUGS

In a recent AMA survey of physicians, the majority of physicians responding reported that their prescribing of controlled drugs was negatively influenced by a fear of licensing board sanctions. The issue of prescribing adequate pain medication for the terminally ill, generally patients with cancer, has received extensive attention. But what about patients with chronic noncancer pain? Little has been done to alleviate physician anxiety that regularly prescribing controlled drugs to such patients will result in the physician being accused of diverting drugs illegally or supporting addictive patients in their habits. How can a physician both meet their patients' needs and avoid coming to the attention of the licensing authorities?

BPQA, by statute, has a minimum of eleven Board members who are actively practicing physicians. We see these patients in our offices, too, and we recognize that there are many painful conditions which cannot be cured and that diagnoses may be totally based on subjective symptoms. As physicians, our role is to relieve suffering; we may have no hard evidence that "proves" the patient is in pain, yet we believe our patients and we try to help them. All the members of BPQA wish to reassure Maryland physicians that they need not under-prescribe needed medications for fear of Board action. Under-prescribing results in unnecessary suffering.

But what about all those Board actions you've read about in which the doctors are sanctioned for "inappropriate" controlled dangerous substance prescribing practices? Were these physicians just trying to alleviate suffering with the end result that the Board sanctioned them? Hardly. Most of the physicians charged under this provision of the Medical Practice Act were clearly acting in other than the best interest of their patients. Usually, obvious addicts were buying prescriptions from the physicians and the transactions were disguised as office visits. Occasionally, truly naive physicians, once they have been targeted as "easy writes," attract every addict in town. All of us in practice occasionally have been duped by a patient in this way. But some physicians simply don't recognize addiction. Usually, in addition to inappropriate prescribing, we find that the physician's practice is substandard in multiple other areas. It is rare that an otherwise well-trained and competent physician is identified as a naive prescriber.

Because the Board is concerned that fear of disciplinary action may lead to inappropriately restrictive prescribing of controlled drugs, the following guidelines are offered by Dr. Charles Hobelmann Jr., who has served on the Board since 1991. Although the primary focus of his remarks is analgesic prescribing, these guidelines can be applied to every prescribing and treatment situation. It's just good medical practice spelled out, and it's how the Board evaluates the delivery of all medical care, not just controlled drug prescribing. His comments follow.

In order to help the physicians whose patients may require long-term analgesic

medications, a common sense approach coupled with experience and medical knowledge is essential. It is important to realize that habituation and tolerance to drugs are not the same as addiction. These are expected consequences of long-term analgesic therapy and do not have the characteristics of sociopathy and psychologic dependence associated with addiction. Whereas it is inappropriate to prescribe analgesics to maintain addiction, it is good medical care to provide relief from chronic pain even in the face of habituation and tolerance. Some general guidelines may be helpful both in the management of these patients and in protecting one's self from legal or Board action in prescribing for them. The following comments have been adapted from published material of the Medical Board of California and provide a useful guide in this area.

History and Physical Generally speaking, it is improper to prescribe any medication for any patient without first taking the steps essential to evaluation. This is particularly true of the chronic pain patients because other treatment modalities may be beneficial and because it is important to recognize the addict who may complain of pain as a means to maintain a habit. Prescribing narcotics without a documented evaluation always represents substandard care.

Treatment Plan Just as treatment for diabetes or hypertension has a specific objective, so should treatment for chronic pain. Frequently, the pain cannot be completely relieved but the use of analgesic drugs may lead to an improved sense of well-being, better sleep or even a return to work. The goal of analgesic therapy should be documented and the patient's progress measured against this goal.

Informed Consent Since long-term narcotic use will usually result in habituation and tolerance, these risks should be discussed with the patient. Alternatives should be offered if they exist and the clinical record should refer to the discussion.

Periodic Review The course of treatment and the meeting of therapeutic goals should be periodically reviewed as is the case with any patient suffering from chronic disease. Modification of treatment or its discontinuation should be considered depending upon how well goals are being met. New information about the etiology of the pain or its treatment should be evaluated.

Consultation The complexity of chronic pain frequently requires evaluation by consultants who may suggest alternatives or additions to therapy. This may be particularly true in the patient who is at risk for drug misuse. The patient with a history of substance abuse requires special care in documentation, evaluation and consultation before long-term opiate treatment can be safely prescribed. Some pain management specialists recommend a written agreement with these and other patients before such therapy.

Records Adequate documentation is the key to management of these difficult patients and is the key to protecting the physician from legal or Board action. Documentation of the steps noted above should be recorded in a fashion that would allow another practitioner to understand and follow through with treatment.

Finally, the physician who uses scheduled drugs should be familiar with federal and local laws regulating their use. The U.S. Drug Enforcement Administration publishes a physicians' manual and Maryland laws are available through the Board. The Board hopes that physicians will use these guidelines to help them manage patients with chronic pain without fear of regula-

tory scrutiny. At the same time, the Board maintains its commitment to prevent the diversion and abuse of controlled substances.

Charles F. Hobelmann Jr., M.D.

MASSACHUSETTS

Massachusetts Board of Registration in Medicine
Source: Prescribing Practices, Policy and Guidelines
Massachusetts Board of Registration in Medicine: 32-34, 1989

Management of Pain

Physicians treating patients who are suffering from pain should take precautions so that they are not engaging in the overmedication *or undermedication* of controlled substances. The Board is particularly disturbed by reports that terminally ill patients in chronic pain may not always be receiving the appropriate medication to alleviate their suffering in their final days. *No patient should ever wish for death because of a physician's reluctance to use opioid analgesics.*

When faced with a patient who is in acute or chronic pain, physicians should consider and explore *appropriate* alternatives to drug therapy, such as established pain clinics. Some forms of pain, such as neuropathic pain, are not usually relieved by the use of narcotic analgesics and physicians should look for drugs which have been shown to be effective for that particular symptom.[51] Somatic pain, on the hand, can often be effectively treated by analgesics and physicians should make available to their patients the best and most effective drugs modern medical science has to offer.[52] When they are used, opiates and opioids should be given in the smallest *effective* dose and as infrequently as possible to minimize the development of tolerance and physical dependence.

The Board does not wish to discourage physicians from prescribing strong analgesics to relieve the suffering of patients who are in severe pain, both acute and chronic, such as the pain of terminal cancer and postoperative pain. Opiates and opioids have legitimate clinical usefulness, and physicians should not hesitate to prescribe them when they are indicated for the comfort and well being of patients who require relief that cannot be provided by non-opiate analgesics and alternative forms of therapy.[53] The Board recognizes that the danger of addiction to analgesics may be relatively low when the patient has no history of addiction.

The Board also acknowledges that there is a distinction between maintaining a dependency and patients becoming tolerant on pain medications. All patients probably develop tolerance and physical dependence to narcotic analgesics. When patients are receiving these drugs for the treatment of legitimate pain, this rarely presents a problem. Problems arise in the relatively small number of individuals who are prone to drug misuse where prescription narcotics are used to promote and sustain drug addiction.

For further information on the appropriateness of prescribing narcotic analgesics to patients in chronic pain, see the General Guidelines for Use of Narcotic Analgesics in Chronic Pain written by Raymond Maciewicz, M.D., Ph.D., which are included in Attachment I. The Board endorses these guidelines.

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51. Address by Raymond Maciewicz, M.D., Ph.D., Massachusetts Medical Society "Current Issues in Prescribing Controlled Substances" Conference, in Cambridge, Massachusetts, October 19, 1988. Dr. Maciewicz is an Associate Professor of Neurology (Neuroscience) at Harvard Medical School and a member of the Massachusetts Medical Society's Committee on Public Health.
52. Id.
53. See AMERICAN MEDICAL ASSOCIATION, PRESCRIBING CONTROLLED DRUGS SOURCE BOOK, 32-38 (1986).

Attachment I.

MASSACHUSETTS GENERAL HOSPITAL - HARVARD MEDICAL SCHOOL
CANCER PAIN CENTER

Raymond Maciewicz, M.D., Ph.D.

General Guidelines for Use of Narcotic Analgesics in Chronic Pain

Narcotic analgesics remain the most effective drugs for the management of moderate to severe pain. The medications are generally well-tolerated, with relatively few side effects. Probably all patients treated with narcotics will develop tolerance and physical dependance to these medications; this rarely presents a problem for patients receiving such drugs for the management of legitimate pain. However, in a small number of individuals prone to drug abuse, prescription narcotics can promote and sustain drug addiction. This problem raises the potential for diversion of prescription narcotic medications from legitimate pain management to the maintenance of individuals who take these drugs for no indicated medical purpose.

Since the potential for diversion of prescription narcotics is a serious problem, there is a need for broad clinical guidelines to facilitate the appropriate use of such drugs in the management of pain patients. For example, there is little disagreement among clinicians that patients with acute pain associated with significant injury (such as a broken bone or abdominal surgery) should be managed temporarily with narcotics. Similarly, most physicians would accept the idea that patients dying with a painful illness should have access to narcotics.

A more difficult area concern the use of narcotic medications in the management of patients with chronic pain not associated with cancer or other similar terminal illness. Although there is little definitive data on the subject, there appears to be a greater potential for inappropriate use and diversion of narcotics in this patient population. Although narcotics probably do have a place in the management of certain patients with chronic pain, there are currently few accepted guidelines for the appropriate use of such drugs in these situations. The Massachusetts Medical Society Committee on Drugs and Therapeutics has considered this issue, and proposes several principles that seem important when narcotics are prescribed on a regular basis for patients with chronic pain.

1. Chronic pain patients receiving narcotics should have a carefully documented medical condition as the cause of their pain. The unsubstantiated statement "headache" or "back pain" in a medical record should not be enough to justify chronic narcotic therapy.

2. The medical record should include some statement documenting the need for continued narcotic therapy in a patient with chronic pain. Such a statement should state specifically why other forms of treatment are less preferable in the specific case.

3. The factors that contribute to the development of chronic pain are complex. Psychologic, pharmacologic, social and rehabilitation issues are all prominent concerns in addition to the obvious medical problem that produced the initial symptoms. Therefore it is important that any pain patient on chronic narcotic therapy (usually greater than six months) be evaluated by a specialists other than the prescribing physician. The consulting physician should be a specialist in the area of the patient's disease, or a specialist in management of chronic pain. The consultant should concur with the need for continued

narcotics in each specific case.

4. Patients who receive narcotics should have their prescriptions documented in their medical records. When patients receive prescriptions in excess of the prescribed amount (for example, when a new prescription is issued a week early) the reason for the discrepancy should be clearly documented in the medical record.

5. Social factors can contribute to diversion. The physician or his staff should document the patient's social situation adequately enough to be reasonablely assured that drug diversion will not occur.

6. Patients on narcotic therapy need to be seen and examined by the prescribing physician at regular intervals to determine whether the need for strong analgesics is still present. The frequency of visits involving direct patient-physician contact should be determined in each case by the nature of the underlying disease; however, any patient receiving narcotics should be clinically reevaluated at least every four months.

There is a wide diversity of opinions about the appropriate use of narcotics in different painful disorders. The Massachusetts Medical Society Committee on Drugs and Therapeutics acknowledges the validity and appropriateness of these various views. The above listed guidelines are hopefully intended to reflect a broader consensus in an effort to facilitate the careful, medical use of narcotic analgesics while limiting the potential for drug diversion.

MINNESOTA

An Act

relating to health; allowing physicians to prescribe and administer controlled substances in cases of intractable pain; proposing coding for new law in Minnesota Statutes, chapter 152.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF MINNESOTA:

Section 1. 152.125 INTRACTABLE PAIN.

Subd. 1. DEFINITION. For purposes of this section, "intractable pain" means a pain state in which the cause of the pain cannot be removed or otherwise treated with the consent of the patient and in which, in the generally accepted course of medical practice, no relief or cure of the cause of the pain is possible, or none has been found after reasonable efforts. Reasonable efforts for relieving or curing the cause of the pain may be determined on the basis of, but are not limited to, the following:

(1) when treating a nonterminally ill patient for intractable pain, evaluation by the attending physician and one or more physicians specializing in pain medicine or the treatment of the area, system, or organ of the body perceived as the source of the pain; or

(2) when treating a terminally ill patient, evaluation by the attending physician who does so in accordance with the level of care, skill, and treatment that would be recognized by a reasonably prudent physician under similar conditions and circumstances.

Subd. 2. PRESCRIPTION AND ADMINISTRATION OF CONTROLLED SUBSTANCES FOR INTRACTABLE PAIN. Notwithstanding any other provision of this chapter, a physician may prescribe or administer a controlled substance in schedules II to V of section 152.02 to an individual in the course of the physician's treatment of the individual for a diagnosed condition causing intractable pain. No physician shall be subject to disciplinary action by the board of medical practice for appropriately prescribing or administering a controlled substance in schedules II to V of section 152.02 in the course of treatment of an individual for intractable pain, provided the physician keeps accurate records of the purpose, use, prescription, and disposal of controlled substances, writes accurate prescriptions, and prescribes medications in conformance with chapter 147.

Subd. 3. LIMITS ON APPLICABILITY. This section does not apply to:

(1) a physician's treatment of an individual for chemical dependency resulting from the use of controlled substances in schedules II to V of section 152.02;

(2) the prescription or administration of controlled substances in schedules II to V of section 152.02 to an individual whom the physician knows to be using the controlled substances for nontherapeutic purposes;

(3) the prescription or administration of controlled substances in schedules II to V of section 152.02 for the purpose of terminating the life of an individual having intractable pain; or

(4) the prescription or administration of a controlled substance in schedules II to V of section 152.02 that is not a controlled substance approved by the United States Food and Drug Administration for pain relief.

Subd. 4. NOTICE OF RISKS. Prior to treating an individual for intractable pain in accordance with subdivision 2, a physician shall discuss with the individual the risks associated with the controlled substances in schedules II to V of section 152.02 to be prescribed or administered in the course of the physician's treatment of an individual, and document the discussion in the individual's record.

Sec. 2. EFFECTIVE DATE.
Section 1 is effective the day following final enactment.

Presented to the governor May 8, 1997.
Approved May 9, 1997.

MINNESOTA

Minnesota Board of Medical Examiners
Source: Minnesota Board of Medical Examiners, Update, Winter 1995, pp. 3-4

THE COMMON DENOMINATOR AND COMMON SENSE

A Letter to the Physicians of Minnesota by
David Kidder, D.O., President
Minnesota Board of Medical Practice

As this letter goes to press, I will have chaired my last meeting of the Board of Medical Practice, attended my last committee deliberation, and indeed completed the entirety of my official appointment to the Board.

During the past four years, I have had the privilege to participate in a number ofthe Board's successes. I think particularly of the Board's work in creating the Health Professionals Services Program, and the expansion of Physician Assistant's scope of practice to include authority to prescribe legend drugs. These past four years have also truly been an educational experience for me, giving me great insight into practice issues which trouble the medical profession, and the public at large, the inner workings of politics, both medical and otherwise, and the basic elements of the human condition.

Of all of the issues which have been brought to me for consideration and resolution in the past four years, the one which is simultaneously a matter of a troubling practice issue, a political issue, and part of the human condition, is the prescribing of controlled substances.

Since the human condition is the common denominator to the practice and politics of everything we engage in, I'll begin with that. It is the basic desire, and in fact, need, to believe, trust, and help others which leads people to become physicians. It is the basic urge to acquire substances of choice which drives people with addictive behaviors to deceive and manipulate those who wish to help them. Denial of an addiction, and, perversely, of life threatening conditions, prevents people from seeking help for their misery, whether it be continued substance abuse, or extreme pain from a malignant disease process. Fear, especially fear generated by uncertainty, precipitates actions which may otherwise defy logic.

Here we have at least a portion of the dynamic which has created a practice anomaly where, in the past, physicians have tended to over-prescribe controlled substances to patients with benign conditions, and under-prescribe to patients with acute pain and intractable pain resulting from malignant conditions.

It has been said that the greatest casualty in the war on drugs is the patient with cancer pain or pain from some other malignant disease process. Worse, it appears that one of the reasons this is so, is the reluctance on the part of physicians to prescribe proper pain relieving drugs to such patients out of the mistaken belief that the Board of Medical Practice will discipline them for doing so. The fact is, the Board has never disciplined anyone for prescribing pain killers to cancer patients. However, in the general uncertainty within the profession as to how to handle these drugs, the perception, no matter how erroneous, has become the reality, despite the fact that it defies logic.

This issue has troubled every medical regulatory board in this country, and created great controversy in the practicing communities and state government systems. Various boards have formulated various means of dealing with the problem, however, if the truth be known, it all boils down to a mixture of about 80% common sense, 15% experience, and 5% knowledge.

The best statements of this mixture, which I have yet encountered, was recently published by the California Board of Medical Practice. The California Board has graciously allowed us to reprint their six step process here, and I believe it will be of great assistance to you in your practice:

1. HISTORY/PHYSICAL EXAMINATION - A medical history and physical examination must be accomplished. This includes an assessment of the pain, physical and psychological function, substance abuse history, assessment of underlying or coexisting diseases or conditions, and should also include the presence of a recognized medical indication for the use of a controlled substance. Prescribing controlled substances for intractable pain [should also be accompanied by] evaluation by one or more specialists.

2. TREATMENT PLAN, OBJECTIVES - The treatment plan should state objectives by which treatment success can be evaluated, such as pain relief and/or improved physical and psychological function, and indicate if any further diagnostic evaluations or other treatments are planned. The physician should tailor drug therapy to the individual medical needs of each patient. Several treatment modalities or a rehabilitation program may be necessary if the pain has differing etiologies or is associated with physical and psychological impairment.

3. INFORMED CONSENT - The physician should discuss the risks and benefits of the use of controlled substances with the patient or guardian.

4. PERIODIC REVIEW - The physician should periodically review the course of opioid treatment of the patient and any new information about the etiology of the pain. Continuation or modification of opioid therapy depends on the physician's evaluation of progress toward treatment objectives. If the patient has not improved, the physician should assess the appropriateness of continued opioid treatment or that of other modalities.

5. CONSULTATION - The physician should be willing to refer the patient as necessary for additional evaluation and treatment in order to achieve treatment objectives. In addition, physicians should give special attention to those pain patients who are at risk for misusing their medications, including those whose living arrangements pose a risk for medication misuse or diversion. The management of pain in patients with a history of substance abuse requires extra care, monitoring, documentation and consultation with addiction medicine specialists, and may entail the use of agreements between the provider and the patient that specify the rules for medication use and consequences for misuse.

6. RECORDS - The physician should keep accurate and complete records according to items 1-5 above, including the medical history and physical examination, other evaluations and consultations, treatments, medications, agreements with the patient, and periodic reviews.

The California Board included a seventh point, which recommended that practitioners become acquainted with the Physicians Manual of the U.S. Drug Enforcement Administration and the appropriate local laws. This too, is common sense, and you can get copies of Minnesota's laws by contacting the Board office. Other sources of useful information, especially if you have cancer patients in your practice, are the Cancer Information Service, at 1-800-4CANCER, and the Minnesota Cancer Pain Initiative, through Paula Sallmen, at (612) 863-4633. I would add that it is also common sense to make sure that we, as physicians, never lose sight of those qualities in ourselves which caused us to become physicians; our trust, our compassion, our belief in our fellow human kind, and our desire to help them. Please remember that to best help them, it is sometimes necessary to insist firmly that they accept medications which provide relief from otherwise excruciating pain, which can only rob them of the strength and desire to go on combating the disease itself. However, in the case of the patient suffering from an addictive disease process, it may be equally necessary to respond to requests for more drugs with a firm "No.", and efforts to enter the patient into the appropriate

form of treatment for an addictive disorder.

These past four years have been of great value to me. I sincerely hope they have been of equal value to the medical profession of Minnesota, and to the public, which the Board of Medical Practice was created to protect.

MISSOURI

Missouri Revised Statutes
Title XXII: Occupations and Progress.
Chapter 334: Physicians and Surgeons - Therapists - Athletic Trainers

Section 334.105.

1. Sections 334.105 to 334.107 shall be known and may be cited as the "Intractable Pain Treatment Act".

2. For purposes of sections 334.105 and 334.107, the following terms mean:

(1) "Board", the state board of registration for the healing arts;

(2) "Intractable pain", a pain state in which the cause of pain cannot be removed or otherwise treated and which in the generally accepted course of medical practice no relief or cure of the cause of the pain is possible or none has been found after reasonable efforts that have been documented in the physician's medical records;

(3) "Physician", physicians and surgeons licensed pursuant to this chapter by the board;

(4) "Therapeutic purpose", the use of controlled substances in acceptable doses with appropriate indication for the treatment of pain. Any other use is nontherapeutic.

Section 334.106

1. Notwithstanding any other provision of law to the contrary, a physician may prescribe, administer or dispense controlled substances for a therapeutic purpose to a person diagnosed and treated by a physician for a condition resulting in intractable pain, if such diagnosis and treatment has been documented in the physician's medical records. No physician shall be subject to disciplinary action by the board solely for prescribing, administering or dispensing controlled substances when prescribed, administered or dispensed for a therapeutic purpose for a person diagnosed and treated by a physician for a condition resulting in intractable pain, if such diagnosis and treatment has been documented in the physician's medical records.

2. The provisions of subsection 1 of this section shall not apply to those persons being treated by a physician for chemical dependency because of their use of controlled substances not related to the therapeutic purposes of treatment of intractable pain.

3. The provisions of subsection 1 of this section provide no authority to a physician to prescribe, administer or dispense controlled substances to a person the physician knows or should know to be using controlled substances which use is not related to the therapeutic purpose.

4. Drug dependency or the possibility of drug dependency in and of itself is not a reason to withhold or prohibit the prescribing, administering or dispensing of controlled substances for the therapeutic purpose of treatment of a person for intractable pain, nor shall dependency relating solely to such prescribing, administering or dispensing subject a physician to disciplinary action by the board.

Section 334.107

Nothing in this section shall deny the right of the board to deny, revoke or suspend the license of any physician or otherwise discipline any physician who:

(1) Prescribes, administers or dispenses a controlled substance that is nontherapeutic in nature or nontherapeutic in the manner in which it is prescribed, administered or dispensed, or fails to keep complete and accurate on-going records of the diagnosis and treatment plan;

(2) Fails to keep complete and accurate records of controlled substances received, prescribed, dispensed and administered, and disposal of drugs listed in the Missouri comprehensive drug control act contained in chapter 195, RSMo, or of controlled substances scheduled in the Federal Comprehensive Drug Abuse Prevention and Control Act of 1970, 21 U.S.C. 801, et seq. A physician shall keep records of controlled substances received, prescribed, dispensed and administered, and disposal of these drugs shall include the date of receipt of the drugs, the sale or disposal of the drugs by the physician, the name and address of the person receiving the drugs, and the reason for the disposal or the dispensing of the drugs to the person;

(3) Writes false or fictitious prescriptions for controlled substances as defined in the Missouri comprehensive drug control act, chapter 195, RSMo, or for controlled substances scheduled in the Federal Comprehensive Drug Abuse Prevention and Control Act of 1970, 21 U.S.C. 801, et seq.; or

(4) Prescribes or administers, or dispenses in a manner which is inconsistent with provisions of the Missouri drug control act contained in chapter 195, RSMo, or the Federal Comprehensive Drug Abuse Prevention and Control Act of 1970, 21 U.S.C. 801, et seq.

(L. 1995 S.B. 125 § 334.106 subsec. 5)

MONTANA

Montana State Board of Medical Examiners
Source: Montana Medical Association Bulletin, Vol. 51, num. 1, March 15, 1996, pp. 3-4

MANAGEMENT OF CHRONIC PAIN

STATEMENT ON THE USE OF CONTROLLED SUBSTANCES IN THE TREATMENT OF INTRACTABLE PAIN

The Montana Board of Medical Examiners continues to be concerned about the use of controlled substances by individuals who seek them for their mood-altering and addictive potential rather than legitimate medical reasons. However, the Board is also concerned about adequate pain management. The Board recognizes that pain from whatever cause is often under treated. The Board is aware that there are a number of factors that continue to interfere with effective pain management. These include exaggerated fears of opioid side effects including addiction, fear of legal consequences when controlled substances are used, low priority of proper pain management in our health care system, and the lack of integration of current knowledge concerning pain management into medical education and clinical practice.

The Board seeks to assure that no Montanan requiring narcotics for pain relief is denied them because of a physician's real or perceived fear that the Board of Medical Examiners will take disciplinary action based solely on the use of narcotics to relieve pain. While improper use of narcotics, like any improper medical care, will continue to be a concern of the Board, the Board is aware that treatment of malignant and especially nonmalignant pain is a very difficult task. The Board does not want to be a hindrance to the proper use of opioid analgesics. Treatment of chronic pain is multifactorial and certainly treatment with modalities other than opioid analgesics should be utilized, usually before long term opioids are prescribed. Use of new or alternative types of treatment should always be considered for intractable pain periodically, in attempts to either cease opioid medications or reduce their use.

The proper use of opioid analgesics for chronic pain must involve certain elements, which are also consistent with any quality medical care. The following guidelines will help assure the proper use of these medications for chronic pain and minimize the improper use:

GUIDELINES FOR PRESCRIBING OPIOID ANALGESICS FOR CHRONIC PAIN

1. Thorough history and physical examination. Included in the history is assessment of the etiology of pain, physical and psychological function of the patient, substance abuse history, other treatments that have been attempted to control the patient's level of pain, identification of underlying or coexisting diseases or conditions and, as much as possible, statements by all treating physicians that the patient's pain is intractable and not controlled by other than the use of opioid analgesics.

2. Treatment plan. A thoroughly documented, written treatment plan should be established and should include how treatment success will be evaluated, such as pain relief and improved physical or psychological functioning. Several treatment modalities should be utilized in most

cases and should be done concurrently with the use of opiates. Periodic review by the physician should be accomplished to determine that there are no other appropriate treatment methods that would then be of additional benefit to the patient.

3. Informed consent. The physician should discuss the risks and benefits of the use of controlled substances with the patient and/or guardian and this should be accomplished on an ongoing basis, not just at the initiation of treatment.

4. Appropriate referral. If treatment objectives are not being realized or if patients appear to be at risk for misuse of medications, referral should be made to appropriate specialists including addiction specialists and chronic pain specialists.

5. Documentation. All the above recommendations and guidelines should be recorded accurately and completely in the patient's medical record.

We hope that the above statements and guidelines will help reverse the trend of under treatment of intractable pain, and that they will facilitate the more appropriate use of controlled substances by duly licensed practitioners with prescriptive authority in the State of Montana.

-Montana Board of Medical Examiners, March 15, 1996

NEVADA

Nevada Revised Statutes
Professions, Occupations, and Businesses
Chapter 630: Physicians and Assistants

Section 630.3066
A physician is not subject to disciplinary action solely for prescribing or administering to a patient under his care:

1. Amygdalin (laetrile), if the patient has consented in writing to the use of the substance.
2. Procaine hydrochloride with preservatives and stabilizers (Gerovital H3).
3. A controlled substance which is listed in schedule II, III, IV or V by the state board of pharmacy pursuant to NRS 453.146, if the controlled substance is lawfully prescribed or administered for the treatment of intractable pain in accordance with accepted standards for the practice of medicine. (1977, p. 1647; 1983, p. 337; 1995, ch.520, § 3, p. 1734.)

Chapter 633: Osteopathic Medicine

Section 633.521
An osteopathic physician is not subject to disciplinary action solely for prescribing or administering to a patient under his care:

1. Amygdalin (laetrile), if the patient has consented to the use of the substance.
2. Procaine hydrochloride with preservatives and stabilizers (Gerovital H3).
3. A controlled substance which is listed in schedule II, III, IV or V by the state board of pharmacy pursuant to NRS 453.146, if the controlled substance is lawfully prescribed or administered for the treatment of intractable pain in accordance with accepted standards for the practice of osteopathic medicine. (1977, p. 1647; 1983, p. 337; 1995, ch. 520, § 4, p. 1734.)

NEVADA

Nevada Administrative Code
Chapter 630: Physicians and Assistants

630.255 "Intractable pain" interpreted. For the purposes of NRS 630.3066, "intractable pain" means a condition of discomfort for which the cause cannot be removed or otherwise treated and for which a method of providing relief, or of which a cure for the cause, has not been found after reasonable efforts have been taken in accordance with accepted standards for the practice of medicine, including, but not limited to, evaluation by an attending physician and one or more physicians specializing in the treatment of the area, system, or organ of the body which is believed to be the source of the discomfort.

(Added to NAC by Bd. of Medical Exam'rs, eff. 7-18-96)

NEW JERSEY

New Jersey Administrative Code
Title 8. Department of Health
Chapter 65. Controlled Dangerous Substances
Subchapter 7. Prescription Requirements for Controlled Dangerous Substances

8:65-7.7 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.

NEW MEXICO

New Mexico Board of Medical Examiners
Source: Newsletter: Information & Report, Board of Medical Examiners, Vol. 2, num 1. July 1997

GUIDELINES ON PRESCRIBING FOR PAIN
GENERAL STATEMENT

As the demand for better pain management grows in the United States, the public is taking an interest in policies that govern the medical use of opioid analgesics for people with chronic pain. The use of opioids in acute pain and cancer pain is well accepted. It is recognized that some dangerous (prescription) drugs and/or controlled substances are indicated for the treatment of pain and are useful for relieving and controlling other related symptoms from which patients may suffer. These guidelines have been prepared to assist New Mexico physicians to avoid action being taken against their license for injudicious prescribing. It is the position of the New Mexico Board of Medical Examiners that under certain circumstances, dangerous drugs and/or controlled substances may be prescribed for the treatment of chronic pain in adequate doses and for appropriate lengths of time after a thorough medical evaluation has been completed. No physician shall be subject to disciplinary action by the Board for appropriately prescribing controlled substances for acute pain of limited duration or for chronic pain due to incurable malignancies. Addicts can be the legitimate victims of pain, independent from their addiction, and can have genuine problems which need to be addressed. Although it is appropriate to prescribe for pain control, extra diligence must be exercised with such patients. Addicts cannot be treated with controlled substances for their addiction, unless the treatment is in compliance with federal laws.

DEFINITIONS:
The following terms are defined as they are used in this text:
Intractable pain - A term which generally refers to a pain state in which the cause cannot be removed or otherwise treated and, after reasonable efforts, no relief or cure has been found. It includes pain due to cancer as well as to other chronic disease.
Addict - A person who is addicted to narcotics, controlled substances or dangerous drugs.
Drug Abuser - A person who takes a drug or drugs for other than legitimate medical purposes.

GUIDELINES

The following guidelines will be used by the New Mexico Board of Medical Examiners to determine whether a physician's conduct violates the Medical Practice Act (§61-6-15 D. (17) and (26).

1. The treatment of pain with dangerous drugs and/or controlled substances is a legitimate medical procedure when done in the usual course of professional practice. It does not preclude treatment of addicts with legitimate pain. However, such patients do require very close monitoring and precise documentation.
2. This section and subsections (A) through (E) refer specifically to the management of chronic or intractable pain not due to malignancy, and could be used for management of any pain problem:

The prescribing, ordering, administering or dispensing of dangerous drugs or controlled substances to meet the individual needs of the patient for management of chronic or intractable pain is appropriate if prescribed, ordered, administered or dispensed in compliance with the following:

(A) A physician shall document the medical history including any previous history of significant pain, past history of alternate treatment for pain, potential for substance abuse, coexisting disease or medical conditions, and the presence of a medical indication for use of a dangerous drug or controlled substance. A physician shall complete a physical examination and include an evaluation of the patient's psychological status;

(B) A written treatment plan should be developed and tailored to the individual needs of the patient with stated objectives by which treatment can be evaluated, i.e., pain relief and/or improved physical and psychosocial function. Such a plan should include the need for further testing, consultation, referral or use of the other treatment modalities;

(C) The physician should discuss the risks and benefits of using controlled substances with the patient and/or guardian;

(D) Complete and accurate records of care provided and drugs prescribed should be maintained. When controlled substances are prescribed, the name of the drug, quantity, prescribed dosage and number of refills authorized should be recorded. Patients with a history of substance abuse or who are in an environment posing a high risk for misuse or diversion of drugs (e.g., living with a drug abuser, living or working in a place where drugs are available) may require special consideration.

(E) The management of patients needing chronic pain control requires monitoring by the physician. In addition, a physician should consult with health care professionals who are experienced (by the length and type of their practice) in the area of chronic pain control; such professionals need not be those who specialize in pain control. Consultation should occur early in the course of long term treatment, and at reasonable intervals during continued long term treatment for assessment of benefit and need. It is especially important, when treating addicts for legitimate pain apart from their addiction, to obtain consultation and to set a schedule for reevaluation at appropriate time intervals.

3. The quantity of pharmaceuticals prescribed and the duration of their use will be evaluated by the Board on the basis of an appropriate diagnosis and treatment of a recognized medical indication and documented persistence of the recognized medical indication and a documented follow-up evaluation with appropriate continuity of care.

4. If a physician complies with the provisions as set out in paragraphs 1, 2, and 3, and if drug treatment is documented, the Board will consider this in determining whether the practice and prescribing is in a therapeutic manner consistent with the proper provision of health care in New Mexico. A licensed physician who appropriately prescribes controlled substances and dangerous drugs, and who follows these "Guidelines for Prescribing for Pain" would not usually be subject to discipline by the Board.

Prepared by the Board of Medical Examiners, Advisory Committee Members:
JoAnn Levitt, M.D., Joan Lewis, M.D., Julia Pfile, M.D., Fredrica E. Smith, M.D.

NORTH CAROLINA

North Carolina Board of Medical Examiners
Source: Forum, num. 4, December, 1996
Adopted: September 13, 1996

NCMB Position Statement

MANAGEMENT OF CHRONIC NON-MALIGNANT PAIN

It has become increasingly apparent to physicians and their patients that the use of effective pain management has not kept pace with other advances in medical practice. There are several factors that have contributed to this. These include a history of relatively low priority given pain management in our health care system, the incomplete integration of current knowledge in medical education and clinical practice, a sparsity of practitioners specifically trained in pain management, and the fear of legal consequences when controlled substances are used--fear shared by physician and patient.

There are three general categories of pain.

> ***Acute Pain*** is associated with surgery, trauma and acute illness. It has received its share of attention by physicians, its treatment by various means is widely accepted by patients, and it has been addressed in guidelines issued by the Agency for Health Care Policy and Research of the U.S. Department of Health and Human Services.
>
> ***Cancer Pain*** has been receiving greater attention and more enlightened treatment by physicians and patients, particularly since development of the hospice movement. It has also been addressed in AHCPR guidelines.
>
> ***Chronic Non-Malignant Pain*** is often difficult to diagnose, often intractable, and often under treated. It is the management of chronic non-malignant pain on which the North Carolina Medical Board wishes to focus attention in this position statement.

The North Carolina Medical Board recognizes that many strategies exist for treating chronic non-malignant pain. Because such pain may have many causes and perpetuating factors, treatment will vary from behavioral and rehabilitation approaches to the use of a number of medications, including opioids. Specialty groups in the field point out that most chronic non-malignant pain is best managed in a coordinated way, using a number of strategies in concert. Inadequate management of such pain is not uncommon, however, despite the availability of safe and effective treatments.

The Board is aware that some physicians avoid prescribing controlled substances such as opioids in treating chronic non-malignant pain. While it does not suggest those physicians abandon their reservations or professional judgement about using opioids in such situations, neither does the Board wish to be an obstacle to proper and effective management of chronic pain by physicians. *It should be understood that the Board recognizes opioids can be an appropriate treatment for chronic pain.*

- It is the position of the North Carolina Medical Board that effective management of chronic pain should include:
  - thorough documentation of all aspects of the patient's assessment and care;
  - a thorough history and physical examination, including a drug and pain history;
  - appropriate studies;
  - a working diagnosis and treatment plan;
  - a rationale for the treatment selected;
  - education of the patient;
  - clear understanding by the patient and physician of methods and goals of treatment;
  - a specific follow-up protocol, which must be adhered to;
  - regular assessment of treatment efficacy;
  - consultation with specialist in pain medicine, when warranted; and
  - use of a multidisciplinary approach, when indicated.

- The Board expects physicians using controlled substances in the management of chronic pain to be familiar with conditions such as:
  - physical dependence;
  - respiratory depression and other side effects;
  - tolerance;
  - addiction; and
  - pseudo addiction.

  There is an abundance of literature available on these topics and on the effective management of pain. The physician's knowledge should be regularly updated in these areas.

- No physician need fear reprisals from the Board for appropriately prescribing, as described above, even large amounts of controlled substances indefinitely for chronic non-malignant pain.

- Nothing in this statement should be construed as advocating the imprudent use of controlled substances.

NORTH DAKOTA

North Dakota Century Code
Chapter 19-03.3
Controlled Substances for Care & Treatment

Section 19-03.3-01. As used in this chapter, unless the context otherwise requires:
1. "Board" means the state board of medical examiners.
2. "Intractable pain" means a pain state in which the cause of the pain cannot be removed or otherwise treated and which in the generally accepted course of medical practice no relief or cure of the cause of the pain is possible or none has been found after reasonable efforts.
3. "Physician" means a physician licensed by the board.

Source: S.L. 1995, ch. 218, § 1.
Effective Date. This section became effective August 1, 1995.

Section 19-03.3-02. Notwithstanding any other provision of law, a physician may prescribe or administer controlled substances to a patient in the course of the physician's treatment of the patient for intractable pain. A physician shall keep records of purchases and disposals of controlled substances prescribed or administered under this section. The records must include the date of purchase, the date of sale or administration by the physician, the name and address of the patient, and the reason for the prescribing or the administering of the substances to the patient.

Source: S.L. 1995, ch. 218, § 2.
Effective Date. This section became effective August 1, 1995.

Section 19-03.3-03. No hospital or health care facility may forbid or restrict the use of controlled substances when prescribed or administered by a physician having staff privileges at that hospital or health care facility for a patient diagnosed and treated by a physician for intractable pain.

Source: S.L. 1995, ch. 218, § 3.
Effective Date. This section became effective August 1, 1995.

Section 19-03.3-04. The board may not discipline a physician for prescribing or administering controlled substances in the course of treatment of a patient for intractable pain under this chapter.

Source: S.L. 1995, ch. 218, § 4.
Effective Date. This section became effective August 1, 1995.

Section 19-03.3-05. This chapter does not apply to a person being treated by a physician for chemical dependency because of the person's use of controlled substances. This chapter

does not authorize a physician to prescribe or administer controlled substances to a person the physician knows is using controlled substances for nontherapeutic purposes. A person to whom controlled substances are prescribed or administered for intractable pain is not exempt from section 39-08-01 or 39-20-04.1.

Source: S.L. 1995, ch. 218, § 5.
Effective Date. This section became effective August 1, 1995.

Section 19-03.3-06. This chapter does not limit the authority of the board to cancel, revoke, or suspend the license of any physician who:

1. Prescribes or administers a drug or treatment that is nontherapeutic in nature or nontherapeutic in the manner the drug or treatment is administered or prescribed.
2. Fails to keep complete and accurate records of purchases and disposals of controlled substances listed in chapter 19-03.1.
3. Writes false or ficticious prescriptions for controlled substances scheduled in chapter 19-03.1.

Source: S.L. 1995, ch. 218, § 6.
Effective Date. This section became effective August 1, 1995.

OHIO

122nd General Assembly
Substitute House Bill Number 187

An Act

To enact sections 4731.052 and 4731.283 of the Revised Code regarding the authority of physicians to prescribe,
dispense, and administer dangerous drugs for management of intractable pain.

Be it enacted by the general Assembly of the State of Ohio:

SECTION 1. That sections 4731.052 and 4731.283 of the Revised Code be enacted to read as follows:

Sec. 4731.052. (A) as used in this section:

(1) "Dangerous drug" has the same meaning as in section 4729.02 of the revised code.

(2) "Intractable pain" means a state of pain that is determined, after reasonable medical efforts have been made to relieve the pain or cure its cause, to have a cause for which no treatment or cure is possible or for which none has been found.

(3) "Physician" means an individual authorized under this chapter to practice medicine and surgery or osteopathic medicine and surgery.

(B) the state medical board shall adopt rules in accordance with chapter 119. Of the revised code that establish standards and procedures to be followed by physicians in the diagnosis and treatment of intractable pain, including standards for managing intractable pain by prescribing, dispensing, or administering dangerous drugs in amounts or combinations that may not be appropriate when treating other medical conditions. In developing the rules, the board shall consult with and permit review by physicians who are experienced in the diagnosis and treatment of intractable pain.

(C) when a physician diagnoses an individual as having intractable pain, the physician may treat the pain by managing it with dangerous drugs in amounts or combinations that may not be appropriate when treating other medical conditions. The physician's diagnosis shall be made after having the individual evaluated by one or more other physicians who specialize in the treatment of the area, system, or organ of the body perceived as the source of the pain. The physician's diagnosis and treatment decisions shall be made according to accepted and prevailing standards for medical care. The physician shall maintain a record of all of the following:

(1) medical history and physical examination of the individual;

(2) the diagnosis of intractable pain, including signs, symptoms, and causes;

(3) the plan of treatment proposed, the patient's response to treatment, and any modification to the plan of treatment;

(4) the dates on which dangerous drugs were prescribed, dispensed, or administered, the name and address of the individual to or for whom the dangerous drugs were prescribed, dispensed, or administered, and the amounts and dosage forms for the dangerous drugs prescribed, dispensed, or administered;

(5) a copy of the report made by the physician or the physician to whom referral for

evaluation was made under this division.

(D) a physician who treats intractable pain by managing it with dangerous drugs is not subject to disciplinary action by the board under section 4731.22 of the revised code solely because the physician treated the intractable pain with dangerous drugs. The physician is subject to disciplinary action only if the dangerous drugs are not prescribed, administered, or dispensed in accordance with this section and the rules adopted under it.

Sec. 4731.283. Not later than ninety days after the effective date of this section, the state medical board shall approve one or more continuing medical education courses of study included within the programs certified by the Ohio State Medical Association and the Ohio Osteopathic Association pursuant to section 4731.281 of the revised code that assist doctors of medicine and doctors of osteopathic medicine in diagnosing and treating intractable pain, as defined in section 4731.052 of the revised code.

OHIO

State Medical Board of Ohio
Source: Your Report, Spring-Summer 1994, pp. 3-5

STATE MEDICAL BOARD OF OHIO - POSITION PAPER

SCHEDULED DRUG THERAPY INCLUDING NARCOTICS FOR CHRONIC BENIGN PAIN

June 14, 1995
Revised August 14, 1996

OVERVIEW

Background

Historically, Chronic Benign Pain (subsequently referred to as CBP, and sometimes termed non-malignant pain) is a difficult medical problem to manage. For physicians and health care workers whose goal is to relieve pain and suffering, CBP management can be frustrating and hazardous. For the physician, the risks include failing to control pain, failing to return an individual to a more normal life, and contributing to patient dependence. For the patient, the risk is continued pain and suffering, and drug addiction.

Scheduled drugs, including opiates, can be appropriately used for treatment of CBP. Yet physicians may be reluctant to prescribe potentially addictive analgesics, fearing that law enforcement agencies and the State Medical Board will prosecute them. No such fear should exist with appropriate and legitimate use. The State Medical Board of Ohio has developed this position on CBP management to guide both the physician and the patient.

Definition

Chronic benign pain (CBP) defined, for purposes of this position paper, is long-standing pain not associated with malignancy or acute pain caused by trauma, surgery, infection or other factors. However, these and other pain sources, such as sprains or twists, may symptomatically persist to become CBP. The intensity will vary from mild to severe disabling pain that may significantly reduce quality of life.

Diagnosis

A diagnosis of CBP is established by a careful and complete history and physical examination, diagnostic studies, and appropriate consultation.

Treatment

There are many effective treatment methods for CBP, including, but not limited to:

-mild analgesic such as caffeine-free acetylsalitic acid (aspirin) and acetaminophen (Tylenol)
- nonsteroidal anti-inflammatory compounds
-antidepressants
-anticonvulsants
-physical therapy
-manipulative therapy (including osteopathic)
-transcutaneous nerve stimulation (TENS)
-nerve block
-mild analgesics with caffeine (non-narcotic)
-psychiatric care or psychological counseling
-biofeedback relaxation techniques.
-surgical techniques

SCHEDULED DRUGS

Some patients are refractory to treatment programs and require scheduled medications, including narcotics, to allow an acceptable quality of life. When narcotic therapy is necessary to control pain, the patient must be carefully managed to reduce the risk of developing addiction and to assure that treatment goals are met. The Medical Board has adopted the following guidelines for managing chronic benign pain when it has been determined that narcotics and other scheduled substances are needed for pain control.

1. The diagnosis of CBP is established through a history and physical examination and appropriate diagnostic studies. The examination includes a documented assessment of pain, physical and psychological function and other medical and psychological problems, as a baseline for management, which includes scheduled drugs.

2. Evidence of previous substance abuse or an addictive personality should be considered in the treatment plan.

3. There is documentation that pain cannot be adequately controlled by other treatment methods such as, but not limited to:

a. Behavior modification
b. Non-narcotic medications
c. Physical therapy
d. TENS
e. Manipulation
f. Other forms of recognized treatment

4. An appropriate drug should be chosen that has the fewest side effects and the least chance of causing addiction or tolerance.

5. There should be evidence of informed patient consent with respect to the risks and benefits of the therapy and drugs utilized.

6. The medication dosage, the route administered and the amount dispensed or prescribed is precisely and clearly documented.

7. The patient is evaluated at regular intervals, based on the stability of the disorder. That review includes:

a. An evaluation of the effectiveness of treatment, including medication, in controlling the patient's pain.

b. Verification of the patient's compliance with medical directions.

c. Consultation with pain management specialists and other consultants if indicated.

d. Follow-up and update of the treatment plan as needed. Continuation or modification of the drug treatment depends on the patient's progress toward the treatment objectives. Without progress, the physician should assess the appropriateness of continued therapy.

8. The physician maintains an accurate and complete clinical record.

9. The treating physician is licensed in the State of Ohio and obeys all State and Federal laws concerning the practice of medicine.

OKLAHOMA

Oklahoma Board of Medical Licensure and Supervision

OKLAHOMA BOARD OF MEDICAL LICENSURE AND SUPERVISION GUIDELINES FOR PRESCRIBING CONTROLLED SUBSTANCES FOR INTRACTABLE PAIN

1. HISTORY PHYSICAL EXAMINATION

A medical history and physical examination must be accomplished. This includes an assessment of the pain, physical and psychological function, substance abuse history, assessment of underlying or coexisting diseases or conditions, and should also include the presence of a recognized medical indication for the use of a controlled substance. Prescribing controlled substances for intractable pain in Oklahoma also requires evaluation by one or more specialists.

2. TREATMENT PLAN, OBJECTIVES

The treatment plan should state objectives by which treatment success can be evaluated, such as pain relief and/or improved physical and psychosocial function, and indicate if any further diagnostic evaluations or other treatments are planned. The physician should tailor drug therapy to the individual medical needs of each patient. Several treatment modalities or a rehabilitation program may be necessary if the pain has differing etiologies or is associated with physical and psychosocial impairment.

3. INFORMED CONSENT

The physician should discuss the risks and benefits of the use of controlled substances with the patient or guardian.

4. PERIODIC REVIEW

The physician should periodically review the course of opioid treatment of the patient and any new information about the etiology of the pain. Continuation or modification of opioid therapy depends on the physician's evaluation of progress toward treatment objectives. If the patient has not improved, the physician should assess the appropriateness of continued opioid treatment or trial of other modalities.

5. CONSULTATION

The physician should be willing to refer the patient as necessary for additional evaluation and treatment in order to achieve treatment objectives. In addition, physicians should give special attention to those pain patients who are at risk for misusing their medications including those whose living arrangements pose a risk for medication misuse or diversion. The

management of pain in patients with a history of substance abuse requires extra care, monitoring, documentation and consultation with addiction medicine specialists, and may entail the use of agreements between the provider and the patient that specify the rules for medication use and consequences for misuse.

6. RECORDS

The physician should keep accurate and complete records according to items 1-5 above, including the medical history and physical examination, other evaluations and consultations, treatment plan objectives, informed consent, treatments, medications, agreements with the patient, and periodic reviews.

7. COMPLIANCE WITH CONTROLLED SUBSTANCES LAWS AND REGULATIONS

To prescribe controlled substances, the physician must be appropriately licensed in Oklahoma, have a valid controlled substances registration and comply with federal and state regulations for issuing controlled substances prescriptions. Physicians are referred to the Physicians Manual of the U.S. Drug Enforcement Administration for specific rules governing issuance of controlled substances prescriptions.

OREGON

Oregon Revised Statutes
Chapter 677
Regulation of Medicine, Podiatry and Related Medical Services

Section 677.470 As used in ORS 677.470 to 677.485:

(1) "Controlled substance" has the meaning given that term under ORS 475.005.

(2) "Intractable pain" means a pain state in which the cause of the pain cannot be removed or otherwise treated and for which, in the generally accepted course of medical practice, no relief or cure of the cause of the pain has been found after reasonable efforts, including, but not limited to, evaluation by the attending physician and one or more physicians specializing in the treatment of the body area, system or organ perceived as the source of the intractable pain.

Section 677.475 (1) Notwithstanding any other provision of ORS chapter 677, a physician licensed under ORS chapter 677 may prescribe or administer controlled substances to a person in the course of the physician's treatment of that person for a diagnosed condition causing intractable pain.

(2) A physician shall not be subject to disciplinary action by the Board of Medical Examiners for prescribing or administering controlled substances in the course of treatment of a person for intractable pain.

(3) Subsections (1) and (2) of this section shall not apply to:

(a) A physician's treatment of a person for chemical dependency resulting from the use of controlled substances;

(b) The prescription or administration of controlled substances to a person the physician knows to be using the controlled substances for nontherapeutic purposes;

(c) The prescription or administration of controlled substances for the purpose of terminating the life of a person having intractable pain; or

(d) The prescription or administration of a substance that is not a controlled substance approved by the United States Food and Drug Administration for pain relief.

(4) Subsection (2) of this section shall not exempt the governing body of any hospital or other medical facility from the requirements of ORS 441.055.

Section 677.480 ORS 677.475 shall not prohibit the Board of Medical Examiners from placing on probation or denying, revoking, limiting or suspending the license of any physician who does any of the following:

(1) Prescribes or administers a controlled substance or treatment that is nontherapeutic in nature or nontherapeutic as administered or prescribed or that is administered or prescribed for a nontherapeutic purpose.

(2) Fails to keep a complete and accurate record of controlled substance purchases, dispensing and disposal as required by the Comprehensive Drug Abuse Prevention and Control Act of 1970 (P.L. 91-513), other federal law or ORS 475.005 to 475.285 and 475.940 to 475.995.

(3) Prescribes controlled substances without a legitimate medical purpose.

(4) Prescribes, administers or dispenses controlled substances in a manner detrimental to the best interest of the public.

(5) Prescribes, administers or dispenses a controlled substance in a manner prohibited under ORS 475.005 to 475.285 or 475.940 to 475.995.

(6) Falsifies prescription information, including, but not limited to, the identity of the recipient. <1995 c.380 s4>

Section 677.485 Prior to commencing the treatment of intractable pain as allowed under ORS 677.475, the physician shall provide to the person and the person shall sign a written notice disclosing the material risks associated with the prescribed or administered controlled substances to be used in the course of the physician's treatment of that person. <1995 c. 380 s5>

Effective 10/10/95

OREGON

Oregon Board of Medical Examiners
Provided by Oregon Board of Medical Examiners to the PPSG
Adopted: May 20, 1991

OREGON BOARD OF MEDICAL EXAMINERS
STATEMENT OF PHILOSOPHY

Appropriate Prescribing of Controlled Substances

Inappropriate prescribing of controlled substances is the Oregon Board of Medical Examiners' number one investigatory and disciplinary problem. Oregon Revised Statutes (ORS) regulates inappropriate prescribing under ORS 677.190 as follows:

(1) Unprofessional conduct;
(24) Violation of Federal Controlled Substances Act; and
(25) Prescribing controlled substances without a legitimate medical purpose and without following accepted procedures for examination of patients and record keeping.

ORS 677.188 defines unprofessional conduct to include any conduct or practice which does or might constitute a danger to the health or safety of a patient or the public, willful performance of any surgical or medical treatment which is contrary to acceptable medical standards, and administration of unnecessary treatments.

Controlled substances offer important health benefits to patients and should be prescribed as medically indicated. A balance must be achieved between appropriate prescribing and adequate safeguards against abuse and diversion. Underprescribing of controlled substances, for example, in the management of cancer pain, can impair optimal patient care. However, when controlled substances are inappropriately prescribed, diverted or abused, public health is damaged.

It is generally accepted in current medical therapy that it is inappropriate to treat nonmalignant pain with narcotics on a routine basis. The use of narcotics in chronic nonmalignant pain decreases the availability of endogenous opioid mechanisms and therefore may actually decrease pain thresholds. It also produces depression and thus decreases the patient's willingness to become actively involved in his/her rehabilitative effort. Sedative controlled substances, including many muscle relaxants, augment this depression in chronic nonmalignant pain.

It is accepted that there are certain patients who will be properly served by the chronic administration of controlled substances for non-malignant pain. It is imperative in these rare patients to have a clear diagnosis (with appropriate consultation, if necessary) and close monitoring of the medication with thorough documentation of records.

It should also be noted that the Drug Enforcement Administration (DEA) rules state that a

physician may not administer or prescribe controlled substances to an addict for maintenance or detoxification except in a DEA-approved program.

In response to its duty to protect the public, the Board investigates all cases involving alleged inappropriate prescribing. The investigation may include personal interviews with the Investigative Committee, examination by the Board's consultant, and review of selected office records of the physician.

From the investigation, the Board can determine the severity and frequency of inappropriate prescribing. The Board may be able to ascertain whether the physician is dishonest, disabled, duped, dated, or dysfunctional. All of these factors influence the final disposition of the case.

The Board has several educational and disciplinary programs available to correct inappropriate prescribing situations. Sometimes the Board requires participation in a triplicate prescription program that allows continuous monitoring of the physician's controlled substance use. Limitations on the prescribing of some classes of controlled substances may be necessary. A three day remedial education program is frequently used to improve a physician's knowledge base and achieve awareness of his/her problem.

To accomplish these programs, the Board has three administrative options:

1. Letter of Agreement

   The physician agrees by letter to voluntarily participate in the desired program at his/her own expence. This is not disciplinary action by the Board and therefore is not reportable to the National Practitioner Data Bank.

2. Voluntary Limitation

   The physician voluntarily requests a limitation of his/her license. This is not a disciplinary action, but is a licensure limitation, and is reported to the National Practitioner Data Bank.

3. Disciplinary Action

   Formal disciplinary action is used in more serious cases when the Board feels the physician is not likely to restrict his/her inappropriate treatment through education alone. A disciplinary action is reportable to the National Practitioner Data Bank.

The Board attempts to avoid disciplinary measures in its effort to rehabilitate physicians. All physicians are encouraged to become knowledgeable about methods of pain treatment, especially in chronic nonmalignant pain.

RHODE ISLAND

97 -- S 0836 As Amended
State of Rhode Island
In General Assembly
January, A.D., 1997
An Act Relating to Intractable Pain Treatment

It is enacted by the General Assembly as follows

SECTION 1. Title 5 of the General Laws is hereby amended by adding the following chapter thereto:

CHAPTER 5-37.4
INTRACTABLE PAIN TREATMENT

5-37.4-1. Title. -- This act shall be known and may be cited as the "INTRACTABLE PAIN TREATMENT ACT".

5-37.42. Definitions. -- For purposes of this act, the following terms mean:

(A) "Board," the Rhode Island board of medical licensure and discipline;

(B) "Intractable pain," a pain state in which the cause of pain cannot be removed or otherwise treated and which in the generally accepted course of medical practice no relief or cure of the cause of the pain is possible or none has been found after reasonable efforts that have been documented in the physician's medical records;

(C) "Physician," physicians and surgeons licensed pursuant to this act by the board;

(D) "Therapeutic purpose," the use of controlled substances in acceptable doses with appropriate indication for the treatment of pain. Any other use is nontherapeutic.

5-37.4-3. Controlled substances.-- (1) A physician may prescribe, administer or dispense controlled substances not otherwise prohibited by law for a therapeutic purpose to a person diagnosed and treated by a physician for a condition resulting in intractable pain, if such diagnosis and treatment has been documented in the physician's medical records. No physician shall be subject to disciplinary action by the board solely for prescribing, administering or dispensing controlled substances when prescribed, administered or dispensed for a therapeutic purpose for a person diagnosed and treated by a physician for a condition resulting in intractable pain, if such diagnosis and treatment has been documented in the physician's medical records.

(2) The provisions of subsection (1) of this section shall not apply to those persons being treated by a physician for chemical dependency because of their use of controlled substances not
related to the therapeutic purposes of treatment of intractable pain.

(3) The provisions of subsection (1) of this section provide no authority to a physician to prescribe, administer or dispense controlled substances to a person the physician knows or should
know to be using controlled substances which use is not related to the therapeutic purpose.

(4) Drug dependency or the possibility of drug dependency in and of itself is not a reason to withhold or prohibit the prescribing, administering or dispensing of controlled substances for the therapeutic purpose of treatment of a person for intractable pain, nor shall dependency relating solely to such prescribing, administering or dispensing subject a physician to disciplinary action by the board.

(5) Nothing in this section shall deny the right of the board to deny, revoke or suspend the license of any physician or otherwise discipline any physician who:

(1) Prescribes, administers or dispenses a controlled substance that is nontherapeutic in nature or nontherapeutic in the manner in which it is prescribed, administered or dispensed, or fails to keep complete and accurate on-going records of the diagnosis and treatment plan;

(2) Fails to keep complete and accurate records of controlled substances received, prescribed, dispensed and administered, and disposal of drugs as required by law or of controlled
substances scheduled in the Federal Comprehensive Drug Abuse Prevention and Control Act of 1970, 21 USC 801, et. seq. A physician shall keep records of controlled substances received, prescribed, dispensed and administered, and disposal of these drugs shall include the date of receipt of the drugs, the sale or disposal of the drugs by the physician, the name and address of the person receiving the drugs, and the reason for the disposal or the dispensing of the drugs to the person;

(3) Writes false or fictitious prescriptions for controlled substances as prohibited by law, or for controlled substances scheduled in the Federal Comprehensive Drug Abuse Prevention and Control Act of 1970, 21 USC 801, et. seq.; or

(4) Prescribes or administers, or dispenses in a manner which is inconsistent with provisions of the law, or the Federal Comprehensive Drug Abuse Prevention and Control Act of 1970, 21 USC 801, et. seq.

SECTION 2. This act shall take effect on July 1, 1997.

RHODE ISLAND

Rhode Island Board of Medical Licensure and Discipline
Source: Newsletter of the Rhode Island Board of Medical Licensure and Discipline, Summer 1995, p.2
Adopted: May 10, 1995

BOARD OF MEDICAL LICENSURE AND DISCIPLINE ADOPTS GUIDELINES FOR LONG TERM PAIN MANAGEMENT

The Rhode Island Board of Medical Licensure and Discipline continues to see cases in which serious problems in the management of long-term intractable pain are encountered by patients and physicians. The board is aware of the perception that many physicians "under-treat" such patients based on a fear of "causing addiction"; on the other hand, we receive many allegations of the improper, sometimes illegal, "over-use" of controlled substances. The prescribing of controlled substances in every state is regulated by state and federal law. The Board is aware that there is a national problem relating to pain management. Accordingly, the Board has undertaken a review of guidelines adopted by various state medical boards (Colorado, Texas, New Jersey, Massachusetts and California) concerning the appropriate management of patients with long-term intractable pain. The Board of Medical Licensure and Discipline was most impressed with the guidelines that the State of California has released.

The California guidelines resulted from a state sponsored summit in which 120 health care practitioners, professional and public educators, representatives from professional schools and associations and health care consumers met to recommend solutions to legal, professional, and educational barriers to effective pain management. A report, **Summit on Effective Pain Management: Removing Impediments to Appropriate Prescribing**, was issued by the Governor of California. This comprehensive report was reviewed by the Board of Medical Licensure and Discipline as part of its decision to adopt the following guidelines to help the practicing physician dealing with this difficult problem.

GUIDELINES FOR LONG TERM PAIN MANAGEMENT

1. **HISTORY/PHYSICAL EXAMINATION**
   A medical history and physical examination must be accomplished. This includes an assessment of the pain, physical and psychological function, substance abuse history, assessment of underlying or coexisting diseases or conditions, and should also include the presence of a recognized medical indication for the use of a controlled substance.

2. **TREATMENT PLAN, OBJECTIVES**
   The treatment plan should state objectives by which treatment success can be evaluated, such as pain relief and/or improved physical and psychosocial function, and indicate if any further diagnostic evaluations or other treatments are planned. The physician should tailor drug therapy to the individual medical needs of each patient. Several treatment modalities or a rehabilitation program may be necessary if the pain has differing

etiologies or is associated with physical and psychosocial impairment.

3. INFORMED CONSENT

The physician should discuss the risks and benefits of the use of controlled substances with the patient, guardian or authorized representative. This discussion should be documented and signed by the patient, guardian or authorized representative.

4. PERIODIC REVIEW

The physician should periodically review the course of opioid treatment of the patient and any new information about the etiology of the pain. Continuation or modification of opioid therapy depends on the physician's evaluation of progress toward treatment objectives. If the patient has not improved, the physician should assess the appropriateness of continued opioid treatment or trial of other modalities.

5. CONSULTATION

The physician should be willing to refer the patient as necessary for additional evaluation and treatment in order to achieve treatment objectives. In addition, physicians should give special attention to those pain patients who are at risk for misusing their medications including those whose living arrangements pose a risk for medication misuse or diversion. The management of pain in patients with a history of substance abuse requires extra care, monitoring, documentation and consultation with addiction medicine specialists, and may entail the use of agreements between the provider and the patient that specify the rules for medication use and consequences for misuse.

6. RECORDS

The physician should keep accurate and complete records according to items 1-5 above, including the medical history and physical examination, other evaluations and consultations, treatment plan objectives, informed consent, treatments, medications, agreements with the patient, and periodic reviews.

7. COMPLIANCE WITH CONTROLLED SUBSTANCES LAWS AND REGULATIONS

To prescribe controlled substances, the physician must be licensed appropriately in Rhode Island, have a valid controlled substances registration and comply with federal and state regulations for issuing controlled substances prescriptions. Physicians are referred to the Physicians Manual of the U.S. Drug Enforcement Administration and the General Laws of the State of Rhode Island relating to the Board of Medical Licensure and Discipline and the Division of Drug Control of the Rhode Island Department of Health.

EXPLANATION
OF
ANACT
RELATING TO INTRACTABLE PAIN TREATMENT

This act prohibits a physician from being subject to disciplinary action by the state board of medical licensure and discipline solely for prescribing, administering or dispensing controlled substances to treat a condition resulting in "intractable pain." "Intractable pain" is defined as pain whose cause cannot be removed or otherwise treated, and in which, in the generally accepted course of medical practice, no relief or cure is possible, or none has been found after reasonable efforts.

The act also provides that drug dependency and the possibility of drug dependency should not be
the sole reasons to withhold or prohibit the prescribing, administering or dispensing of a controlled substance to treat intractable pain. It prohibits the state board of medical licensure and discipline from subjecting a physician to disciplinary action solely due to prescribing, administering or dispensing controlled substances for treating intractable pain of drug-dependent people.

97S0836AA
Text of Bills provided by the Joint Committee on Legislative Services

Effective Date: July 1, 1997.

TENNESSEE

Tennessee State Board of Medical Examiners
Source: BME Prescribing Policy p. 1-2, provided by the Tennessee Board to the PPSG
Approved: September 19, 1995

Policy Statement
Tennessee State Board of Medical Examiners

POLICY: MANAGEMENT OF PRESCRIBING WITH EMPHASIS ON ADDICTIVE OR DEPENDENCE-PRODUCING DRUGS

The Tennessee Board of Medical Examiners is charged by the General Assembly to protect the citizens of the State from harmful physician management. A significant number of physicians who are asked to appear before the Board are required to do so because of their lack of information about the management and responsibilities involved in prescribing controlled substances. Frequently, the inadvertent offender is a physician with a warm heart and a desire to relieve pain and misery, who is always pressed for time and finds himself or herself prescribing controlled drugs on demand over prolonged periods without adequate documentation. These are often for chronic ailments such as headache, arthritis, old injuries, chronic orthopedic problems, backache and anxiety. (Terminal cancer pain management is not a consideration here.) The purpose of the Board of Medical Examiners in presenting the following information is to help licensed physicians in Tennessee consider and reevaluate their prescribing practice of controlled substances. Practicing physicians have often mentioned the abrupt education they received in their own prescribing patterns. Moreover, there have been many request to the Board from physicians requesting detailed information on prescribing in certain specific situations.

It is not what you prescribe, but how well you manage the patient's care, and document that care in legible form, that is important.

The prescribing matters that come before the Board are almost always related to the prescription of controlled substances. We feel that a majority of instances where physicians have been disciplined by the Board for prescribing practices could have been avoided completely if they had followed the steps that are being outlined here.

To prevent any misunderstanding, it is necessary to state what the Board **does not** have.

It **does not** have a list of "bad" or "disallowed" drugs, except in certain circumstances, amphetamines, amphetamine-like substances and central nervous system stimulants. (See, Board of Medical Examiner Rule 0880-2-.14, a copy of which is available to you by contacting the Board's administrative office at (615) 367-6231.) All formulary drugs, except as previously noted, are good if prescribed and administered when properly indicated. Conversely, all drugs are ineffective, dangerous, or even lethal when used inappropriately.

It **does not** have a some magic formula for determining the dosage and duration of administration for any drug. These are aspects of prescribing that must be determined within the confines of the individual clinical case, and continued under proper monitoring. What is good for one patient may be insufficient or fatal for another.

What the Board **does** have is the expectation that physicians will create a record that shows:
- Proper indication for the use of drug or other therapy;
- Monitoring of the patient where necessary;
- The patient's response to therapy based on follow-up visits; and
- All rationale for continuing or modifying the therapy.

STEP ONE

First and foremost, before you prescribe anything, start with a diagnosis which is supported by history and physical findings, and by the results of any appropriate tests. Too many times a doctor is asked why he or she prescribed a particular drug, and the response is, "Because the patient has arthritis." Then the doctor is asked "How did you determine that?", and the answer is," Because that's what the patient complained of." Nothing in the record or in the doctor's recollection supports the diagnosis except the patient's assertion. **Do a workup sufficient to support a diagnosis** including all necessary tests.

STEP TWO

Create a treatment plan which includes the use of appropriate non-addictive modalities, and make referrals to appropriate specialists, such as neurologists, orthopedists, psychiatrists, etc. The result of the referral should be included in the patient's chart.

STEP THREE

Before beginning a regimen of controlled drugs, make a determination through trial or through a documented history that **non-addictive modalities are not appropriate or they do not work.** A finding of intolerance or allergy to NSAIDs is one thing, but the assertion of the patient that, "Gosh, Doc, nothing seems to work like that Percodan stuff!" is quite another. Too many of the doctors the Board has seen have started a treatment program with powerful controlled substances without ever considering other forms of treatment.

STEP FOUR

Make sure you are not dealing with a drug-seeking patient. If you know the patient, review the prescription records in the patient's chart and discuss the patient's chemical history before prescribing a controlled drug. If the patient is new or otherwise unknown to you, at a minimum obtain an oral drug history, and discuss chemical use and family chemical history with the patient.

STEP FIVE

It is a good idea to obtain the informed consent of the patient before using a drug that has the potential to cause dependency problems. **Take the time to explain the relative risks and benefits of the drug and record in the chart the fact that this was done.** When embarking on what appears to be the long term use of a potentially addictive substance, it may be wise to hold a family conference and explain the relative risks of dependency or addiction and what that may mean to the patient and to the patient's family. Refusal of the patient to permit a family conference may be significant information.

STEP SIX

Maintain regular monitoring of the patient, including frequent physical monitoring. If the regimen is for a prolonged drug use, it is very important to monitor the patient for the root condition which necessitates the drug **and** for the side effects of the drug itself. This is true no matter what type of controlled substance is used or what schedule it belongs to. Also, remember that with certain conditions, drug holidays are appropriate. This allows you to check to see whether the original symptoms recur when the drug is not given - indicating a continuing legitimate need for the drug or whether withdrawal symptoms occur - indicating dependence.

STEP SEVEN

Make sure YOU are in control of the supply of the drug. To do this, at a minimum you must keep detailed records of the type, dose, and amount of the drug prescribed. You must also monitor, record and personally control all refills. Do not authorize your office personnel to refill prescriptions without consulting you. **One good way to accomplish this is to require the patient to return to obtain refill authorization, at least part of the time.** Records of the cumulative dosage and average daily dosage are especially valuable. A thumbnail sketch of three hypothetical cases will illustrate our point here. In the first case, a physician prescribes Tussionex to a patient for approximately five years for a cumulative dosage of nineteen and one half gallons. In the second case, a physician prescribes, Tylenol 3's to a patient for slightly more than a year at the average daily rate of 30 per day! The third case is very similar, except that it was Tylenol 4's at the rate of 20 per day. Some quick observations:

- No physician who was aware of that kind of prescribing would have continued with it.
- Few, if any, patients could have been consuming that much Tylenol with codeine. In all likelihood, they were reselling it.

Another important part of controlling the supply of drugs is to check on whether the patient is obtaining drugs from other physicians. Checking with pharmacies and pharmacy chains and other health care providers may tell you whether a patient is obtaining extra drugs or the patient is doctor shopping. If you are aware it is occurring, contact other physicians and health professionals in your area.

STEP EIGHT

Maintaining regular contact with the patient's family is a valuable source of information on the patient's response to the therapy regimen, and may be much more accurate and objective than feedback from the patient alone.

The family is a much better source of information on behavioral changes, especially dysfunctional behavior, than is the patient. Dysfunctional changes may be observable when the patient is taking the drug, or when the drug is withdrawn. These changes, at either time, may be a symptom of dependency or addiction.

The family is also a good source of information on whether the patient is obtaining drugs from other sources, or is self-medicating with other drugs or alcohol.

STEP NINE

To reiterate, one of the most frequent problems faced by a physician when he or she comes before the Board or other outside review bodies is **inadequate records**. It is entirely possible that the doctor did everything correctly in managing a case, but without records which reflect all the steps that went into the process, the job of demonstrating it to any outside reviewer becomes many times more difficult. Luckily, this is a problem which is solvable.

Adopted by the Board of Medical Examiners on this the 19th day of September, 1995.

Note

The above policy was taken almost verbatim from the practice statement issued by the Board of Medical Examiners of the State of North Carolina in February of 1991 to all its licensees. We express our appreciation to them, and the Minnesota Board of Medical Examiners who originally distributed this information in 1990, and acknowledge the authorship by those two Boards of this nine step process.

TEXAS

Texas Civil Statutes
Title 71: Health Public
Art. 4495c. Intractable Pain Treatment Act

Short Title

Sec. 1. This article may be cited as the Intractable Pain Treatment Act.

Definitions

Sec. 2. For the purposes of this Act:

(1) "Board" means the Texas State Board of Medical Examiners.

(2) "Physician" means a licensee of the Texas State Board of Medical Examiners.

(3) "Intractable pain" means a pain state in which the cause of the pain cannot be removed or otherwise treated and which in the generally accepted course of medical practice no relief or cure of the cause of the pain is possible or none has been found after reasonable efforts.

Prescription or administration of drugs by physician

Sec. 3. Notwithstanding any other provision of law, a physician may prescribe or administer dangerous drugs or controlled substances to a person in the course of the physician's treatment of a person for intractable pain.

Restriction by hospital or health care facility of prescribed drug use prohibited

Sec. 4. No hospital or health care facility may forbid or restrict the use of dangerous drugs or controlled substances when prescribed or administered by a physician having staff privileges at that hospital or health care facility for a person diagnosed and treated by a physician for intractable pain.

Disciplinary action against physician for prescribing or administering drug treatment prohibited

Sec. 5. No physician may be subject to disciplinary action by the board for prescribing or administering dangerous drugs or controlled substances in the course of treatment of a person for intractable pain.

Application of act to chemically dependent persons

Sec. 6. (a) The provisions of this Act shall not apply to those persons being treated by the physician for chemical dependency because of their use of dangerous drugs or controlled substances.

(b) The provisions of this Act provide no authority to a physician to prescribe or administer dangerous drugs or controlled substances to a person the physician knows or should know to be using drugs for nontherapeutic purposes.

Cancellation, revocation or suspension of physician's license

Sec. 7. Nothing in this Act shall deny the right of the Texas State Board of Medical Examiners to cancel, revoke, or suspend the license of any physician who:

(1) prescribes or administers a drug or treatment that is nontherapeutic in nature or nontherapeutic in the manner the drug or treatment is administered or prescribed;

(2) fails to keep complete and accurate records of purchases and disposals of drugs listed in the Texas Controlled Substances Act (Chapter 481, Health and Safety Code), or of controlled substances scheduled in the federal Comprehensive Drug Abuse Prevention and Control Act of 1970, 21 U.S.C.A. Section 801 et seq. (Public Law 91-513). A physician shall keep records of his purchases and disposals of these drugs to include the date of purchase, the sale or disposal of the drugs by the physician, the name and address of the person receiving the drugs, and the reason for the disposal of or the dispensing of the drugs to the person;

(3) writes false or fictitious prescriptions for dangerous drugs as defined by Chapter 483, Health and Safety Code, for controlled substances scheduled in the Texas Controlled Substances Act (Chapter 481, Health and Safety Code), or for controlled substances scheduled in the federal Comprehensive Drug Abuse Prevention and Control Act of 1970, 21 U.S.C.A. Section 801 et seq. (Public Law 91-513); or

(4) prescribes, administers, or dispenses in a manner not consistent with public health and welfare dangerous drugs as defined by Chapter 483, Health and Safety Code, controlled substances scheduled in the Texas Controlled Substances Act (Chapter 481, Health and Safety Code), or controlled substances scheduled in the federal Comprehensive Drug Abuse Prevention and Control Act of 1970, 21 U.S.C.A. Section 801 et seq. (Public Law 91-513).

Added by Acts 1989, 71st Leg., 1st C.S., ch. 5, § 1, eff. Nov. 1, 1989.

TEXAS

H.B. No. 120
An Act

relating to a physician's treatment of acute or chronic pain.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF TEXAS:

SECTION 1. Section 6, Article 4495c, Revised Statutes, is amended to read as follows:

Sec. 6. APPLICATION OF ACT TO CHEMICALLY DEPENDENT PERSONS. (a) Except as provided by Subsection (c) of this section, the provisions of this Act shall not apply to those persons being treated by the physician for chemical dependency because of their use of dangerous drugs or controlled substances.

(b) The provisions of this Act provide no authority to a physician to prescribe or administer dangerous drugs or controlled substances to a person for other than legitimate medical purposes as defined by the board and who the physician knows or should know to be using drugs for nontherapeutic purposes.

(c) The provisions of this Act authorize a physician to treat a patient who develops an acute or chronic painful medical condition with a dangerous drug or a controlled substance to relieve the patient's pain using appropriate doses, for an appropriate length of time, and for as long as the pain persists. A patient under this subsection includes a person who:

(1) is a current drug abuser;

(2) is not currently abusing drugs but has a history of drug abuse; or

(3) lives in an environment that poses a risk for drug misuse or diversion of the drug to illegitimate use.

(d) A physician who treats a patient under Subsection (c) of this section shall monitor the patient to ensure the prescribed dangerous drug or controlled substance is used only for the treatment of the patient's painful medical condition. To ensure that the prescribed dangerous drug or controlled substance is not being diverted to another use and the appropriateness of the treatment of the patient's targeted symptoms, the physician shall:

(1) specifically document:

(A) the understanding between the physician and patient about the patient's prescribed treatment;

(B) the name of the drug prescribed;

(C) the dosage and method of taking the prescribed drug;

(D) the number of dose units prescribed; and

(E) the frequency of prescribing and dispensing the drug; and

(2) consult with a psychologist, psychiatrist, expert in the treatment of addictions, or other health care professional, as appropriate.

SECTION 3. Article 4495c, Revised Statutes, is amended by adding Section 8 to read as follows:

Sec. 8. ILLEGAL SUBSTANCES. This Act is not intended nor shall it be interpreted to allow for the prescription of any illegal substance to any patient or person at any time in violation of federal law.

SECTION 4. This Act takes effect September 1, 1997, and applies only to a dangerous

drug or controlled substance prescribed by a physician on or after that date. A dangerous drug or controlled substance prescribed by a physician before the effective date of this Act is governed by the law in effect on the date the drug or controlled substance was prescribed, and the former law is continued in effect for that purpose.

TEXAS

Texas Administrative Code
Texas State Board of Medical Examiners
Chapter 170. Authority of Physician to Prescribe for the Treatment of Pain

22 TAC §§170.1-170.3

§170.1. *Purpose.* The purpose of this chapter is to recognize that some dangerous drugs and controlled substances listed in Chapter 481 and 483 of the Texas Health and Safety Code are indispensable for the treatment of pain, and are useful for relieving and controlling many other related symptoms that patients may suffer. It is the position of the board that these drugs may be prescribed for the treatment of pain and other related symptoms after a reasonably based medical diagnosis has been made, in adequate doses, and for appropriate lengths of time, which in some cases may be as long as the pain or related symptoms persist. The board recognizes that pain, including intractable pain, and many other related symptoms are subjective complaints and that the appropriateness and the adequacy of drug and dose will vary from individual to individual. The practitioner is expected to exercise sound medical judgment in treating pain and related symptoms with dangerous drugs and controlled substances.

§170.2. *Definitions.* The following words and terms, as used in the Medical Practice Act, Article 4495b, §3.08, shall have the following meanings in the context of providing medications for pain and related symptoms.

Abuser of narcotic drugs, controlled substances and dangerous drugs--A person who takes a drug or drugs for other than legitimate medical purposes.

Intractable pain--A pain state in which the cause of the pain cannot be removed or otherwise treated and which in the generally accepted course of medical practice no relief or cure of the cause of the pain is possible or none has been found after reasonable efforts.

Non-therapeutic in nature or manner--A medical use or purpose that is not legitimate.

Prescribing pharmaceuticals or practicing consistent with the public health and welfare--Prescribing pharmaceuticals and practicing medicine for a legitimate medical purpose in the usual course of professional practice.

§170.3 *Guidelines.* The Texas State Board of Medical Examiners will use the following guidelines to determine whether a physician's conduct violates the Medical Practice Act, Sections 3.08(4)(E), 3.08(4)(F), and 3.08(18) in regard to the prescribing, administering, ordering, or dispensing of pain medications and other drugs necessary to address their side effects.

(1) The treatment of pain, including intractable pain, with dangerous drugs and controlled substances is a legitimate medical purpose when done in the usual course of professional practice.

(2) A physician or surgeon duly authorized to practice medicine in Texas and to prescribe controlled substances and dangerous drugs in this state shall not be subject to disciplinary action by the board for prescribing, ordering, administering, or dispensing dangerous drugs or controlled substances for the treatment and relief of pain, including intractable pain, in the usual course of professional practice for a legitimate medical purpose in compliance with applicable state and federal law.

(3) Prescribing, ordering, administering, or dispensing dangerous drugs or controlled substances for pain will be considered to be for a legitimate medical purpose if based upon accepted scientific knowledge of the treatment of pain, including intractable pain, not in contravention of applicable state or federal law, and if prescribed, ordered, administered, or dispensed in compliance with the following guidelines where appropriate and as is necessary to meet the individual needs of the patient:

(A) After a documented medical history, which may be provided orally or in writing by the patient, and physical examination by the physician providing the medication including an assessment and consideration of the pain, physical and psychological function, any history and potential for substance abuse, coexisting diseases and conditions, and the presence of a recognized medical indication for the use of a dangerous drug or controlled substance;

(B) Pursuant to a written treatment plan tailored for the individual needs of the patient by which treatment progress and success can be evaluated with stated objectives such as pain relief and/or improved physical and psychosocial function. Such a written treatment plan shall consider pertinent medical history and physical examination as well as the need for further testing, consultations, referrals, or use of other treatment modalities;

(C) The physician should discuss the risks and benefits of the use of controlled substances with the patient or guardian;

(D) Subject to documented periodic review of the care by the physician at reasonable intervals in view of the individual circumstances of the patient in regard to progress toward reaching treatment objectives which takes into consideration the course of medications prescribed, ordered, administered, or dispensed as well as any new information about the etiology of the pain;

(E) Complete and accurate records of the care provided as set forth in subparagraphs (A)-(D) of this paragraph should be kept. When controlled substances are prescribed, names, quantities prescribed, dosages, and number of authorized refills of the drugs should be recorded, keeping in mind that pain patients with a history of substance abuse or who live in an environment posing a risk for medication misuse or diversion require special consideration. Management of these patients may require closer monitoring by the physician managing the pain and consultation with appropriate health care professionals.

(4) A decision by a physician not to strictly adhere to the provisions of paragraph (3) of this section will, for good cause shown, be grounds for the board to take no disciplinary action in regard to the physician. Each case of prescribing for pain will be evaluated on an individual basis. The physician's conduct will be evaluated to a great extent by the treatment outcome, taking into account whether the drug used is medically and/or pharmacologically recognized to be appropriate for the diagnosis, the patient's individual needs including any improvement in

functioning, and recognizing that some types of pain cannot be completely relieved.

(5) If the provisions as set out in paragraphs (1)-(4) of this section are met, and if all drug treatment is properly documented, the board will consider such practices as prescribing in a therapeutic manner, and prescribing and practicing medicine in a manner consistent with public health and welfare.

(6) Quantity of pharmaceutical and chronicity of prescribing will be evaluated on the basis of the documented appropriate diagnosis and treatment of the recognized medical indication, documented persistence of the recognized medical indication, and properly documented follow-up evaluation with appropriate continuing care as set out in this chapter.

(7) A physician may use any number of treatment modalities for the treatment of pain, including intractable pain, which are consistent with legitimate medical purposes.

(8) These rules shall not be construed so as to apply to the treatment of acute pain with dangerous drugs or controlled substances for purposes of short-term care.

Effective April 7, 1995.

TEXAS

Texas State Board of Medical Examiners
Source: Newsletter, Volume 15, num. 1, Spring/Summer 1993, p.1

Pain Control and the Texas State Board of Medical Examiners

by C. Richard Stasney, M.D. and C. Stratton Hill, M.D.

Quality medical practice dictates that those citizens of Texas who suffer pain and other distressing symptoms should be adequately relieved so that their quality of life is as optimum as can be. Therefore, in agreement with the International Narcotic Control Board, Section 21 of the Code of Federal Regulations and the Intractable Pain Treatment Act of Texas, the Texas State Board of Medical Examiners recognizes that opioids (narcotics) and other Scheduled Controlled substances, are indispensable for the treatment of pain; and, are useful for relieving and controlling many other distressing symptoms that patients may suffer. It is the position of the Board that these drugs be prescribed for the treatment of these symptoms in appropriate and adequate doses after an appropriate diagnosis is made.

In determining the standard of practice for the use of these drugs the Board will focus on their use for the targeted symptom diagnosed after a careful history, physical examination, and appropriate laboratory studies have been done. The Board recognizes that pain, and many other symptoms are subjective complaints and appropriateness and adequacy of drug and dose will vary from individual to individual. The standard will be determined largely by the treatment outcome taking into account that the drug used is pharmacologically recognized to be appropriate for the diagnosis as determined by a consensus of medical practitioners in the State, or by recognized experts in the field for which the drug is being used. Quantity and chronicity of prescribing will be judged on the basis of the diagnosis and treatment of the targeted symptoms and neither of these factors are prima facie evidence of inappropriate or excessive prescribing.

The Board further recognizes that controlled substances are subject to abuse by individuals who seek them for mood altering and other psychological effects rather than their legitimate medical uses. When prescribing controlled substances, the practitioner should be diligent in preventing them from being diverted from legitimate to illegitimate use. Tolerance and physical dependence are normal consequences of sustained use of these drugs and are not synonymous with psychological dependency (addiction) on them. Psychological dependency is characterized by the compulsion to take the drug despite its harmful and destructive effect on the individual.

The Board hopes this statement will clarify its position on the appropriate use of opioids and other scheduled drugs for treatment of pain and other distressing symptoms.

UTAH

Utah Physicians Licensing Board
Source: Journal of Pharmaceutical Care in Pain and Symptom Control, Volume 1(1) 1993, pp. 109-112

COMMENTARIES

Prescribing Controlled Substances for Cancer Pain: Position Paper of the Utah Division of Occupational and Professional Licensing

David E. Robinson

The Division of Occupational and Professional Licensing of the Utah State Department of Commerce is the agency charged with the responsibility of licensing and regulating the practice of various practitioners who have the right to dispense, administer, and prescribe controlled substances as they are defined by federal and state law. The Division is also responsible for the administration and enforcement of the Utah Controlled Substances Act as it relates to the regulated professions. The Division has the authority, upon finding of cause, to revoke, suspend, restrict, or place on probation both the professional license and the Utah controlled substance license issued to an individual.

There is within the Division a professional licensing board for each of the regulated professions. Each board is generally made up of four to six professionals and one member representing the general public. The boards are created to advise the Division and recommend appropriate sanctions in cases of unprofessional or unlawful conduct by a licensee.

Regulation of the licensed professions is approached by the Division from the position that the licensees are usually competent in the practice of their professions and justified in their conduct. It is inappropriate, except on rare occasions upon a showing of good cause, for the Division to insert itself into the near sacred relationship which must exist between a licensed health care professional and his patient. That relationship must be founded in the competence and wisdom of the practitioner coupled with the trust and cooperation of the patient. The unnecessary and unwise intrusion into that relationship by the "regulator" is the classic representation of abusive government acting at its worst.

In its effort to fulfill its statutory responsibilities under the professional licensing acts and the Utah Controlled Substance Act, the Division both receives complaints and proactively seeks information regarding uses of controlled substances. After identifying prescribing patterns involving high uses of controlled substances, and/or repeated and frequent prescriptions over a period of time, our experience has shown in well over 90% of the cases that one of the following is occurring:

1. an honest and well intentioned practitioner is being duped by a drug seeking person; or

2. a patient in need is appropriately receiving high doses of a controlled substance to handle intractable pain associated with a terminal illness or other serious condition.

In the event of either of the above, it is clear from our experience that a courteous call upon the practitioner with a request for an explanation usually determines that the practitioner has been an innocent victim, or the practitioner is properly treating a patient's need. When the circumstances involve a drug seeking individual, the practitioner is grateful for the information indicative of the extent of the patient use, the fact that the patient may be seeing other practitioners for the same purpose, and the article used by the patient to receive controlled drugs. The dialogue results in an educational experience for the practitioner and a positive interchange with the regulatory representative. In those cases involving proper treatment for pain, there results again a positive experience between the practitioner and the regulatory representative. It is rare that the practitioner expresses or displays any resentment over a courteous and professional inquiry.

On rare occasions, inquiry determines inappropriate prescribing of controlled substances. Over 90% of those rare cases involve one of the following:

1. inappropriate prescribing by a practitioner for "profit," with profit found to be money, sexual favors, splitting use of the drugs with the patient, or other creative reasons which are usually unlawful as well as unprofessional; or
2. the physician is well intentioned; but, he is simply not adequately prepared to handle the total circumstances with which he is presented and his prescribing of controlled substances is inappropriate.

With respect to the first circumstance, the Division proceeds with appropriate action against the license(s) of the practitioner and considers filing of criminal charges when appropriate.

On occurrence of the second circumstance, a relatively infrequent occurrence, the Division considers the appropriate course of action to be education. We are not dealing with an intentional inappropriate act or a practitioner of poor character or ability. It is our position that such a contact by the regulator's representative with the practitioner should result in a positive experience when handled in a courteous, caring, and professional manner.

Utah has considered the adoption of a triplicate prescription program noting that per capita consumption of certain controlled drugs has been ranked very high nationally. Those drugs have typically been amphetamine, methamphetamine, methylphenidate, cocaine, hydrocodone, opium tincture, and sufentanil. Upon a belief that a triplicate prescription program unnecessarily intrudes into the conscious process of a practitioner's decisions with respect to treatment of a patient, the State of Utah has rejected the triplicate program as the best option. Alternatively the course being studied is the adoption of a program which will directly "read" the computers of all retail pharmacies and transfer information regarding controlled substances dispensed on prescription into a Division data base. The same information available through a triplicate program will be available to the Division much more quickly and without the need to enter data a second time. Most importantly, the information will be available without imposing upon the physician the conscious reminder that the regulator is looking at his prescribing of a controlled substance for that patient. The influence of the regulator is left, if ever to be exposed, to a private, courteous, and professional interchange between the practitioner and regulator's representative when such appears necessary.

Old expectations die hard and practitioners' fear of regulators watching over their shoulders remains active in the minds of too many practitioners. An effective regulating

agency known for its understanding of the professions which it regulates, and a policy of fairness, best serves the interest of the public it is directed to serve. Such a policy may result in a failure to administratively handle or criminally prosecute an offending practitioner as quickly as it otherwise might. Such a policy will probably prevent, however, the inappropriate intervention of that regulator in that near sacred relationship which must exist between a competent and dedicated practitioner and his patient in need. That inappropriate intervention would be the greater wrong.

VERMONT

Vermont Board of Medical Practice
Source: Provided by the Vermont Board of Medicine to the PPSG
Adopted: June 5, 1996

VERMONT BOARD OF MEDICAL PRACTICE
REPORT OF THE PRESCRIBING PRACTICES COMMITTEE

Statement of Problem

Pain comes in many shapes and sizes: acute pain following random trauma and following surgical procedures; chronic pain associated with cancer and other progressive conditions, chronic pain with other etiologies sometimes difficult to clearly establish. Physicians must conscientiously and adequately treat pain. Many treatment modalities are available, including federally-regulated drugs. Pain management specialists suggest some pain, as examples, chronic cancer pain and post-operative pain, may be inadequately treated because of ill-founded concerns about the development of dependence or addiction. At the other end of the spectrum, physicians may be duped or lulled into over-prescribing controlled drugs for patients with poorly-defined pain complaints.

The Board seldom receives complaints suggesting inadequate treatment of acute pain and cancer pain. In reviewing patient records for other concerns, we do have a non-scientific sample which supports the observation that acute pain and chronic cancer pain are adequately treated by our licensees. However, we must accept literature findings that offer a less favorable picture, that is, both post-operative and cancer pain are often inadequately treated.

We do receive complaints and reports of suspicious prescribing practices for chronic non-cancer pain. Let us emphasize that we recognize that chronic non-cancer pain does exist and should be adequately treated. However, the physician who treats these often challenging patients should adhere to certain basic principles which have been more precisely delineated in recent years.

A surprising number of licensees appear to be unaware of the very real potential for being sought out as a source of controlled substances by drug-seeking individuals who want these agents for purposes other than legitimate pain relief.

The Board of Medical Practice, which must review all complaints and reports, views either under or over treatment (prescribing) as a quality-of-care issue which requires a determination whether the practice rises to the level of unprofessional conduct. This report represents a consensus statement which will guide the Board in the evaluation of complaints regarding treatment of pain in general and prescribing practices for non-cancer pain in particular.

Consensus Statement of Practice Principles

Numerous drug and non-drug therapies are used for pain management. The proper treatment of pain requires careful diagnosis of etiology, selection of appropriate therapies and ongoing evaluation of treatment efficacy. Opioid analgesics and other controlled drugs remain the cornerstone in the management of acute pain due to trauma and surgery and in chronic pain resulting from progressive diseases such as cancer. Large doses may be necessary to control pain, because of severity. Extended therapy may be necessary when pain is chronic. A physician who fails to adequately relieve pain under these circumstances is open to criticism regarding the quality of care provided.

The Board recognizes that opioid analgesics can be useful in the treatment of intractable non-cancer pain, especially when efforts to use other therapeutic modalities have failed. The pain may have multiple etiologies which require several concurrent therapies, including opioid analgesics and other controlled drugs. The extent to which pain is associated with physical and psychosocial impairment varies greatly. Thus, patient selection for a trial of opioid therapy should include a careful assessment of the disability experienced by the patient as well as the pain. Reasonable use of other health resources and evaluation of the results of therapy, including the degree of pain relief and improvements in physical and psychosocial function, are essential parts of the total care plan. As a general rule, the primary treating physician should consult with a specialist in pain management before committing to a long-term opioid treatment plan.

Physicians should pay particular attention to patients who misuse prescriptions or have a history of drug abuse or diversion. Failure to make a conscientious inquiry into these areas could create a problem for the physician in defending the overall quality of the ultimate care plan, while quickly earning a reputation as an "easy mark" for access to drugs for other than legitimate purposes. Managing drug-seeking patients presents a special challenge in monitoring. Undoubtedly, consultation with a specialist colleague with training and experience in pain management and addiction medicine is a wise choice, both for optimal patient care and physician education and protection.

Management of chronic non-cancer pain, especially when long-term opioid therapy is involved, presents a time-consuming challenge to the practitioner. Meticulous attention to adequate record keeping is essential. Careful documentation of the rationale for the management plan provides the best defense against any accusation of inappropriate controlled drug prescribing.

Under federal and state law, it is illegal to prescribe controlled substances for other than legitimate medical purposes. Addiction maintenance or withdrawal therapy is permitted only within a legally-endorsed methadone maintenance program.

We believe the following Basic Principles summarize a reasonable set of requirements for safe and effective management of chronic pain.

Basic Principles

1. History and Physical Examination

A medical history and physical examination must be accomplished. This includes an assessment of the pain, physical and psychological function, substance abuse history, assessment of underlying or coexisting diseases or conditions, and should also include the presence of a recognized medical indication for the use of a controlled substance.

2. Treatment Plan

The treatment plan should state objectives by which treatment success can be evaluated, such as pain relief and/or improved physical and psychosocial function, and indicate if any further diagnostic evaluations or other treatments are planned. The physician should tailor drug therapy to the individual needs of each patient. Several treatment modalities or a rehabilitation program may be necessary if the pain has differing etiologies or is associated with physical and psychological impairment.

3. Informed Consent

They physician should discuss the risks and benefits of the use of controlled substances with the patient or guardian.

4. Periodic Review

The physician should periodically review the course of opioid treatment of the patient and any new information about the etiology of the pain. Continuation or modification of opioid therapy depends on the physician's evaluation of progress toward treatment objectives. If the patient has not improved, the physician should assess the appropriateness of continued opioid treatment or trial of other modalities.

5. Consultation

The physician should be willing to refer the patient, as necessary, for additional evaluation and treatment in order to achieve treatment objectives. In addition, physicians should give special attention to those pain patients who are at risk for misusing their medications, including those whose living arrangements pose a risk for medication misuse or diversion. The management of pain in patients with a history of substance abuse requires extra care, monitoring, documentation and consultation with addiction medicine specialists, and may require the use of agreements between the provider and the patient that specify the rules for medication use and consequences arising from misuse.

6. Records

The physician should keep accurate and complete records describing 1 through 5 above.

VIRGINIA

The Code of Virginia
Title 54.1: Professions & Occupations

§ 54.1-2971.01 Prescription in excess of recommended dosage in certain cases. A. Consistent with §54.1-3408.1, a physician may prescribe a dosage of a pain-relieving agent in excess of the recommended dosage upon certifying the medical necessity for the excess dosage in the patient's medical record. Any practitioner who prescribes, dispenses or administers an excess dosage in accordance with this section and §54.1-3408.1 shall not be in violation of the provisions of this title because of such excess dosage, if such excess dosage is prescribed, dispensed or administered in good faith for recognized medicinal or therapeutic purposes.

B. The Board of Medicine shall advise physicians of the provisions of this section and §54.1-3408.1.

§ 54.1-3408.1. Prescription in excess of recommended dosage in certain cases. - In the case of a patient with intractable pain, a physician may prescribe a dosage in excess of the recommended dosage of a pain relieving agent if he certifies the medical necessity for such excess dosage in the patient's medical record. Any person who prescribes, dispenses or administers an excess dosage in accordance with this section shall not be in violation of the provisions of this title because of such excess dosage, if such excess dosage is prescribed, dispensed or administered in good faith for accepted medicinal or therapeutic purposes.

Nothing in this section shall be construed to grant any person immunity from investigation or disciplinary action based on the prescription, dispensing or administration of an excess dosage in violation of this title. (1988, c. 870, § 54-524.65:1; 1990, c. 681; 1995, c. 277.)

VIRGINIA BOARD OF MEDICINE

Guidelines for the Use of Opioids in the Management of Chronic, Noncancer Pain

All practitioners with the authority to prescribe controlled substances Schedule II-V must have a clear understanding of their obligations and responsibilities when using these agents. As the medical community promotes the new advances in the management of the patient with chronic pain, all practitioners must understand not only that the use of opioids is an important part of the armamentarium for managing the chronic pain patient, but also that opioids must be prescribed, dispensed and administered in good faith for accepted medicinal or therapeutic purposes.

In 1997, the Medical Society of Virginia, at the request of the Joint Subcommittee of the General Assembly, appointed a special committee, which included Board members and staff, to develop guidelines to meet the needs of physicians in the Commonwealth regarding the prescribing of opioids for chronic, noncancer pain management. These guidelines were passed by the House of Delegates of the Medical Society during an annual meeting in November 1997.

The Executive Committee of the Virginia Board of Medicine endorsed these guidelines on December 5, 1997, and the Board confirmed this endorsement on February 5, 1998. The Board welcomes these guidelines and, although they do not carry the weight of law or regulation, believes these guidelines will be of help to those who treat pain patients as to the proper use of opioids and the documentation required.

Guidelines for the Use of Opioids in the Management of Chronic, Noncancer Pain

For the purposes of this document the following terms shall have the following definitions:

***Addiction** is a disease process involving use of opioids(s) wherein there is a loss of control, compulsive use, and continued use despite adverse social, physical, psychological, occupational, or economic consequences.*

***Substance abuse** is use of any substance(s) for nontherapeutic purposes; or use of medication for purposes other than those for which it is prescribed.*

***Physical dependence** is a physiologic state of adaptation to a specific opioid(s) characterized by the emergence of a withdrawal syndrome during abstinence, which may be relieved in total or in part by re-administration of the substance. Physical dependence is a predictable sequelae of regular, legitimate opioid or benzodiazepine use, and does not equate with addiction.*

***Tolerance** is a state resulting from regular use of opioids(s) in which an increased dose of the substance is needed to produce the desired effect. Tolerance may be a predictable sequelae of opiate use and does not imply addiction.*

Withdrawal syndrome *is a specific constellation of signs and symptoms due to the abrupt cessation of, or reduction in, a regularly administered does of opioids(s). Opioid withdrawal is characterized by three or more of the following symptoms that develop within hours to several days after abrupt cessation of the substance: (a) dysphoric mood, (b) nausea and vomiting, (c) muscle aches and abdominal cramps, (d) lacrimation or rhinorrhea, (e) pupillary dilation, piloerection, or sweating, (f) diarrhea, (g) yawning, (h) fever, (8) insomnia.*

Acute pain *is the normal, predicted physiological response to an adverse (noxious) chemical, thermal, or mechanical stimulus. Acute pain is generally time limited and is historically responsive to opioid therapy, among other therapies.*

Chronic pain *is persistent or episodic pain of a duration or intensity that adversely affects the function or well-being of the patient, attributable to any nonmalignant etiology.*

Co-Assessment, Documentation and Treatment

A. *History and Physical Examination*

The physician must conduct a complete history and physical exam of the patient prior to the initiation of opioids. At a minimum the medical record must contain documentation of the following history from the chronic pain patient:

1. *Current and past medical, surgical, and pain history including any past interventions and treatments for the particular pain condition being treated.*
2. *Psychiatric history and current treatment.*
3. *History of substance abuse and treatment.*
4. *Pertinent physical examination and appropriate diagnostic testing.*
5. *Documentation of current and prior medication management for the pain condition, including types of pain medications, frequency with which medications are/were taken, history of prescribers (if possible), reactions to medications, and reasons for failure of medications.*
6. *Social/work history.*

B. *Assessment*

A justification for initiation and maintenance of opioid therapy must include at a minimum the following initial workup of the patient:

1. *The working diagnosis (or diagnoses) and diagnostic techniques. The original differential diagnosis may be modified to one or more diagnoses.*
2. *Medical indications for the treatment of the patient with opioid therapy. These should include, for example, previously tried (but unsuccessful) modalities/medication regimens, diverse reactions to prior treatments, and other rationale for the approach to be utilized.*
3. *Updates on the patient's status including physical examination data must be periodically reviewed, revised, and entered in the patient's record.*

C. *Treatment Plan and Objectives*

The physician must keep detailed records on all patients, which at a minimum include:

1. *A documented treatment plan.*
2. *Types of medication(s) prescribed, reason(s) for selection, dose, schedule administered and quantity.*
3. *Measurable objectives such as:*
    a. *Social functioning and changes therein due to opioid therapy.*
    b. *Activities of daily living and changes therein due to opioid therapy.*
    c. *Adequacy of pain control using standard pain rating scale(s) or at least statements of the patient's satisfaction with the degree of pain control.*

D. ***Informed Consent and Written Agreement for Opioid Treatment***

Written documentation of both physician and patient responsibilities must include:

1. *Risks and complications associated with treatment using opioids.*
2. *Use of a single prescriber for all pain related medications.*
3. *Use of a single pharmacy, if possible.*
4. *Monitoring compliance of treatment;*
    a. *Urine/serum medication levels screening (including checks for nonprescribed medications/substances) when requested.*
    b. *Number and frequency of all prescription refills.*
    c. *Reason(s) for which opioid therapy may be discontinued (e.g. violation of written agreement item(s)).*

E. *Periodic Review*

Intermittent review and comparison of previous documentation with the current medical records are necessary to determine if continued opioid treatment is the best option for a patient. Each of the following must be documented at every office visit:

1. *Efficacy of Treatment*
    a. *Subjective pain rating (e.g. 0-10 verbal assessment of pain)*
    b. *Functional changes.*
        i. *Improvement in ability to perform activities of daily living (ADLs)*
        ii. *Improvement in home, work, community or social life.*
2. *Medication side effects.*
3. *Review of the diagnosis and treatment plan.*
4. *Assessment of compliance (e.g. counting pills, keeping record of number of medication refills, frequency of refills and disposal of unused medications/prescriptions).*
5. *Unannounced urine/serum drug screens and indicated laboratory testing, when appropriate.*

F. ***Consultation***

Most chronic noncancer patients, like their cancer pain counterparts can be adequately and safely managed by most physicians without regard for specialty. However, the treating physician must be cognizant of the availability of pain management specialists to whom the complex patient may be referred. The physician must be willing to refer the patient to a physician or a center with more expertise when indicated or when difficult issues arise. Consultations must be documented. The purpose of this referral should not necessarily be to prescribe the patient opioids.

G. ***Medical Records***

Accurate medical records must be kept, including, but not limited to documentation of:

1. *All patient office visits and other consultations obtained.*
2. *All prescriptions written including date, type(s) of medication, and number (quantity) prescribed.*
3. *All therapeutic and diagnostic procedures performed.*
4. *All laboratory results.*
5. *All written patient instructions and written agreements.*

A licensed practitioner who prescribes opioids in the Commonwealth of Virginia does not need a license from the Virginia Board of Pharmacy, but must have a valid controlled substance registration from the Drug Enforcement Agency of the United States Department of Justice.

The Revised Code of Washington
Title 69: Food, Drugs, Cosmetics, and Poisons
Chapter 50

RCW 69.50.308 Prescriptions.

(a) A controlled substance may be dispensed only as provided in this section.

(b) Except when dispensed directly by a practitioner authorized to prescribe or administer a controlled substance, other than a pharmacy, to an ultimate user, a substance included in Schedule II may not be dispensed without the written prescription of a practitioner.

(c) In emergency situations, as defined by rule of the state board of pharmacy, a substance included in Schedule II may be dispensed upon oral prescription of a practitioner, reduced promptly to writing and filed by the pharmacy. Prescriptions shall be retained in conformity with the requirements of RCW 69.50.306. A prescription for a substance included in Schedule II may not be refilled.

(d) Except when dispensed directly by a practitioner authorized to prescribe or administer a controlled substance, other than a pharmacy, to an ultimate user; a substance included in Schedule III or IV, which is a prescription drug as determined under RCW 69.04.560, may not be dispensed without a written or oral prescription of a practitioner. Any oral prescription must be promptly reduced to writing. The prescription shall not be filled or refilled more than six months after the date thereof or be refilled more than five times, unless renewed by the practitioner.

(e) A valid prescription or lawful order of a practitioner, in order to be effective in legalizing the possession of controlled substances, must be issued in good faith for a legitimate medical purpose by one authorized to prescribe the use of such controlled substance. An order purporting to be a prescription not in the course of professional treatment is not a valid prescription or lawful order of a practitioner within the meaning and intent of this chapter; and the person who knows or should know that the person is filling such an order, as well as the person issuing it, can be charged with a violation of this chapter.

(f) A substance included in Schedule V must be distributed or dispensed only for a medical purpose.

(g) A practitioner may dispense or deliver a controlled substance to or for an individual or animal only for medical treatment or authorized research in the ordinary course of that practitioner's profession. Medical treatment includes dispensing or administering a narcotic drug for pain, including intractable pain.

(h) No administrative sanction, or civil or criminal liability, authorized or created by this chapter may be imposed on a pharmacist for action taken in reliance on a reasonable belief that an order purporting to be a prescription was issued by a practitioner in the usual course of professional treatment or in authorized research.

(i) An individual practitioner may not dispense a substance included in Schedule II, III, or IV for that individual practitioner's personal use.

[1993 c 187 § 19; 1971 ex.s. c 308 §69.50.308.]

WASHINGTON

Medical Quality Assurance Commission
Source: Provided by the Board of Medical Examiners and Medical Disciplinary
Approved: April 18, 1996

Medical Quality Assurance Commission
Guidelines for Management of Pain
State of Washington

BACKGROUND

Substitute Senate Bill 5365 Uniform Disciplinary Act Amendments directed the Secretary of the Department of Health to "...coordinate and assist the regulatory boards and commissions of the health professions with prescribing authority in the development of uniform guidelines for addressing opiate therapy for acute pain and chronic pain associated with cancer and other terminal diseases, or other chronic or intractable pain conditions. The purpose of the guidelines is to assure the provision of effective medical treatment in accordance with recognized national standards and consistent with requirement of public health safety".

The Department of Health convened a group entitled Task Force on Policies for Management of Pain. This task force included representation from the medical, pharmacy, and nurses' associations and commissions; physicians from pain management clinics and private practice; a Washington state Representative; and patients with chronic intractable pain.

INTRODUCTION

There are widespread concerns among patients throughout the state about access to appropriate medical treatment, including opioid therapy, for addressing chronic intractable pain. Similarly, providers express apprehensions about challenges by state disciplinary authorities when prescribing opioid analgesics for indicated medical treatment when serving the legitimate medical needs of pain patients. The under treatment of chronic pain due to concerns about addiction and drug diversion affect the public health, safety and welfare. There is a need for guidance which would: a) encourage appropriate treatment for pain management; b) reduce providers' fear of injudicious discipline; and, c) protect the public from inappropriate prescribing practices and diversion.

PURPOSE STATEMENT

The Secretary of the Department of Health recommends the uniform adoption, by appropriate state regulatory authorities, of the following guidelines when managing pain. It is not the intent of these guidelines to define complete standards of acceptable medical care in the treatment of pain patients. These guidelines are not intended to direct clinical practice parameters. It is the intent that providers will have confidence that these guidelines are the standard by which opioid usage is evaluated.

POLICY STATEMENT

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 pain conditions. Prescribing opioids requires special consideration. It is the position of the Department of Health that opioids may be prescribed, dispensed, or administered when there is an indicated medical need without fear of injudicious discipline

GUIDELINES FOR OPIOID USAGE

Acute Pain

Opioids are useful for patients with acute pain such as surgery, burn, or trauma. The goal of such treatment is to provide adequate and timely pain management to the patient. Side effects of opioids that are difficult to treat may occur and must be balanced against the benefits of pain relief. The provider should, for any patient who has a history of alcoholism or other drug addictions, carefully monitor medications and when available seek appropriate consultation.

Chronic Pain Associated With Cancer

Chronic pain associated with cancer may often be successfully managed with opioids. If use of opioids is the primary analgesic strategy, adequate doses should be given frequently enough to keep the patient continuously comfortable. Addiction is rare in patients with cancer pain; tolerance and physical dependency are often unavoidable and should not interfere with opioid prescribing. Not all pain in patients with cancer is responsive to opioids; alternative strategies for managing the pain should also be made available.

Other Chronic Pain Conditions

Opioid analgesics can be useful in the treatment of patients with intractable non-cancer pain especially, where efforts to remove the cause of pain or to treat it with other modalities have failed or were not fully successful. The pain of such patients may have a number of different etiologies and may require several modalities. In addition, the extent to which pain is associated with psychological, physical, and social impairment varies greatly. Therefore, the selection for a trial of opioid therapy should be based on a careful assessment of the pain as well as the impairment experienced by the patient. Continuation of opioid therapy should be based on the provider's evaluation of the results of treatment, including the degree of pain relief, changes in psychological, physical, and social functioning, and appropriate utilization of health services. Providers are encouraged to obtain consultation from providers who are knowledgeable in pain management, particularly when managing patients with a history of alcohol abuse or previous chronic opioid use.

DEFINITIONS

1. **Addiction** - A disease process involving use of psychoactive substances wherein there is loss of control, compulsive use, and continued use despite adverse social, physical, psychological, or spiritual consequences.

2. **Physical Dependence** - A physiologic state of adaptation to a specific psychoactive substance characterized by the emergence of a withdrawal syndrome during abstinence, which may be relieved in total or in part by re-administration of the substance. Physical dependence is not necessarily associated with full blown addiction, and condition does not always equate with addiction.

3. **Psychological Dependence** - A subjective sense of need for a specific substance, either for its positive effects or to avoid negative effects associated with its abstinence.

4. **Tolerance** - State in which an increased dosage of a psychoactive substance is needed to produce a desired effect.

5. **Withdrawal Syndrome** - The onset of a predictable constellation of signs and symptoms following the abrupt discontinuation of, or rapid decrease in, dosage of a psychoactive substance.

6. **Acute Pain** - An essential biologic signal of the potential for or the extent of injury. It is usually short-lived and is associated with hyperactivity of the sympathetic nervous system; e.g. tachycardia, increased respiratory rate and blood pressure, diaphoresis, and papillary dilation. The concurrent affect is anxiety.

7. **Chronic Pain** - Pain persistent beyond expected healing time and often cannot be ascribed to a specific injury. Chronic pain may not have a well-defined onset and by definition does not respond to treatment directed at its causes.

8. **Intractable Pain in a Non-Cancer Patient** - Pain in which the cause cannot be removed or otherwise treated and no relief or cure has been found after reasonable efforts.

GUIDELINES FOR ASSESSMENT AND DOCUMENTATION IN NON-CANCER PAIN

Alternative strategies for managing pain must be explored. If alternative strategies for managing the pain are unsuccessful, long term opioid therapy can be added. The goal is not merely to treat the symptoms of pain, but to devise pain management strategies which deal effectively with all aspects of the patient's pain syndrome, including psychological, physical, social, and work-related factors. Documentation in the patient's medical record should include:

1. **History and medical examination** - A complete physical examination and comprehensive medical history should be part of the active treatment record including, but not limited to, a review of past pain treatment outcomes and any history of addiction risks to establish a diagnosis and treatment plan.

2. **Diagnosis and medical indication** - A working diagnosis must be delineated, which

includes the presence of a recognized medical indication for the use of any treatment or medication.

3. **Written treatment plan with recorded measurable objectives** - The plan should have clearly stated, measurable objectives, indication of further planned diagnostic evaluation, and alternative treatments.

4. **Informed consent** - Discussions of risks and benefits should be noted in some format in the patient's record.

5. **Periodic reviews and modifications indicated** - At these periodic reviews, the provider should reassess the treatment plan, the patient's clinical course, and outcome goals with particular attention paid to disease progression, side effect and emergence of new conditions.

6. **Consultation** - The treating provider should be knowledgeable and competent in referring patients to the appropriate specialist if needed and noting in the patient's record the treating providers interpretation of the consultation reports. Additionally, a new patient with evidence of at-risk patterns of opioid usage should be evaluated by a knowledgeable specialist.

7. **Records** - the provider should keep accurate and complete records documenting the dates and clinical findings for all evaluations, consultations, treatments, medications and patient instructions.

8. **Assessment and monitoring** - Some patients with chronic pain not associated with cancer may be at risk of developing increasing opioid consumption without objective improvement in functional status. Subjective reports by the patient should be supported by objective observations. Objective measures in the patient's condition are determined by an ongoing assessment of the patient's functional status, including the ability to engage in work or other gainful activities, patient consumption of health care resources, positive answers to specific questions about the pain intensity and its interference with activities of daily living, quality of family life and social activities, and physical activity of the patient as observed by the physician.

   Physical dependence and tolerance are normal physiologic consequences of extended opioid therapy and are not the same as addiction. Addiction is a disease with behavior characterized by psychological dependence and aberrant drug related behaviors. Addicts compulsively use drugs for non-medical purposes despite harmful effects; a person who is addicted may also be physically dependent or tolerant. Patients with chronic pain should not be considered addicts or merely because they are being treated with opioids

   The physician is responsible for monitoring the dosage of the opioid. Monitoring includes ongoing assessment of patient compliance with drug prescriptions and related treatment plans. Communication between health care providers is essential. The patient should receive long term analgesic medications from one physician and where possible one pharmacy. All providers should be particularly cautious with patients with a history of alcoholism or other drug addiction when prescribing long term opioids. Consults with addiction specialists are recommended.

PATIENT RESPONSIBILITIES

1. It is the patient's responsibility to candidly provide the treatment provider with a complete and accurate treatment history, including past medical records, past pain treatment and alcohol and other drug addiction history.

2. The patient should participate as fully as possible in all treatment decisions.

3. The patient and family members, if available, should inform the prescriber of all drug side effects and concerns regarding prescription drugs.

4. The patient should not use other psychoactive agents, including alcohol, naturopathic products or over-the-counter drugs without agreement of the prescriber.

5. The patient should use the same name when receiving medical care to assure completeness of the medical record.

6. The patient should demand respect and expect to be believed.

7. The patient should keep an open mind and be willing to work with the treatment provider, including:
   a. negotiate with the provider to arrive at an acceptable plan of treatment;
   b. be open in trying alternative treatment strategies; and
   c. follow the treatment provider's instructions precisely.

8. The patient should, where possible, get all central nervous system medications from one provider. If this is not possible, the patient should inform each provider of all medication he/she is receiving.

9. The patient should, where possible, have all prescriptions filled at a single pharmacy.

10. The patient should not horde, share, or sell medications.

11. The patient should be aware that providers may, by law, share information with other providers about the patient's care.

WEST VIRGINIA

West Virginia Board of Medicine
Position Statement on the Use of Opioids for the Treatment of Chronic Non-Malignant Pain.
Adopted on July 14, 1997
Provided by the West Virginia Board of Medicine to the PPSG

WEST VIRGINIA BOARD OF MEDICINE POSITION STATEMENT ON THE USE OF OPIOIDS FOR THE TREATMENT OF CHRONIC NON-MALIGNANT PAIN.

Recent national guidelines have clarified the use of opioids in the management of acute pain and cancer pain. There is general consensus that opioids have a place in relieving intractable pain and suffering in the terminally ill when other measures fail, regardless of diagnosis. However, the problem of treatment of chronic non-malignant pain in the non-terminal patient is a controversial and difficult area, and guidelines are needed. The Board of Medicine appreciates the significance of this problem and urges that high priority be given to the suffering patient.

The purpose of this statement is to clarify the Board of Medicine's position on the appropriate use of opioids for patients with chronic non-malignant pain so that these patients will receive quality pain management and so that their physicians will not fear legal consequences, including disciplinary action by the Board, when they prescribe opioids in a manner described in this statement. It should be understood that the Board recognizes that opioids are appropriate treatment for chronic non-malignant pain in ***selected*** patients.

Complete documentation is essential to support the evaluation, the reason for opioid prescribing, and the overall pain management treatment plan, including documentation of all opioid prescriptions. All consultations and periodic reviews of treatment efficacy should be documented.

A physician need not fear disciplinary action by the Board if complete documentation of prescribing of opioids in chronic non-malignant pain, even in large doses, is contained in the medical records.

Nothing in this statement should be interpreted as endorsing inappropriate or imprudent prescribing of opioids for chronic non-malignant pain.

SUGGESTED REFERENCES:

Journal of Pain and Symptom Management, Volume 11, No. 4, April 1996, "Opioid Therapy For Chronic Non-Malignant Pain; A Review Of The Critical Issues", Russell K. Portenoy, M.D.

"The Use Of Opioids For The Treatment of Chronic Pain", A Consensus Statement from the American Academy of Pain Medicine and the American Pain Society, 1997.

It is the position of the Board that effective management of chronic non-malignant pain should include:

1. a complete assessment of the pain history and the impact of pain on the patient and family;

2. a comprehensive drug history with special attention to substance abuse and effective use of analgesics;

3. a psychosocial history with special attention to psychiatric disorders or a home environment that might place the patient at high risk for noncompliance with a therapeutic regimen that would include chronic use of opioids;

4. an appropriate physical exam;

5. appropriate diagnostic studies;

6. a working diagnosis and a treatment plan that may involve a formal pain rehabilitation program, the use of behavioral strategies, the use of noninvasive techniques, or the use of medications, depending on the physical and psychosocial impairment related to the pain;

7. a specific clinical protocol that requires monthly monitoring until stable dosing is obtained and then no less often than every three month physician visits, and a single physician prescribing, or a designee in his or her absence, and a single pharmacy dispensing all opioid prescriptions;

8. education of the patient as to the practice protocol for prescribing chronic opiates, and the treatment plan detailing the risk and benefits of opioid use, and the responsibilities of the patient;

9. an assessment at each visit of control of pain, opioid-related side effects, patient functional status (physical and psychological) and patient use of the medication in the manner prescribed;

10. periodic review of treatment efficacy to ensure that the goal of minimizing pain and improving function is achieved and that opioid therapy is still indicated; and

11. consultation with a medical provider with experience and training in the management of chronic pain if the duration of prescribing opioids exceeds three to six months.

A. Paul Brooks, Jr., M.D., President

Adopted by the West Virginia Board of Medicine on July 14, 1997

WISCONSIN

95-96 Wisconsin Statutes
Chapter 961: Uniform Controlled Substances Act

961.001 Declaration of intent. The legislature finds that the abuse of controlled substances constitutes a serious problem for society. As a partial solution, these laws regulating controlled substances have been enacted with penalties. The legislature, recognizing a need for differentiation among those who would violate these laws makes this declaration of legislative intent:

(1g) Many of the controlled substances included in this chapter have useful and legitimate medical and scientific purposes and are necessary to maintain the health and general welfare of the people of this state.

(1m) The manufacture, distribution, delivery, possession and use of controlled substances for other than legitimate purposes have a substantial and detrimental effect on the health and general welfare of the people of this state.

961.38 Prescriptions. (1g) In this section, "medical treatment" includes dispensing or administering a narcotic drug for pain, including intractable pain.

(4g) A practitioner may dispense or deliver a controlled substance to or for an individual or animal only for medical treatment or authorized research in the ordinary course of that practitioner's profession.

(4r) A pharmacist is immune from any civil or criminal liability and from discipline under s.450.10 for any act taken by the pharmacist in reliance on a reasonable belief that an order purporting to be a prescription was issued by a practitioner in the usual course of professional treatment or in authorized research.

[redacted]

WYOMING

Wyoming State Board of Medical Examiners
Source: Letter to Wyoming physicians dated March 11, 1996
Provided by the Wyoming State Board to the PPSG

Board of Medicine

COLONY BUILDING
211 WEST 19TH STREET 2ND FLOOR
CHEYENNE, WYOMING 82002

TELEPHONE: (307) 778-7053

March 11, 1996

Dear Wyoming Physicians:

Over the last few years some Wyoming physicians have voiced concerns about the Board's position concerning the management of patients with intractable pain. A few physicians have indicated that they fear Board sanctions should they treat patients over the long term or with high doses of controlled substances.

Please note the Board has NEVER sanctioned a physician for appropriate pain management. We have investigated cases that involve extraordinary amounts of controlled substances. However, in all cases, the physicians involved presented an adequate diagnostic basis for the therapy and extensive records in support of their treatment and the investigations were closed without further action.

Recently some physicians suggested the Board pursue amendment to the Wyoming Medical Practice Act specifically and explicitly allowing appropriate treatment for patients with intractable pain. The Board believes this approach is both unnecessary and potentially problematic. The existing statute speaks to this issue by noting that disciplinary action may be taken against licensees who willfully or consistently utilize "medical service or treatment which is inappropriate or unnecessary." W.S. 33-26-402(a) (xviii).

The Board believes any amendment is unnecessary because the existing statute already allows appropriate and necessary treatment implicitly including use of controlled substances for pain.

In determining the appropriateness and necessity of long term prescriptions of controlled substances the Board may consider the following factors:

1. Does the record contain an ADEQUATE HISTORY and PHYSICAL including an

assessment of pain, physical and psychological function? An inquiry into substance abuse history, if any, is helpful as is an assessment of underlying and co-existing diseases and conditions, and a review of any recognized medical indication for controlled substances. Additionally, the Board would look to whether attempts had been made to maintain the patient on the lowest dose possible to achieve relief and improve function.

2. Is there a TREATMENT PLAN WITH OBJECTIVE CRITERIA by which progress, if any, can be measured? Though physicians should tailor pain relief to the individual needs of each patient, goals such as pain relief and/or improved physical and psychosocial function should be included and progress toward these goals monitored.

3. Have you thoroughly discussed and DOCUMENTED the risks and benefits of controlled substance usage?

4. Have you PERIODICALLY REVIEWED the course of treatment? Any new information should be added to the record as should appropriate assessment of continued treatment and necessity of trial of other modalities.

5. Has there been a DOCUMENTED CONSULTATION WHERE APPROPRIATE? The treating physician should be willing to refer the patient for necessary evaluation and treatment to achieve goals of the treatment plan. Physicians should also pay special attention to patients at risk of misuse, diversion and/or past or potential substance abuse disorders. Physicians should also ascertain, if possible, if the patient is currently receiving prescriptions for controlled substances from any other physician.

6. DOCUMENT, DOCUMENT, DOCUMENT. The more thorough and detailed the record keeping on these patients, the more easily a physician may respond to any inquiry.

7. Assure yourself that you are in COMPLIANCE WITH FEDERAL AND STATE SUBSTANCE LAWS AND REGULATIONS. To prescribe controlled substances the physician must hold a current valid license in Wyoming, possess a controlled substance registration and comply with all Federal and State regulations for issuing controlled substances prescriptions.

A Wyoming physician keeping these seven (7) check points in mind should encounter no difficulty with the Board of Medicine arising from prolonged prescribing of controlled substances for patients.

Please let us know if you have questions or comments.
Yours truly, Howard Mussell, M.D., President

Appendix A

Question: What can state legislatures do to improve pain management?

First, study the problem. Create a multi disciplinary task force, commission[1] or committee with public hearings to study carefully the barriers to pain management for all types of pain patients in the state (cancer, chronic non-cancer, post-surgical, sickle cell, AIDS, etc.); review relevant state policies outlined below; make and implement recommendations in legislation (policy, budget), in leadership, public information, education, training, program development, etc.

1. Drug, pharmacy, controlled substances policy

a. Does the state controlled substances act recognize the essential medical uses of controlled substances as in federal law and as recommended by the National Conference of Commissioners on Uniform State Laws?

b. Does state law or regulations unduly restrict prescribing of controlled substances, e.g., government-required prescription forms; exclusion of addicts even if they have pain; require second opinion, consultation or informed consent; legal terminology confusing addicts with pain patients/addict reporting, limit number of dosage units of controlled substances (e.g., opioids) that can be prescribed at one time, or limit unrealistically the period of validity of a prescription for a scheduled substance?

c. Does state policy allow physicians and pharmacists to take full advantage of the flexibility in federal controlled substances regulation regarding faxing and partial dispensing of controlled substances prescriptions?

2. Medical policy

a. Do the medical practice act or regulations contain any policies with regard to prescribing controlled substances which are unduly restrictive or confusing when applied to the prescribing of controlled substances for the treatment of pain? (i.e., no prescribing to addicts, even if they have pain?)

b. Does the medical board have a policy statement or guidelines which clarifies that the board recognizes that the use of controlled substances for the treatment of chronic pain is accepted medical practice and clarifies the principles which a physician can follow to confidently avoid the risk of discipline or arrest by any agency in the state?

3. Facility regulation (hospice, nursing home, home care, etc.)

a. What is the attitude of the state facility regulators: is pain a priority or is the priority only reducing the use of controlled drugs; do certification and inspection criteria include assessment and treatment of pain and training of patient care staff; is technical assistance on pain and symptom management available?

4. State health policy

a. Does the state cancer control program include a funded emphasis on pain management and palliative care for cancer patients in the state?
b. Is there a state cancer pain initiative and does it have adequate support?
c. Does the public have access to information about pain and symptom management including chronic non-cancer pain, and where to go for help?
d. Does the 800 number for cancer information also include information about pain management?
e. Do managed care organizations have adequate policies: pain assessment, treatment, reimbursement, appropriate access to specialists?
f. Does state Medicaid policy reimburse the controlled drugs used in pain and symptom management?
g. Does Workers Compensation adequately address the needs of people with chronic severe pain?

5. Drug enforcement policy

a. Do the agencies in the state which are involved in drug law enforcement and monitoring of controlled substances prescribing, dispensing and patient use have adequate safeguards against the inappropriate scrutiny of practitioners who prescribe and dispense legitimate controlled substances?

Question: Are intractable pain treatment acts what we need?

A number of states have adopted legislation called "intractable pain treatment acts" (IPTAs).[2] The 1997 Supreme Court decision on assisted suicide is likely to stimulate even more interest in state legislation to address inadequate pain management, including IPTAs.

IPTAs are often modeled after the highly publicized Texas Act which was passed in 1989; in 1990 California passed a similar law. The main goal of these laws was to address physician reluctance to prescribe opioids for the treatment of chronic pain, due to their concern about regulatory scrutiny, by providing immunity from discipline by state medical boards. Stimulated by patients and physicians who were concerned about the undertreatment of chronic non-cancer pain, most IPTAs nevertheless would apply to prescribing for intractable pain, including patients with cancer or AIDS.

IPTAs may not be the most direct way to address the desirable goal of relieving physician concern about regulatory scrutiny, and they may create additional barriers for physicians and for patients in pain: for example, the language used in IPTAs implies that opioids are a last resort; IPTAs may exclude pain patients with a history of drug abuse; they may impose additional requirements, such as required consultation with another physician, which could be barriers to pain management.

Further, IPTAs do not directly address the critical issue of how to improve patient access to pain treatment or improve education of health professionals about pain management. The potential benefits and risks of IPTAs are discussed in an article about the current status of intractable pain treatment policy.[2]

A number of state medical boards have taken steps to improve pain management including clarification of policy to address physician reluctance to prescribe. Working with state medical boards is a more direct approach than legislation to clarify state opioid prescribing policy and to encourage better pain management.[3]

The increasing interest of governments in pain management is an opportunity to make lasting improvements in pain management, for example to provide better patient access to pain care. Several states have created pain study commissions or task forces.[1] This is a promising approach. It avoids "quick fix" legislation and more importantly, it is a mechanism to study the unique needs of individual states, and respond appropriately. A number of government agencies and professional organizations can be involved in the study process. A commission or task force can take the time to identify the needs of a state, including regulatory barriers that might otherwise be overlooked in simply adopting an IPTA.

References

1. Joranson DE. State Pain Commissions: New vehicles for progress? *APS Bulletin* 1996 (1):7-9.

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Appendix B

American Pain Society

C. Richard Chapman, Editor

Bulletin

Volume 5, Number 3 May/June 1995

Inside

The American Pain Society is a National Chapter of the International Association for the Study of Pain (IASP).

Pain and Public Policy

Robert T. Angarola, Esq., and David E. Joranson, MSSW

State Medical Board Guidelines for Treatment of Intractable Pain

David E. Joranson, MSSW

Department editors' note: This is the second of two articles concerning federal and state policy on the use of opioids to treat people who have intractable pain. In part 1 in the last issue of APS Bulletin, *we addressed federal and state laws and regulations. Part 2 discusses state medical board guidelines. Also, please note the second article in this department (see page 5), which provides information on potential federal legislation that would significantly affect pain clinicians and patients.*

The belief that opioids should not be used for patients with chronic noncancer pain is undergoing a scientific and clinical appraisal to clarify the criteria for patient selection and appropriate clinical management (Portenoy, 1994). Policy changes are also under way to correct overly restrictive regulatory policies and practices that have discouraged physicians from prescribing opioid analgesics to patients with intractable pain. *Intractable pain* has been defined as pain in which the cause cannot be removed or otherwise treated and no relief or cure has been found after reasonable efforts (*Code of Federal Regulations*, 1988; *Medical Practice Act of Texas*, 1989; *California Business and Professions Code*, 1990). The term includes pain due to cancer as well other diseases and chronic conditions.

The first article on this subject appeared in the last issue of APS *Bulletin* and summarized the current status of laws and regulations regarding intractable pain treatment. No laws or regulations actually prohibit the use of opioids for intractable pain (Joranson, 1995). Federal and state controlled substances laws have been silent on the use of opioids for pain; these laws are not intended to regulate medical conduct, a matter left up to state medical practice laws and regulations. However, a U.S. Drug Enforcement Administration (DEA) regulation was adopted specifically to recognize that use of opioids for the intractable pain is legal under federal law, compared to prescribing opioids to maintain narcotic addiction, which is not (*Code of Federal Regulations*, 1988).

In the last 6 years, five states (California, Colorado, Florida, Texas, and Washington) have adopted laws that recognize the legality of using opioids for intractable pain. The previous article (Joranson, 1995) also discussed the benefits and risks of using the force of law to make legitimate the use of opioid analgesics for the treatment of intractable pain. For example, a simple provision that has been recommended by legal and medical experts can be added to state law to establish that medical use of opioids for intractable pain is a legitimate medical practice (National Conference of Commissioners on Uniform State Laws, 1990).

There are concerns about enacting detailed laws or regulations that specify the conditions under which physicians can prescribe opioids. The legal route may seem an attractive way to address inadequate prescribing of opioids, particularly if access to the legislative or rule-making process is close at hand. However, it should be clear that legislating the particulars of medical practice does not directly redress

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inadequate physician education or improve practice patterns—and can also have unforeseen consequences.

State medical board guidelines

In addition to laws and regulations, another method of policy development is used by states to clarify the role of opioids in medical treatment of chronic noncancer pain: state medical board guidelines or policy statements. A *guideline* is an official statement of a medical board's attitude or policy about a particular issue. Guidelines do not have the legal status of laws and regulations, but guidelines can explain what activities the medical board considers to be within the boundaries of professional practice. Guidelines alert licensees to unprofessional practices of concern to the board and give practitioners practical information about how to avoid these problems.

In the last 10 years, a number of state medical boards, including those of Alaska, Arizona, California, Georgia, Idaho, Massachusetts, Minnesota, North Carolina, Oregon, Texas, and Washington, have published guidelines that address the prescribing of opioids for intractable pain. In California, the pharmacy and nursing boards have also developed guidelines.

In some cases, boards have adopted these guidelines to address inappropriate uses of opioids and unprofessional prescriptive practices that they have identified. More recently, however, some boards have begun using guidelines to address physicians' fears of board investigation or discipline for prescribing opioids for chronic noncancer pain. Indeed, the 1991 national survey of medical board members supports the need for medical boards to clarify their policies; most medical board members across the country who were surveyed said (at that time) that they would discourage a physician from prescribing opioids for a patient with chronic noncancer pain, and approximately one-third said they would investigate the practice as a potential violation of law (Joranson, Cleeland, Weissman, & Gilson, 1992).

Recent progress in California

In 1993, the Medical Board of California (MBC) undertook a review of "malprescribing." A special task force on appropriate prescribing heard testimony that physicians avoid prescribing controlled substances including "triplicate" drugs for patients with intractable pain for fear of discipline by the MBC (Medical Board of California, 1994b). The MBC took several actions to emphasize to all California physicians that it supports appropriate prescribing of opioids for pain, including intractable pain.

Under the leadership of Board President Jacquelin Trestrail, MD, and Executive Director Dixon Arnett, the MBC provided information about the new Agency for Health Care Policy and Research (AHCPR) clinical practice guidelines on acute and cancer pain to all state physicians and encouraged them to apply these guidelines in their clinical practices. The MBC cosponsored the California Summit on Effective Pain Management held in 1994 (Angarola & Joranson, 1994), which recommended that the triplicate prescription system be replaced with a less invasive and more efficient system. Further, the MBC adopted a proactive policy statement, "Prescribing Controlled Substances for Pain" (Medical Board of California, 1994a) and announced that it would publish guidelines to help physicians avoid investigation when they used opioids for management of intractable pain.

The MBC asked the University of Wisconsin Pain Research Group (PRG) to draft the new guidelines. The PRG reviewed existing law, regulations, and guidelines published in the United States as well as in Canada (College of Physicians and Surgeons of Alberta, 1993). The new California guidelines were constructed around the fundamental principles that guide professional medical practice, as generally recognized by medical boards. Drafts were reviewed by medical and legal experts before MBC approval.

The American Pain Society endorsed the California guidelines early in 1995, with the exception of the provision that restricts prescribing of opioids to substance abusers, even if they have pain ("APS OKs," 1995). According to a 1995 PRG telephone survey, other state medical boards have begun to consider adopting the same or similar guidelines (executive directors of state medical boards to

D.E. Joranson & A.M. Gilson, personal communications, January 1995). In early 1995, the president of the Minnesota Board of Medical Practice endorsed the "common sense" guidelines from California (Kidder, 1995, p. 3).

Review of medical board guidelines

Current state medical board guidelines vary considerably in several ways, including the extent to which they accept opioid therapy for patients with chronic noncancer pain. These guidelines are summarized below.

Minnesota: As Sigel (1988) described, guidelines from the Minnesota Board of Medical Examiners state that the diagnosis of intractable pain should be based on a history, physical examination, and appropriate empirical data, not simply on the assertion of the patient. The treatment plan should reflect the use of other treatment modalities, appropriate referrals, and documentation of why those modalities are inappropriate or ineffective. The patient should be monitored regularly. The physician should control the drug supply, including detailed records of each drug dosage, amount, and number of refills. The physician should be aware of the potential for habituation or addiction and provide a justification for maintaining an addictive state, if appropriate. Violations include prescribing to a patient who is an addict or is dependent.

Massachusetts: The Massachusetts Board of Registration in Medicine (1989) guidelines indicate that treatment of chronic pain should be based on a carefully documented medical condition and a statement justifying the need for continued narcotic use and explaining why past modalities have been inappropriate or ineffective. The physician must identify and treat factors contributing to the pain, use a consulting specialist, document prescriptions, assess potential for narcotic diversion, and monitor the patient.

Idaho: The Idaho State Board of Medicine (1990) guidelines for controlled substances prescriptions incorporate language from the federal regulation that recognizes the legality of using opioids to treat intractable pain.

Arizona: The Arizona Board of Medical Examiners' (1990) guidelines follow the basic principles of professional practice: a history and medical examination sufficient to establish a diagnosis, a treatment plan, and contraindications to drug therapy. The physician should establish a working diagnosis including the presence of an accepted medical indication for the drug therapy. The risk of iatrogenic dependence should be minimized. The treatment plan should have clear, measurable objectives and include a record of the further evaluations that are planned, the alternative treatments that are contemplated, and the expected dosing and duration of the treatment with medications. The physician should discuss with the patient the risks and benefits of treatment and periodically review all aspects of the treatment plan. For patients who have not improved despite controlled substance treatment, the physician should document the appropriateness of a less dangerous treatment. The physician should discuss the patient's compliance, abuse, and diversion with other caregivers. If treatment is not producing the desired result, the physician should obtain consultation or refer the patient to specialists. The physician should keep accurate and complete records. In addition, the physician must remain alert for any indications of patient manipulation and should stay current with new developments, approaches, and recommendations in prescribing.

North Carolina: The Board of Medical Examiners of the State of North Carolina (1991) issued a nine-step set of guidelines to its licensees in 1991. These guidelines are patterned after the Minnesota guidelines.

Georgia: The Georgia Composite State Board of Medical Examiners (1991) stated that the diagnosis should be based on the patient's history and a physical examination, not simply on the assertion of the patient. The treatment plan should reflect the use of other modalities of treatment, including appropriate referrals and their results, and documentation of the reasons that past modalities have been inappropriate or ineffective. The physician should determine that the patient is not taking opioids for nontherapeutic purposes and should obtain the informed consent of the patient before using opioids. The patient should be monitored regularly, and the physician should have adequate control of the drug supply, including detailed records of each drug dosage, amount, and number of refills. The physician should maintain regular contact with the patient's family to assess treatment effectiveness. Adequate records should be maintained.

Oregon: The guidelines from the Oregon Board of Medical Examiners (1991) state that it is not "generally accepted in current medical therapy" to treat nonmalignant pain with narcotics on a routine basis (p. 1); for those rare patients for whom chronic administration of opioids is appropriate, there must be a clear diagnosis and close monitoring of the effectiveness of the treatment regime.

Washington: The Washington State Medical Disciplinary Board (1992) stated that chronic pain conditions are "best not treated with opioids" (p. 1). If alternate strategies are unsuccessful, however, a documented working diagnosis must be based on history and physical examination, not simply on the assertion of the patient. A treatment plan should be written with measurable objectives, further planned diagnostic evaluation, and alternative treatments. The physician should determine that the patient is not obtaining drugs from other physicians or from illicit sources, and caution should be taken with long-term prescribing of controlled substances to patients with a history of drug abuse. The informed consent of

Recently, some medical boards have begun using guidelines to address physicians' fears of board investigation or discipline for prescribing opioids for chronic noncancer pain.

the patient should be obtained before using opioids. The appropriateness of treatment should be reviewed periodically, and consultation should be used to determine the appropriate treatment plan. Adequate records must be maintained.

Texas: According to Stasney and Hill (1993), the Texas State Board of Medical Examiners developed a policy statement in response to physician reluctance to use opioids for fear of discipline by the board. It states that controlled substances are indispensable for the treatment of pain. The diagnosis should be based on the patient's history and a physical examination, not simply on the assertion of the patient. The treatment standard will be determined largely by the treatment outcome, taking into account that the drug used is recognized to be appropriate for the diagnosis as determined by medical consensus. The appropriateness of the quantity and chronicity of prescribing will be judged on the basis of the diagnosis and treatment of the targeted symptoms, as opposed to the quality or duration of prescribing. The physician should determine that the patient is not taking narcotics for nontherapeutic purposes, according to state law.

Alaska: The Alaska State Medical Licensing Board (1993) developed guidelines to respond to complaints from patients and physicians that licensees were uncomfortable about prescribing opioids for fear of disciplinary action. The Alaska board borrowed the Minnesota guidelines. In addition, the Alaska board recommended "drug holidays" to evaluate for symptom recurrence or withdrawal (Alaska State Medical Licensing Board, p. 1).

California: The Medical Board of California (1994a) guidelines state that the prescribing of opioid analgesics for patients with intractable noncancer pain may be beneficial, especially when efforts to remove the cause of pain or treat it have been unsuccessful. Physicians should not fear disciplinary action from any enforcement or regulatory agency in California if they adhere to the following principles of professional practice.

A physician's diagnosis should be based on a history and physical examination and on evaluation by one or more specialists. A treatment plan should be written that includes measurable objectives and alternative treatments. The physician should discuss risks and benefits with the patient. New information about the etiology of the pain should be sought in periodic reviews of treatment. Continuation of treatment depends on the physician's evaluation of the patient's progress toward treatment objectives. Physicians are encouraged to use consultation to determine an appropriate treatment plan. Special attention is required for patients who are at risk for diverting or misusing medications. Management of pain in substance abusers requires extra care, including consultation with addiction medicine specialists and medication-use agreements with patients. Physicians should document treatment, maintain adequate records, and comply with controlled substances laws and regulations.

It should be noted that California law requires that two physicians make the diagnosis of intractable pain and restricts prescribing of controlled substances to an individual using drugs for nontherapeutic purposes.

Discussion and conclusions

Medical board guidelines vary considerably. The attitude taken by medical boards toward the use of opioids ranges from "It is generally accepted in current medical therapy that it is inappropriate to treat nonmalignant pain with narcotics on a routine basis" (Oregon Board of Medical Examiners, 1991, p. 1) to "The Board recognizes that opioid analgesics can also be useful in the treatment of patients with intractable nonmalignant pain especially where efforts to remove the cause of pain or to treat it with other modalities have failed" (Medical Board of California, 1994b, p. 5).

The conditions and qualifications for opioid use also vary considerably. The pain management community may not support some provisions, such as the requirement of two physicians to diagnose intractable pain, the recommendation for "drug holidays," the use of undefined terms such as *addict* and *dependent*, or restrictions on prescribing to the entire class of people who are substances abusers, even if they have pain.

In my experience, most medical and other professional licensing boards are keenly interested in improving public health. As the demand for better pain management increases and medical boards become aware of the advances in medical knowledge about the use of opioids, they will likely want to revise their prescribing policies. But these revisions should take place in a systematic manner and in consultation with members of the pain community. One effective forum for discussing the appropriate use of opioid analgesics is the pain seminars that have been conducted for medical boards during 1994 and 1995. These seminars have been sponsored by the Federation of State Medical Boards of the United States in cooperation with the Pain Research Group, and with the participation of members of the American Pain Society who serve as faculty.

Medical board guidelines, like intractable pain treatment laws and regulations, can encourage better treatment of intractable pain. Guidelines vary from state to state and may also restrict appropriate prescribing. Before medical boards issue new guidelines for prescribing opioids for intractable pain, they should evaluate the situation in their state and systematically review the issues with experts. New guidelines, if they are needed, should reflect current knowledge about pain management and addiction and recognize the need for flexibility in the management of patients with intractable pain.

The current positive dialogue that is developing among medical boards, pain clinicians, and addiction specialists should be increased in order to ensure the development of rational and consistent intractable pain treatment guidelines at the state level.

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State Intractable Pain Policy: Current Status

David E. Joranson, MSSW; Aaron M. Gilson, MS MSSW

Editor's note: Previous issues of the Bulletin *have addressed intractable pain treatment laws and medical board guidelines (Joranson, 1995a, 1995b). This article reviews recent educational initiatives for state medical boards and the status of state pain policy initiatives, including medical board guidelines and intractable pain treatment laws.*

Medical board workshops and guidelines

Physicians' concern about regulatory scrutiny acting as a barrier to the ability to prescribe appropriately for pain management has attracted substantial study and discussion (Hill, 1993; Max, 1990; McIntosh, 1991; Nowak, 1992; Portenoy, 1990; Turk & Brody, 1992; Turk, Brody, & Okifuji, 1994; Weissman, Joranson, & Hopwood, 1991). A 1991 Pain Research Group survey of state medical board members demonstrated a need to provide updated information about opioids and pain management to medical board members (Joranson, Cleeland, Weissman, & Gilson, 1992). Indeed, a national survey revealed a need to provide more education about pain management to oncology physicians (Von Roenn, Cleeland, Gonin, & Pandya, 1991).

Discussions of the survey findings with the Federation of State Medical Boards led to cooperative efforts to sponsor a series of educational workshops entitled "Pain Management in a Regulated Environment." The workshops gave state medical boards the opportunity to review and discuss advances in knowledge and practice and the development of board guidelines concerning the use of opioids in pain management. The workshop faculty included June L. Dahl, PhD, Albert Brady, MD, J. David Haddox, DDS MD, David Joranson, MSSW, and Seddon Savage, MD. Six workshops were presented from 1993 to 1996: one for the Alabama State Board of Medical Examiners in 1993 (Angarola & Joranson, 1994), one for the North Carolina Medical Board in 1996, and four regional workshops for board members from a variety of state medical boards, during 1994 and 1995. A total of 125 board members attended (approximately 20% of the 630 state medical board members nationwide), representing 32 state medical boards.

Following these workshops, a number of boards, including those in Alabama and North Carolina, developed and disseminated guidelines for the prescribing of controlled substances for pain (Alabama State Board of Medical Examiners, 1995; North Carolina Medical Board, 1996). In most cases, the purpose of these guidelines has been to clarify that the board accepts that opioids may be used to manage chronic noncancer pain and to outline the board's basic expectations of prescribers. Table 1 lists the states having laws and/or medical board guidelines.

Some state medical boards have taken advantage of the work in states such as Texas and California. The Medical Board of California (MBC) guidelines (California Medical Board, 1994, May, October; American Pain Society, 1995) have served as a model for medical boards. The MBC guidelines addressed the California doctors' reluctance to prescribe opioids for chronic pain for fear of investigation and possibly disciplinary action. The MBC guidelines afford California a framework within which a physician may prescribe without concern about interference from regulatory agencies (California Medical Board, 1994, July). Built on principles of good medical practice, the California guidelines do not establish specific prescribing or pain management parameters. The guidelines were reviewed by pain and legal experts, adopted unanimously, and disseminated to all California physicians. The California guidelines received endorsement from APS (1995). The California boards of nursing and pharmacy (California Board of Registered Nursing, 1994; California State Board of Pharmacy, 1996) have adopted complementary guidelines. Medical boards in Florida (Florida Board of Medicine, 1996), North Carolina (North Carolina Medical Board, 1996), and Washington (Washington Medical Quality Assurance Commission, 1996) have adopted similar guidelines.

Further guidance for state policy appears in the American Academy of Pain Medicine (AAPM) and APS consensus statement, *The Use of Opioids for the Treatment of Chronic Pain* (1996). This statement is the product of a joint task

Table 1. States Having Laws and/or Medical Board Guidelines for the Treatment of Intractable Pain

Laws	
State	**Year Enacted**
CA	1990*
CO	1992
FL	1994*
MO	1995*
NV	1995
OR	1995*
TX	1989*
VA	1988
WA	1993
WI	1996

Guidelines	
State	**Year Enacted**
AL	1994
AK	1993
AZ	1990
CA	1994
CO	1996
FL	1996
GA	1991
ID	1995
MA	1989
MD	1996
MN	1988
MT	1996
NC	1996
OR	1991
TX	1993
UT	1987
WA	1996
WY	1993

*Restricts opioid use and provides for physician immunity

force of the two organizations chaired by J. David Haddox, DDS MD.

Intractable pain treatment laws

While the use of opioid analgesics to manage chronic noncancer pain is being reassessed clinically and scientifically (Portenoy, 1996; Portenoy & Payne, in press), it is clear that medical boards are issuing guidelines to recognize this use.

State legislatures are also deciding the legal parameters for prescribing opioids. The states that have enacted intractable pain treatment acts (IPTAs) are listed in Table 1. Legislative consideration of IPTAs is usually stimulated by chronic pain patients who are concerned about access to opioids or by physicians who are concerned about the attitude of their state medical board. However, some of these laws may further restrict rather than expand access to opioids for chronic pain management.

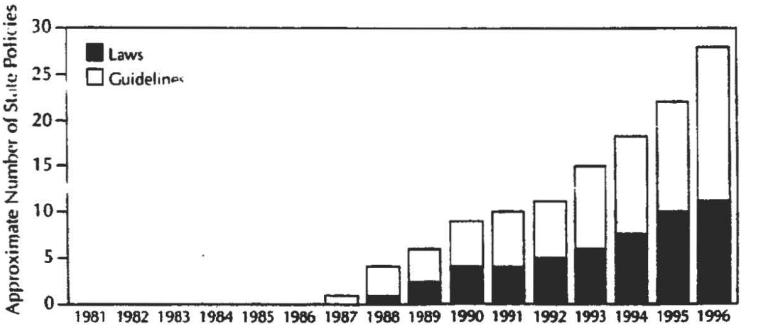
Most IPTAs are based on the Texas law adopted in 1989 (Medical Practice Act of Texas, 1989). The Texas IPTA defines intractable pain and grants immunity from disciplinary action by the medical board to physicians when they prescribe opioids for intractable pain. After adoption of the IPTA, the Texas Board of Medical Examiners issued a positive statement that recognized the value of controlled substances in the treatment of pain and specified that the appropriateness of treatment will not be defined solely on the basis of quantity or duration of prescribing, but rather on the basis of diagnosis and treatment objectives (Stasney & Hill, 1993). More recently, the board issued another positive policy on intractable pain, in this case a regulation (not a guideline) (Texas State Board of Medical Examiners, 1995).

In 1990, California adopted an IPTA that followed closely the Texas provisions but in addition required that all patients have a consultation so that the physician can qualify for immunity (*California Business and Professions Code*, 1990).

Benefits of IPTAs

One possible benefit of an IPTA is to recognize in the law that there is a legitimate place for opioids in the treatment of chronic pain. Another perceived benefit is that an immunity provision may protect physicians from discipline, although perhaps not from investigation and its attendant legal costs. Another benefit of legislative consideration of IPTAs may be the enhancement of public attention to the inadequate treatment of pain. Such consideration could lead to creation of a state pain commission, which would have access to all of state government and which could conduct a careful study of the problem and guide the development of a variety of needed responses (Joranson, 1996).

Figure 1. Cumulative State Intractable Pain Policies in Effect, 1980-1996



Risks of IPTAs

IPTAs are state pain policies created by elected officials, not by organizations representing medicine and science. Opening the door to legislative action on medical issues requires careful consideration. This process is political and complex, and its outcomes are difficult to foresee.

Although IPTAs are not always alike, the following lists potentially restrictive aspects that are now official policy in some states:

- IPTAs generally define medical use of opioids for intractable pain as a therapy of last resort.
- IPTAs apply to all intractable pain patients, even if they have cancer.
- IPTAs imply that opioids may be used for pain only in cases where the cause of pain cannot be removed.
- IPTAs exclude pain patients who use drugs "for nontherapeutic purposes."
- IPTAs require an evaluation of every pain patient by a specialist in the organ system believed to be the cause of pain.
- Some IPTAs require a signed informed consent form in every case.

It is not difficult to imagine how each of these limitations, if actually enforced, could interfere with medical practice and patient care. It is also difficult to see how IPTAs would actually increase patient access to pain management.

Alternative models

Some state legislatures, instead of adopting IPTAs, have adopted simpler model intractable pain language, which neither affords immunity nor establishes restrictions but does clarify that it is a legitimate medical practice to use opioids for intractable pain (Joranson, 1990; National Conference of Commissioners on Uniform State Laws, 1994). Washington, Colorado, and Wisconsin have adopted such language as a part of their uniform controlled substances law.

The American Society for Law, Medicine, & Ethics (ASLME) has developed a model act aimed at affording legal protection from boards for physicians who prescribe opioids for chronic pain (Dubler, Levine, & Johnson, 1996). ASLME considered a model immunity statute similar to the Texas law but settled instead on language that would allow physicians and their lawyers to claim a rebuttable presumption that their prescribing practice was legal, if they could show that they were substantially in compliance with accepted professional guidelines.

The American Medical Association House of Delegates approved in 1996 a model IPTA based on the Texas model (American Medical Association, 1996). It is therefore possible that state medical societies may become interested in legislative consideration of intractable pain treatment policy.

Conclusion

State legislatures are likely to continue considering intractable pain policy. (See Figure 1 for the cumulative number of state intractable pain policies enacted since 1980.) With the national focus on assisted suicide likely to shift to the states following the Supreme Court decision, state legislators may become even more interested in legislative action to improve pain management. Professional pain organizations should closely monitor the development of state pain policy and provide information and assistance to their elected representatives.

We should recall that state medical boards have a duty to protect the public from improper prescribing, but that they are also interested in promoting public health. A number of boards have recognized the need to clarify their policy regarding prescribing for pain. Increased collaboration between the pain community and state professional licensing boards should be encouraged and should aim to harmonize clinical practice and regulatory policy.

In all of these deliberations, we should strive to achieve a balance so that the management of pain, including the use of opioids when needed, is not impeded by state laws, regulations, or other policies that are based on outdated information.

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Improving Pain Management Through Policy Making and Education for Medical Regulators

David E. Joranson, Aaron M. Gilson

Physician concern about regulatory scrutiny as a barrier to appropriate prescribing for pain management has been identified and studied.[1] A 1991 Pain Research Group survey demonstrated a need to provide updated information about opioids and pain management to state medical board members.[2] Indeed, a national survey even showed a need to provide more education about pain management to oncology physicians.[3] Two approaches for responding to these concerns have been undertaken in several states by the state medical boards and the pain management community: (1) the development and adoption of administrative policies designed to bring disciplinary standards in line with clinical practice; and (2) the creation of education programs for state medical board members and staffs. Each can have a substantial impact on removing real and perceived regulatory barriers to effective pain relief.

Guidelines

State medical boards have a duty to protect the public from improper prescribing, but they also have an interest in promoting public health. Although the use of opioid analgesics to manage chronic noncancer pain is being reassessed clinically and scientifically,[4] some state medical boards have already recognized and responded to the need to clarify their policies regarding prescribing for pain.[5] Policy making and clarification by the boards themselves, especially when produced through collaboration with the pain management community, can significantly contribute to harmonizing clinical practice and regulatory policy.

In some instances, boards have adopted guidelines on the use of controlled substances in pain management to address inappropriate uses of opioids and unprofessional prescriptive practices. More recently, however, some boards have begun using guidelines to address physicians' fear of board investigation or discipline for prescribing opioids for chronic noncancer pain. Indeed, respondents to the 1991 national survey of U.S. medical board members supported a call for medical boards to clarify their policies. Most members who were surveyed said, at that time, they would discourage a physician from prescribing opioids for a patient with chronic noncancer pain, and approximately one-third said they would investigate the practice as a potential violation of law.[6]

Medical board guidelines vary considerably. The attitudes of medical boards toward the use of opioids ranges from "It is generally accepted in current medical therapy that it is inappropriate to treat nonmalignant pain with narcotics on a routine basis"[7] to "[T]he Board recognizes that opioid analgesics can also be useful in the treatment of patients with intractable nonmalignant pain especially where efforts to remove the cause of pain or to treat it with other modalities have failed."[8]

The conditions and qualifications in medical board policies on opioid use also vary considerably. The pain management community may not support some provisions, such as: a requirement that two physicians diagnose intractable pain; the recommendation or requirement of "drug holidays";[9] the use of undefined terms such as *addict* or *habitué*; or restrictions on prescribing to the entire class of people who use drugs nontherapeutically, even if they have pain.

In 1993, the Medical Board of California (MBC) undertook a review of "malprescribing." A special task force on appropriate prescribing heard testimony that physicians avoid prescribing controlled substances, including "tripli-

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cate" drugs,[10] for patients with intractable pain out of fear of discipline by MBC.[11] As will be illustrated, MBC then took several actions to emphasize that it supports appropriate prescribing of opioids for pain, including intractable pain.

MBC initially provided information about the then new Agency for Health Care Policy and Research clinical practice guidelines on acute and cancer pain to all state physicians and encouraged them to apply the guidelines in clinical practices. MBC cosponsored the California Summit on Effective Pain Management held in 1994,[12] which recommended that the triplicate prescription system be replaced with a less invasive and more efficient system. Further, MBC adopted a proactive policy statement, "Prescribing Controlled Substances for Pain,"[13] and announced that it would publish guidelines to help physicians avoid investigation when they used opioids to manage intractable pain. The resulting guidelines[14] were issued in 1994 and have been used as a model by other medical boards.

The new California guidelines were constructed on the fundamental principles that guide professional medical practice, as generally recognized by medical boards. The MBC guidelines do not establish specific prescribing or pain management parameters; rather, they afford California physicians a framework within which a physician may prescribe without concern about interference from regulatory agencies. Drafts of the guidelines were reviewed by medical and legal experts, adopted unanimously by MBC, and disseminated to all California physicians. The American Pain Society (APS) endorsed the California guidelines in 1995.[15]

Subsequent to the development of the MBC guidelines, complementary guidelines were adopted by the boards of nursing and pharmacy.[16] Similar guidelines were then adopted by the medical boards in Florida,[17] North Carolina,[18] and Washington.[19] Further guidance for state policy is contained in the recently approved "Consensus Statement on the Use of Opioids for the Treatment of Chronic Pain," available from the American Academy of Pain Medicine and APS.[20] This statement was developed by a joint task force of the two organizations chaired by Dr. J. David Haddox.

Legislation

Legislative activity has also led to policy addressing pain management; it presents special risks. Some benefits might be gained from legislation in increased public and professional awareness that opioids can legitimately be used to treat chronic pain. Legislation may also help to ease some physicians' fears of ultimate disciplinary action, though perhaps not board investigation and its attendant legal costs. However, standards of medical practice would be established by elected officials, for example, who may or may not involve organizations that represent medicine and science in the drafting process. Opening the door to legislative consideration of medical issues must be carefully considered because this process is political and complex, and the consequences are difficult to foresee. A serious concern is whether legislatures and some regulatory boards might even further restrict rather than expand access to opioids for chronic pain management. Conversely, some policies focus exclusively on use of opioids and fail to acknowledge the legitimate use of nonpharmacological methods of pain management.

Unfortunately, some specific restrictions could create problems for good clinical practice if they are uniformly applied or enforced. These restrictions include: (1) defining medical use of opioids for intractable pain as a therapy of last resort (as is the case in many current intractable pain statutes); (2) application of intractable pain treatment acts to all intractable pain patients, including those with cancer; (3) implying that opioids may be used for pain only in cases where the cause of pain *cannot* be removed; (4) excluding pain patients who use drugs for nontherapeutic purposes; (5) requiring an evaluation of every patient by a specialist in the organ system believed to be the cause of pain; and (6) requiring a signed informed consent form in every case where controlled substances are used to relieve pain.

State legislatures will probably continue to consider intractable pain policy. With the national focus on assisted suicide likely to return to the states following the United States Supreme Court decision,[21] state legislators may become even more interested in legislative action to improve pain management. With the development of model pain legislation by the American Medical Association,[22] it is possible that state and local medical societies will become interested in such legislation. Professional pain organizations should closely monitor the development of state pain policy and provide information and assistance to their elected representatives.

Alternatively, once a particular state has identified inadequate treatment of pain as a problem, a state pain commission could be established. Such a commission could enlist the assistance of other state agencies, could produce a careful study of the problem, and could guide the development of a variety of needed responses,[23] including educational programs and administrative policy making. This process can provide a foundation for change. However, the greatest risk with government studies is the lack of funding for follow-up and implementation.

Education for medical boards

Discussions of the findings of the 1991 survey of medical board members with the Federation of State Medical Boards of the United States (FSMB) led to cooperative efforts to

sponsor educational workshops, "Pain Management in a Regulated Environment."[24] The workshops provided various state medical boards with an educational forum in which to review and discuss advances in knowledge and practice and to develop board guidelines concerning the appropriate medical use of opioids in pain management and related disciplinary policy. Six workshops were presented between 1993 and 1996: one for the Alabama Board of Medical Examiners in 1993, four regional workshops for board members from various state medical boards in 1994 and 1995, and one for the North Carolina Board of Medical Examiners in 1996. A total of 125 board members attended these workshops, and they represented thirty-two state medical boards and approximately 20 percent of the total number of board members. The seminars were sponsored by FSMB in cooperation with the Pain Research Group (now the Pain & Policy Studies Group). Members of APS and the American Society for Addiction Medicine served as faculty.

Such workshops may stimulate a change in policy. For example, following these workshops, the medical boards in Alabama and North Carolina developed and disseminated new guidelines for prescribing controlled substances for pain.[25] In most cases, the purpose of these post-seminar guidelines has been to clarify that the medical board accepts use of opioids to manage chronic noncancer pain. They also outline each board's basic expectations of prescribers.

Conclusion

Medical board guidelines, like intractable pain treatment statutes and regulations, can encourage better management of intractable pain. Guidelines vary from state to state, and some ultimately restrict appropriate prescribing. Before medical boards issue new guidelines for prescribing opioids for intractable pain, they should evaluate the situation in their state and systematically review the issues, seeking advice from experts who can provide accurate information about current clinical practice and pharmacology. New guidelines, if needed, should reflect current knowledge about pain management and permit flexibility in the management of patients with intractable pain. The present positive dialogue that is developing among medical boards, pain clinicians, and addiction specialists should be enhanced in order to ensure the development of rational and consistent intractable pain treatment guidelines at the state level.

In our experience, professional licensing boards are keenly interested in improving public health. As the demand for better pain management increases and medical boards learn about medical advances in pain management, they may revise their disciplinary policies. But these revisions should take place systematically and in consultation with members of the pain management community.

Acknowledgment

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CHAPTER EIGHT

Controlled Substances, Medical Practice, and the Law

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The development of drug control policy in the United States has been characterized by vacillation between tolerance and intolerance toward drugs (Musto 1987). Today's war on drugs is distinguished by intense media coverage of drug-related crime, new antidrug laws, and efforts to educate schoolchildren and the public to "just say no" to drugs. The message is clear: Drugs are dangerous and must be avoided. The United States continues to have significant drug abuse problems that must be addressed, but we should be careful not to reject the medical benefits of drugs or restrict the ability of physicians to care for patients.

Antidrug efforts are directed not only at the illegal controlled substances such as marijuana, heroin, and cocaine, but also at the legal controlled substances that have important medical uses: the opioids (narcotics), stimulants, and sedative hypnotics. These efforts involve media campaigns against perceived overprescribing (Safer and Krager 1992), vigorous enforcement efforts against suspect prescribers (Benton 1993; Hill 1989; McIntosh 1991a, 1991b; Nowak 1992), regulations to increase restrictions on prescribing (Weintraub et al. 1991), and federal proposals to monitor all prescribing to patients of all controlled substances (Stark 1990).

When controlled substances are used for medical purposes, they can provide great improvements in the quality of life for millions of people with debilitating diseases and conditions, including pain, severe anxiety, narcolepsy, and epilepsy. However, when diverted from the

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legitimate distribution system, the nonmedical use of controlled substances can lead to serious public health problems. For example, there are a small percentage of practitioners who abuse their privilege to prescribe and are a source of drugs for addicts and the illicit market. Consequently, it is in the public interest to protect the medical uses of controlled substances while at the same time preventing their diversion and abuse. Public policy should recognize the dual effect of controlled substances on public health to obtain the broadest medical benefit while reducing the risks of diversion and abuse.

There is troubling evidence that some controlled substances laws and regulations and their enforcement interfere with medical practice and patient care. In this chapter we explore whether controlled substances laws and regulations achieve an appropriate balance between controlling abuse and protecting medical use. The primary focus is on the opioids (narcotics) that are used in the somatic treatment of pain, in particular pain due to cancer.

Tragically, cancer pain is often undertreated. Several factors impede pain management, including inadequate preparation of health care professionals, the low priority given to pain management, and the effects of antidrug policies. Although most, if not all, cancer pain can be relieved (Foley 1985; Takeda 1987), it is estimated that one-half to three-quarters of cancer patients with pain are inadequately treated and that nearly 25% die with severe unrelieved pain (Daut and Cleeland 1982). The mainstay of cancer pain management is opioid therapy (World Health Organization 1986). Efforts to improve pain management and eradicate misuse and abuse of prescription controlled substances take place in a medical and regulatory environment characterized by misinformation about opioids. Misinformation about opioids and exaggerated fears of addiction are prevalent among the professions and medical regulators and are partly responsible for the undertreatment of pain (Ferrell et al. 1992; Jaffe 1989; Jasinski 1989; Joranson et al. 1992; Morgan 1986).

The Framework of Controlled Substances Policy

Three tiers of law establish the policy framework that governs the medical use and diversion of controlled substances: 1) international

treaties, 2) federal laws and regulations, and 3) state laws and regulations. As will be seen, international and federal laws clearly recognize the principle that a balance should be maintained between controlling drug abuse and ensuring that controlled substances are available for medical use. However, most state laws do not achieve this balance and, in some instances, interfere with medical practice.

International Treaties, Drug Control, and Medical Use

Treaties provide the basic legal framework for controlling international and domestic production and distribution of drugs that have been determined to have an abuse liability. The principal treaties recognize that many controlled substances are ***indispensable*** to public health and that their availability for legitimate medical and scientific purposes must be ensured. These treaties are the Single Convention on Narcotic Drugs, 1961 (United Nations 1977b), and the Convention on Psychotropic Substances, 1971 (United Nations 1977a). In becoming a party to a treaty, a government agrees to ensure the availability of controlled substances for medical purposes. Most, but not all, of the governments of the world have acceded to these treaties (International Narcotics Control Board 1991).

The International Narcotics Control Board, the United Nations agency responsible for monitoring governments' compliance with the treaties, has reported that opioids are not sufficiently available for legitimate medical purposes throughout the world and that this is due in part to antidrug abuse laws and regulations that unduly restrict the availability of opioids for medical use (International Narcotics Control Board 1989).

A World Health Organization expert committee has also expressed concern that the fear of drug abuse has curtailed appropriate medical use of opioids, particularly for the treatment of cancer pain (World Health Organization 1990); laws are so strict in some countries that physicians cannot prescribe morphine for cancer pain. The expert committee commented on "multiple copy prescription programs" that are used in several countries as well as in several states in the United States.

> The extent to which these programmes restrict or inhibit the prescribing of opioids to patients who need them should be questioned. . . . 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. (World Health Organization 1990, p. 39)

Thus, although the purpose of the international treaties is to ensure availability of drugs for medical use, restrictive laws in some countries limit the use of opioids for the treatment of pain. To what extent do laws and regulations in the United States maintain a balance between the control of drug abuse and the appropriate medical use of opioid analgesics or other controlled substances?

Federal Law and Medical Practice

THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

The Food and Drug Administration (FDA) has approved opioids, stimulants, and sedative hypnotics as safe and effective for medical use and commercial marketing under the Federal Food, Drug, and Cosmetic Act of 1962. This act does not restrict a physician's prescribing either to labeled indications or to recommended doses. This policy is clearly stated in the foreword to the *Physician's Desk Reference* (1993). Once a product has been approved under the Federal Food, Drug, and Cosmetic Act for marketing, a physician may prescribe it for uses, in treatment regimens, or in patient populations that are not included in the approved labeling (Federal Register 1983). Appropriate medical practice and patient interest require that physicians be free to administer drugs according to their best knowledge and judgment (Federal Register 1975).

> New uses for drugs are often discovered, reported in medical journals and at medical meetings, and subsequently may be widely used by the medical profession. . . . When physicians go beyond the directions given in the package insert it does not mean they are acting illegally or unethically, and Congress does not intend to empower the FDA to interfere with medical practice by limiting the ability of physicians to prescribe according to their best judgment. (*United States v. Evers* 1981)

In addition, the federal courts have supported the principle that the FDA does not regulate medical practice (*United States v. Evers* 1981). It is generally recognized that the states, not the federal government, regulate the practice of medicine and that federal law generally defers to state law in areas where there is not a direct conflict (see amendments to the Federal Food, Drug, and Cosmetic Act 1962).

THE CONTROLLED SUBSTANCES ACT

Opioids, stimulants, and sedative hypnotics are additionally subject to controlled substances laws because of their abuse liability. The federal Controlled Substances Act (CSA) (1970) parallels the international treaties, by regulating production and distribution and prohibiting nonmedical use of controlled substances, while clearly recognizing their medical value to public health. The CSA states that "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" (p. 834).

Controlled substances are placed in five schedules. Drugs with no accepted medical use are placed in Schedule I and are available only for scientific research. Drugs that have been approved for medical use are placed in Schedules II–V according to potential for abuse, with drugs having the highest potential for abuse assigned to Schedule II. Although prescriptions for certain controlled substances must be in writing, and refills are limited, the fact that a drug has been approved for medical use does not change when it becomes a controlled substance.

Today's medical and psychiatric practitioners are probably more familiar with legal restrictions over controlled substances prescribing than they are with the legal provisions that were included in the CSA to ensure that drug law enforcement does not interfere with medical practice. For many years prior to the adoption of the CSA in 1970, narcotic prescribing was marked by controversy between drug law enforcers and physicians (Musto 1987). This controversy reached its pinnacle in 1970 during congressional consideration of the new Controlled Substances Act. Congress was considering legislation drafted by the Bureau of Narcotics and Dangerous Drugs in the Department of Justice. The bill proposed that the Department of

Justice and an advisory committee appointed by the attorney general would be solely responsible for making the scientific and medical findings necessary to place a drug under the control of the CSA (Committee on Ways and Means 1970). There was deep concern in the scientific and medical community when it was learned that this bill would give law enforcement complete authority over scientific and medical decisions (Committee on Ways and Means 1970). Following testimony from numerous physicians, the American Medical Association, and the American Psychiatric Association, Congress adopted a different bill that placed the responsibility for medical and scientific determinations in the Department of Health, Education, and Welfare (now the Department of Health and Human Services) and specified that its determinations were binding on drug control decisions made by the attorney general (Controlled Substances Act 1970). Other provisions of law and legislative history make it clear that the CSA is not intended to interfere either with medical practice or the availability of these drugs for patient care (Joranson 1990a; United States House of Representatives 1970).

The Availability of controlled substances for medical purposes is ensured. In an effort to control diversion from excessive manufacture of drugs, the CSA gives the Drug Enforcement Administration (DEA) authority to set production quotas for a number of opioids, stimulants, and sedative hypnotics. Quotas must accommodate all legitimate medical and scientific needs (Controlled Substances Act 1970). In one instance, however, the DEA tried to stop diversion of methylphenidate at the retail level by setting a very low production quota. This action led to an official statement of the principle of "undisputed proposition of drug availability":

> The CSA requirement for a determination of legitimate medical need is based on the ***undisputed proposition*** that patients and pharmacies should be able to obtain sufficient quantities of methylphenidate, or of any Schedule II drug, to fill prescriptions. A therapeutic drug should be available to patients when they need it. . . . The harshest impact of actual and threatened shortages falls on the patients who must take methylphenidate, not on the manufacturers to whom the quotas directly apply. Actual drug shortages, or even threatened ones, can seriously interfere with patients' lives and those of their families. (Federal Register 1988, pp. 50593–50594; italics added)

In addition to recalculating the quotas for methylphenidate, the DEA has expressed willingness to grant additional quotas for opioids to respond to improvements in the treatment of cancer pain (Max 1989).

Medical practice is not regulated by the CSA. The states, not the federal government, have the authority to regulate medical practice. This authority is based on the police power in state constitutions and underlies the medical practice acts that are designed to protect the public health and safety (Parmet 1989). The CSA was not intended to supersede the authority of the Federal Food, Drug, and Cosmetic Act (United States House of Representatives 1970) and provides no authority for the DEA to regulate medical decisions such as the indications for which a drug may be prescribed and the amount or the duration of therapy.

However, the DEA promulgated a regulation in 1986 that could negatively affect medical practice in the care of cancer patients. The regulation placed the new synthetic tetrahydrocannabinol product (THC) into Schedule II following its approval for medical use by the FDA (Federal Register 1986). Because of the drug's chemical relation to marijuana, the regulation stated that physicians who choose to prescribe the drug for other than the specifically labeled use (for the treatment of cancer chemotherapy-induced nausea and vomiting that is unresponsive to other modalities) may subject themselves to investigation for possible violation of the CSA. The DEA argued that the policy was necessary to comply with United States treaty obligations governing marijuana and THC under the Convention on Psychotropic Drugs. Many medical organizations objected to this interference in medical decisions and in FDA policy that allows off-label prescribing. Any rationale for the DEA policy disappeared when THC's international classification was changed to reflect its medical use, but the regulation has not been repealed.

Further, the *Pharmacist's Manual* (United States Department of Justice 1986) lists indications "which may indicate that a purported prescription order was not issued for a legitimate medical purpose in the course of the physician's professional practice" (p. 31), including "Does the purported prescription order contain an indication other than one found in the package insert?" (p. 32).

The DEA's enforcement authority is intended to be concentrated on those practitioners who engage in unlawful use of controlled substances outside of medical practice. Indeed, it is unlawful for a practitioner to prescribe a controlled substance except in the course of professional practice. The phrase *in the course of professional practice* defines the boundaries of practitioner investigations and prosecutions for the DEA.

> It matters not that such acts might constitute terrible medicine or malpractice. They may reflect the grossest form of medical misconduct or negligence. They are nevertheless legal. On the other hand, any act of prescribing, dispensing or distributing of a controlled substance other than in the course of the registrant's professional practice is an illegal distribution of that controlled substance, subject to the same penalties as if the drug were sold by the lowest pusher on the street. (Stone 1983, p. 23)

The intent of the CSA to avoid interference with medical practice was reaffirmed in 1978 when Congress enacted a law to satisfy United States obligations under the Convention on Psychotropic Substances. In so doing, Congress determined that control of psychotropic substances (e.g., tetrahydrocannabinol, benzodiazepines) in the United States should be accomplished within the framework of the CSA to ensure that their availability "for useful and legitimate medical and scientific purposes will not be unduly restricted" (Controlled Substances Act 1970, p. 836). Further, the law stated that nothing in the treaties was to "interfere with ethical medical practice in this country as determined by the secretary of Health and Human Services on the basis of a consensus of the American medical and scientific community" (p. 836).

Treatment of addiction is distinguished from treatment of intractable pain. It is essential to differentiate between prescribing opioids for intractable pain and prescribing them for addiction. When Congress adopted the new CSA, it also settled a long controversy between drug law enforcement and health officials about the lengths a physician could go in prescribing opioids to narcotic addicts (United States House of Representatives 1970). Congress decided that prescribing opioids for narcotic addiction was outside of professional practice and, therefore, unlawful under the CSA, unless the physician was specifically

registered in the Narcotic Treatment Program to use methadone to maintain or detoxify narcotic addicts. Consequently, the definition of ***addict*** becomes critically important, particularly in view of long-standing problems in defining terms associated with drug abuse phenomena. The CSA defines ***addict*** as a person who "habitually uses any narcotic drug so as to endanger the public morals, health, safety, or who is so far addicted to the use of narcotic drugs as to have lost power of self-control with reference to his addiction" (Controlled Substances Act 1970, p. 836).

The CSA definition of ***addict*** is imprecise and does not parallel the definition of ***drug dependence*** of the World Health Organization (1969) or the DSM-IV (American Psychiatric Association 1994). The definition does not distinguish an addict from a patient who is simply physically dependent on an opioid for pain management. However, controlled substances regulations promulgated by the DEA make it clear that a physician who prescribes opioids to treat intractable pain over an extended period is considered to be acting within the professional practice of medicine.

> This section is not intended to impose any limitation on a physician or authorized hospital staff to . . . administer or dispense (including prescribe) 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 Part 1306.07 [c], April 1988)

State Laws and Prescribing of Controlled Substances

Like federal law, state controlled substances laws prohibit nonmedical use of controlled substances. Unlike federal law, most state controlled substances laws, although they permit prescribing, do not explicitly recognize either the public health benefits of controlled substances or the need to balance their control by ensuring availability for medical purposes. In fact, some state laws and regulations that have been enacted to deal with drug abuse and diversion clearly interfere with medical practice and patient care.

Today's state controlled substances laws are based on a 1970 model law called the Uniform Controlled Substances Act (UCSA). The purpose of the 1970 UCSA was to repeal a plethora of antidrug laws

that individual states had adopted since the turn of the century and replace them with a single unified framework to achieve consistency in national drug control policy (National Conference of Commissioners on Uniform State Laws 1970). But instead of establishing a federal-like balance of power between law enforcement and medical science, the UCSA only mentioned in a prefatory note that states could consider establishing an advisory committee to the regulatory agency, an alternative that was rejected by the Congress. The UCSA did not mention the importance of ensuring the availability of controlled substances. A definition of *addict* was also not included, leaving the states without a uniform definition, such as had been developed by the World Health Organization (1969). The UCSA, like the CSA, did not regulate medical decisions such as the quantity of a drug that may be prescribed at one time.

Although the UCSA was adopted in some form in most states, a number of states did not repeal old laws. In addition, some states have adopted new laws and regulations that restrict prescribing and dispensing of FDA-approved drugs. For example, South Carolina's controlled substances law prohibits the prescribing of any controlled substance for a use other than approved by the FDA, and the use of methadone as an analgesic is restricted to patients in hospitals (South Carolina Health Code 1984). A review of state-controlled substances law reveals additional examples of nonuniform provisions that interfere with the use of controlled substances in medical practice (Joranson 1990a). The following are several examples:

Pain Patients May Be Confused With Addicts

It should be recalled that federal law, which is applicable in every state, defines *addict* as an individual who is a danger to society, whose need for opioids can be legally provided for only by specially registered narcotic treatment programs, and for whom a physician may not prescribe opioids unless for pain. A number of state definitions allow confusion of an *addict* with a pain patient who is only physically dependent on an opioid (Joranson 1990a). However, physical dependence is a common physiologic consequence of using opioids to treat chronic pain and should not be confused with *addiction* (American Pain Society 1992). For example, the New York State Controlled Substances Act defines *addict* as "a person who habitually uses a narcotic drug and who by reason of such use is dependent thereon" (New York State Controlled Substances Act, Sect 3302.1, p. 467). A companion provision states that controlled substances may not be prescribed for an addict, unless he or she is a "bona fide patient suffering from an incurable and fatal disease such as cancer or advanced tuberculosis" (New York State Controlled Substances Act, Sect 3351 [b], p. 524). Some states require physicians to report to the government those patients who have been treated longer than several months with a Schedule II controlled substance. New York requires these people to be reported on a special state form *as addicts* (Joranson 1990a). These laws are similar to one in California that was enacted many years ago, apparently as an alternative to "the removal of abusable Schedule II drugs from the commercial market" (Tennant 1981, p. 193). The law required physicians to report habitués to the state's Bureau of Narcotic Enforcement. Before repeal, the largest single category of habitués to opioids that had been reported were individuals with diagnoses of cancer (Joranson 1990a).

The Quantity Prescribed May Be Limited to Less Than Medically Indicated

Although federal law does not limit the amount that can be prescribed, a number of states have restricted the number of dosage units that can be dispensed to as little as 100 dosage units or a 5-day supply (Joranson 1990a) (see Table 8–1). Since it is not uncommon for a cancer patient to take 30–50 pills a day for pain management, prescriptions must be dated every 2 or 3 days. Restricting the prescription amount to less than the medical needs of the patient can result in greater expense to obtain more frequent prescriptions as well as additional dispensing fees. Unfortunately, pain management may also be affected. One Indiana physician has a number of cancer pain patients who need large quantities of opioids and whose insurance plan requires the use of a mail-order pharmacy in New Jersey (which limits dispensing to 120 dosage units per prescription). This physician, whose prescriptions are mailed to New Jersey every few days, reports that his patients ration

their medication because of delays in delivery (Joranson 1990a). As a result, these patients experience pain that could be relieved if they had a predictable and sufficient supply of medication.

In Wisconsin, the Controlled Substances Board found that the "120 dosage units or a 34-day supply whichever is less" rule was confusing and unnecessarily limited prescribing of controlled substances, especially in the treatment of cancer pain. Further, the rule was not useful in preventing diversion (Joranson and Bachman 1988). In cooperation with the Pharmacy Examining Board, the rule was amended in 1991

Table 8–1. Examples of state restrictions for Schedule II controlled substances

State	Restriction
Missouri	30-day supply (may be increased up to 6 months if medical reason is described on prescription)
New Hampshire	34-day supply or 100 dosage units, whichever is less (C-III also) (up to 60-day supply for amphetamine or methylphenidate if for ADD or narcolepsy)
New Jersey	30-day supply or 120 dosage forms, whichever is less
New York	30-day supply for C-II (triplicate) (except up to 3 months if for relief of pain in patients 65 years of age or over and suffering from diseases known to be chronic and incurable; minimal brain dysfunction in patients not more than 16 years of age; convulsive disorders, narcolepsy, or panic disorders). Same if for written Rx for C-III, IV, and V; if an oral Rx for C-III or V, up to a 5-day supply; if an oral Rx for C-IV, up to 30 days or 100 dosage units, whichever is less
Rhode Island	100 dosage units per prescription; no more than 100 dosage units may be dispensed at one time (C-II, III, IV)
South Carolina	30-day supply or 120 dosage units, whichever is less
Utah	1-month supply
Wisconsin	34-day supply (except up to a 90-day supply for C-III or IV anticonvulsant substance)

to delete the 120 dosage unit restriction.

Limitations on the number of dosage units for controlled substance prescriptions are not confined to laws and regulations. Mail-order pharmacy members of the American Managed Care Pharmacy Association have guidelines that specify that dispensing of Schedule II controlled substances must be limited to the amount necessary to meet the legitimate medical needs of the patient.

> The dispensing of Schedule II substances should be limited to a 30 day supply, or 120 dosage units, whichever is less. . . . These maximum quantity limitations enable the patient to obtain a reasonable quantity of controlled substances to assist in an established medical regimen. (American Managed Care Pharmacy Association, undated, p. 3)

American Managed Care Pharmacy Association materials state that these guidelines are consistent with the policies of the DEA, although as stated previously, neither federal law nor the DEA regulations limit the quantity of a Schedule II prescription. Nevertheless, the DEA wrote to the American Managed Care Pharmacy Association in 1990: "The DEA commends the efforts your members have made to the implementation of the Guidelines. The Office of Diversion Control is pleased to offer our continued support of your Association" (American Managed Care Pharmacy Association, undated, p. 3).

Prescription Monitoring Programs Interfere With Medical Practice

Multiple copy prescription programs (MCPPs), or "triplicate" prescription programs, began in the United States with the New York program in 1913 (see Table 8–2). These programs are established to curtail diversion of Schedule II drugs "without adversely affecting the supply of medication to the legitimate user" (United States Department of Justice 1987, p. 4). MCPPs typically require physicians and pharmacists to use a special multipart government prescription form so that prescribing and dispensing of certain drugs to patients can be monitored by a designated state regulatory or enforcement agency. MCPPs differ from state to state. For example, the New York law provides that prescriptions for all drugs subject to the triplicate program must be written and are not refillable; these are controls that are

reserved for Schedule II drugs under the CSA and UCSA. The result is that Schedule II prescription controls were imposed on the benzodiazepines (Schedule IV) when New York added these drugs to the triplicate prescription program in 1989.

The DEA reports that implementation of MCPPs results in prescription decreases of 50% or more in the period following implementation, reduction in the state's per capita consumption of the substances, and significant reduction in physician requests for triplicate forms in successive years. Administrators of MCPPs insist that these programs do not compromise the quality of medical care; indeed, they claim that medical practice has been improved because practitioners tend to examine more closely their reasons for prescribing and often choose a less potent analgesic or a smaller quantity (United States Department of Justice 1987). The DEA strongly supports implementation of legislation to adopt these programs in all states (United States Department of Justice 1987, 1990).

The Risk of Regulatory Scrutiny

Researchers, clinicians, and policy specialists have expressed concern that strict prescription monitoring can interfere with appropriate prescribing and limit patient care (Angarola and Wray 1989; Foley

Table 8-2. Multiple copy prescription programs

Year	State
1913–1915; 1972	New York
1940	California
1943	Hawaii (duplicate)
1961	Illinois
1967	Idaho
1978	Rhode Island (duplicate)
1982	Texas
1989	Michigan
1989	Indiana

1989; Hill 1989; Joranson 1990a; Max 1990; Portenoy 1990). Indeed, researchers have reported that an MCPP hampered the prescribing of Schedule II opioids for terminally ill patients with chronic pain (Berina et al. 1985). The substitution of weaker opioids in lower schedules for more potent opioids was encouraged by an MCPP (Sigler et al. 1984). Furthermore, factors such as "excessive regulation" and "reluctance to prescribe" were identified as significantly greater barriers to pain management by physicians who treat cancer patients in states with MCPPs than by physicians in states without these programs (Von Roenn et al. 1993). Of the physician members of the American Pain Society who responded to a survey, 40% agreed that their prescribing of opioids for chronic nonmalignant pain was influenced by legal concerns (D. C. Turk, personal communication to D. E. Joranson, December 1992; Turk and Brody 1992). A pilot study found that more than one-half of physicians surveyed reported that they would reduce the dose or quantity, reduce the number of refills, or choose a drug in a lower schedule because of concern about regulatory scrutiny (Weissman et al. 1991).

Although documented, these concerns are not necessarily recognized as valid by regulatory agencies:

> Nothing in the multiple copy program limits or restricts medical judgement as to which drug or amount to prescribe. They must simply write the prescription on a different form. . . . Physicians do not abandon their professional training, oath, and duty to their patients because a prescription for a specific drug requires a state-issued prescription blank. . . . The concern about MCPPs interfering in the management of pain is frequently raised in reference to, specifically, cancer pain. The word cancer evokes an emotional, fearful response in most people, and this fear and emotion have been exploited by MCPP opponents. . . . The management of pain is not influenced by MCPPs, rather, it is a function of physician education. (United States Department of Justice 1990, pp. 40–42)

To explore further whether there is valid cause for physicians to perceive risk associated with investigation by regulatory agencies, we studied a sample of the members of state medical examining boards throughout the United States (Joranson et al. 1992). State medical boards administer medical practice laws and have the duty to protect the public health from substandard, incompetent, and unlawful practices. These boards determine what constitutes unprofessional con-

duct and have the authority to grant, suspend, deny, limit, or revoke a license to practice medicine.

A total of 627 medical board members were surveyed in 1991 with the cooperation of the Federation of State Medical Boards of the United States. We obtained a 49% response rate. The mean age of the respondents was 55, and they had received their medical degrees between 1926 and 1987; the median year was 1961. The physician board members were asked to rank the opioid analgesics they would and would not recommend for management of moderate to severe cancer pain. These regulator-physicians tended to prefer drugs like aspirin and acetaminophen alone or in combination with codeine instead of the potent opioids like morphine and hydromorphone that are preferred for moderate to severe pain. This may be an example of the customary prescribing patterns that have been discussed by Morgan (1986) in his treatise on "opiophobia." Further, most of the board members indicated that "addiction" includes physical dependence. Only 10% chose psychological dependence alone.

Board members were also asked to give their opinion on the legality of prescribing opioids for more than several months to chronic pain patients with and without cancer. Only 75% of medical board members were confident that prescribing opioids for chronic cancer pain was both legal and acceptable medical practice; 14% felt it was legal but would discourage it; and 5% believed the practice to be illegal. If the patient's chronic pain was from a nonmalignant source, only 12% were confident that the practice was both legal and medically acceptable; 47% would discourage it; and nearly 33% would investigate the practice as illegal. If the patient had a history of drug abuse, the perception that prescribing opioids was illegal greatly increased. The fact that 80% of the medical board members stated that their medical board was the agency most likely to investigate improper prescribing of controlled substances in their state underscores the significance of these data.

Overall, the survey suggested that medical board members lack knowledge about the use of opioids and other controlled substances to manage pain. To varying degrees they would also discourage or investigate the prescribing of opioid analgesics for intractable pain, particularly if the patient does not have cancer but especially if the patient had a history of drug abuse. It is important to recognize that

the presenting problem in each scenario was pain, not addiction. There was also confusion about the definition of addiction. Addiction is not established by the presence of physical dependence or tolerance, but rather by psychological dependence (American Pain Society 1992). Given these results, it is not hard to understand why physicians might avoid extended opioid prescribing for a patient with pain. In fact, concerns have been expressed about vigorous investigations of physicians for what was considered to be appropriate prescribing of opioids for pain (Benton 1993; Hill 1989; McIntosh 1991a, 1991b; Nowak 1992).

Conclusions and Future Directions

If it is in the public interest that drugs meet rigorous standards of effectiveness and safety, it should be of equal interest to public health that drug laws and regulations be held to the same standards (Woods 1990). In fact, efforts are emerging to examine controlled substances policy as it relates to the prescribing of opioids for pain and to take appropriate action (Joranson 1990a). The Federation of State Medical Boards and the American Pain Society have sponsored educational symposia for medical regulators, and some medical boards are issuing new prescribing policies in the area of pain management (Joranson et al. 1992). The DEA has issued a statement that controlled substances should be prescribed when there is a legitimate medical need (United States Department of Justice 1990). Ultimately, if state and federal agencies have reasonable policies that are communicated to physicians, it may be possible to reach the ideal circumstance in which physicians will not view as a threat inquiries from these agencies about their prescribing.

A revised UCSA was given to the states in 1990 in an effort to help bring state controlled substances laws up to date with many new drug control provisions in the federal CSA and to improve the balance between drug control and medical use of controlled substances (National Conference of Commissioners on Uniform State Laws 1990). The 1990 UCSA 1) gives modest recognition to the medical value of controlled substances—alternative language has been suggested to

emphasize this key principle (Joranson 1990b); 2) urges states to ensure that their definition of terms does not allow patients who are physically dependent on opioids for the treatment of pain to be confused with addicts; 3) clarifies that opioid treatment of intractable pain is part of medical practice and thus outside the scope of controlled substances violations; and 4) establishes a model interagency diversion control program to coordinate the use of existing information, authority, and resources to identify and prosecute individuals who are responsible for diverting controlled substances to illicit uses. The progress to balance state-controlled substances laws could be facilitated if professional organizations were to take an interest in adoption of the 1990 UCSA in their respective state legislatures.

As we pass through another cycle of intense concern about drugs, we must take care not to discard medical and scientific knowledge nor to ignore or stigmatize those among us, especially those with chronic illnesses, who benefit from the essential medical uses of controlled substances. Controlled substances are essential to the quality of life of millions of patients. A balanced drug policy should provide ample authority to address diversion problems without interfering in the use of controlled substances in the medical care of patients. Drug laws have a dual purpose; achieving both ends must be emphasized, for only in this way will the greatest health benefit be realized.

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Appendix C

DEFINITIONS OF LAWS (STATUTES & REGULATIONS), GUIDELINES, AND SCHEDULES OF CONTROLLED SUBSTANCES

The following working definitions are provided to clarify the meaning of "laws," "regulations," and "guidelines" and to distinguish between them, and to explain the Schedules of Controlled Substances.

Law

"Law" is a broad term that refers to rules of conduct with binding legal force, adopted by governments at the international, federal, state or local levels. Law can be found in treaties, constitutional provisions, decisions of the court, statutes and regulations. A number of laws have been adopted by the states concerning pain management.

"Statute" is a law created by a legislative body, whether federal, state, county or city. "Statute" may mean a single act or a collection of acts. Statutes are commonly referred to as laws or acts.

"Regulation" is an official rule or order issued by agencies of the executive branch of government. Regulations have the force of law, and are intended to implement a specific statute, often to direct the conduct of those regulated by the agency.

Guideline

We use the term "guideline" to mean an official policy statement, which does not have the force of law. Guidelines may be issued by a professional association or a government agency to express the group's attitude about a particular matter. While guidelines themselves do not have binding legal force, they define the parameters of conduct for professionals which are consistent with accepted standards of practice.

State medical boards have issued guidelines regarding the medical use of opioids which define the conduct which the board considers to be within the legitimate practice of medicine. Guidelines may also be called a position statement or policy statement; and these may appear in a position paper, report, article, letter or newsletter.

Schedules of controlled substances

Controlled substances are drugs which have a potential for abuse. They are classified by the U.S. Controlled Substances Act of 1970 and the individual state laws into five schedules according to three basic considerations: (1) the degree of potential for abuse; (2) whether the substance has currently accepted medical use; and (3) whether the use under medical circumstances is considered safe.[1] The schedules are known as schedule I, II, III, IV, V, schedule I being the most restrictive and V the least restrictive. Schedule I substances have no accepted medical uses and are illegal (heroin, LSD, marijuana); schedules II, III, IV, and V have accepted medical uses and generally have Food and Drug Administration (FDA) approval for medical use. Schedule II substances can be narcotic or non-narcotic. Schedule II narcotics include morphine, methadone, hydromorphone, and oxycodone.[2]

[1] Controlled Substances Act, 812, Schedules of controlled substances.
[2] District Court of Appeal of Florida, Third District.676 So.2d 1380, June 26, 1996