Guidelines for Prescribing Controlled Substances for Pain

Adopted Unanimously by the Board in 1994 and revised in 2007

"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 section 2241.5(c)

Preamble

In 1994, the Medical Board of California formally adopted a policy statement titled, "Prescribing Controlled Substances for Pain." The statement outlined the board's proactive approach to improving appropriate prescribing for effective pain management in California, while preventing drug diversion and abuse. The policy statement was the product of a year of research, hearings and discussions. California physicians and surgeons are encouraged to consult this policy statement and the guidelines below.

In May 2002, as a result of AB 487, a task force was established to review the 1994 Guidelines and to assist the Division of Medical Quality to "develop standards to assure the competent review in cases concerning the management, including, but not limited to, the under treatment, under medication, and over medication of a patient's pain." The task force expanded the scope of the Guidelines from intractable pain patients to all patients with pain.

Under past law, both Business and Professions Code section 2241 and Health and Safety Code section 11156 made it unprofessional conduct for a practitioner to prescribe to an addict. However, the standard of care has evolved over the past several years such that a practitioner may, under certain circumstances, appropriately prescribe to an addict. AB 2198, which became law on January 1, 2007, sought to align existing law with the current standard of care. Accordingly, a physician is permitted to prescribe, dispense, or administer prescription drugs, including prescription controlled substances, to an addict under his or her treatment for a purpose other than maintenance on, or detoxification from, prescription drugs or controlled substances. The law, Business and Professions Code section 2241, also set forth the conditions under which such prescribing may occur. Further, Business and Professions Code 2241.5 now permits a physician to prescribe for or dispense or administer to a person under his or her treatment of pain or a condition causing pain, including, but not limited to, intractable pain.

Inappropriate prescribing of controlled substances, including opioids, can lead to drug abuse or diversion and can also lead to ineffective management of pain, unnecessary suffering of patients, and increased health costs. The Medical Board recognized that some physicians do not treat pain appropriately due to a lack of knowledge or concern about pain, and others may fail to treat pain properly due to fear of discipline by the board. These Guidelines are intended to improve effective pain management in California, by avoiding under treatment, over treatment, or other inappropriate treatment of a patient's pain and by clarifying the principles of professional practice that are endorsed by the Medical Board so that physicians have a higher level of comfort in using controlled substances, including opioids, in the treatment of pain. These Guidelines are intended to promote improved pain management for all forms of pain and for all patients in pain.

A High Priority

The board strongly urges physicians and surgeons to view effective pain management as a high priority in all patients, including children, the elderly, and patients who are terminally ill. 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 medications and non-pharmacological treatment modalities, often in combination. For some types of pain, the use of medications is emphasized and should be pursued vigorously; for other types, the use
of medications is better de-emphasized in favor of other therapeutic modalities. Physicians and surgeons should have sufficient knowledge or utilize consultations to make such judgments for their patients.

Medications, in particular opioid analgesics, are considered the cornerstone of treatment for pain associated with trauma, surgery, medical procedures, or cancer. A number of medical organizations have developed guidelines for acute and chronic pain management.

The prescribing of opioid analgesics for patients with pain may also be beneficial, especially when efforts to alleviate the pain with other modalities have been unsuccessful.

Business and Professions Code section 2241.5 provides in part: "(a) A physician and surgeon may prescribe for, or dispense or administer to, a person under his or her treatment for a medical condition dangerous drugs or prescription controlled substances for the treatment of pain or a condition causing pain, including, but not limited to, intractable pain. (b) No physician and surgeon shall be subject to disciplinary action for prescribing, dispensing, or administering dangerous drugs or prescription controlled substances in accordance with this section."

However, this section does not affect the power of the board to discipline a physician and surgeon for any act that violates the law, including gross negligence, repeated negligent acts, or incompetence; violation of section 2241 regarding treatment of an addict; violation of section 2242 regarding performing an appropriate prior examination and the existence of a medical indication for prescribing, dispensing, or furnishing dangerous drugs; violation of section 2242.1 regarding prescribing on the Internet; failure to keep complete and accurate records of purchases and disposals of controlled substances; writing false or fictitious prescriptions for controlled substances; or prescribing, administering, or dispensing in violation of the pertinent sections of the Health and Safety Code.

The Medical Board expects physicians and surgeons to follow the standard of care in managing pain patients.

Guidelines

● History/Physical Examination

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

● Annotation One: The prescribing of controlled substances for pain may require referral to one or more consulting physicians.

● Annotation Two: The complexity of the history and physical examination may vary based on the practice location. In the emergency department, the operating room, at night or on the weekends, the physician and surgeon may not always be able to verify the patient's history and past medical treatment. In continuing care situations for chronic pain management, the physician and surgeon should have a more extensive evaluation of the history, past treatment, diagnostic tests and physical exam.

● Treatment Plan, Objectives

The treatment plan should state objectives by which the treatment plan 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 and surgeon should tailor pharmacological therapy to the individual medical needs of each patient. Multiple treatment modalities and/or a rehabilitation program may be necessary if the pain is complex or is associated with physical and psychosocial impairment.
• **Annotation One:** Physicians and surgeons may use control of pain, increase in function, and improved quality of life as criteria to evaluate the treatment plan.

• **Annotation Two:** When the patient is requesting opioid medications for their pain and inconsistencies are identified in the history, presentation, behaviors to physical findings, physicians and surgeons who make a clinical decision to withhold opioid medications should document the basis for their decision.

• **Informed Consent**

The physician and surgeon should discuss the risks and benefits of the use of controlled substances and other treatment modalities with the patient, caregiver or guardian.

• **Annotation:** A written consent or pain agreement for chronic use is not required but may make it easier for the physician and surgeon to document patient education, the treatment plan, and the informed consent. Patient, guardian, and caregiver attitudes about medicines may influence the patient's use of medications for relief from pain.

• **Periodic Review**

The physician and surgeon should periodically review the course of pain treatment of the patient and any new information about the etiology of the pain or the patient's state of health. Continuation or modification of controlled substances for pain management therapy depends on the physician's evaluation of progress toward treatment objectives. If the patient's progress is unsatisfactory, the physician and surgeon should assess the appropriateness of continued use of the current treatment plan and consider the use of other therapeutic modalities.

• **Annotation One:** Patients with pain who are managed with controlled substances should be seen monthly, quarterly, or semiannually as required by the standard of care.

• **Annotation Two:** Satisfactory response to treatment may be indicated by the patient's decreased pain, increased level of function, or improved quality of life. Information from family members or other caregivers should be considered in determining the patient's response to treatment.

• **Consultation**

The physician and surgeon should consider referring the patient as necessary for additional evaluation and treatment in order to achieve treatment objectives. Complex pain problems may require consultation with a pain medicine specialist.

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.

• **Annotation One:** Coordination of care in prescribing chronic analgesics is of paramount importance.

• **Annotation Two:** In situations where there is dual diagnosis of opioid dependence and intractable pain, both of which are being treated with controlled substances, protections apply to physicians and surgeons who prescribe controlled substances for intractable pain provided the physician complies with the requirements of the general standard of care and California Business and Professions Code sections 2241 and 2241.5.

• **Records**

The physician and surgeon should keep accurate and complete records according to items above, including the medical history and physical examination, other evaluations and consultations, treatment plan
objectives, informed consent, treatments, medications, rationale for changes in the treatment plan or medications, agreements with the patient, and periodic reviews of the treatment plan.

- **Annotation One**: Documentation of the periodic reviews should be done at least annually or more frequently as warranted.
- **Annotation Two**: Pain levels, levels of function, and quality of life should be documented. Medical documentation should include both subjective complaints of patient and caregiver, and objective findings by the physician.

**Compliance with Controlled Substances Laws and Regulations**

To prescribe controlled substances, the physician and surgeon 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 and surgeons 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.

- **Annotation One**: There is not a minimum or maximum number of medications which can be prescribed to the patient under either federal or California law.
- **Annotation Two**: Physicians and surgeons who supervise Physician Assistants (PA's) or Nurse Practitioners (NP's) should carefully review the respective supervision requirements.

Additional information on PA supervision requirements is available at [http://www.pac.ca.gov/](http://www.pac.ca.gov/)

PA's are able to obtain their own DEA number to use when writing prescriptions for drug orders for controlled substances. Current law permits physician assistants to write and sign prescription drug orders when authorized to do so by their supervising physician for Schedule II-IV. Further, a PA may only administer, provide or transmit a drug order for Schedule II through V controlled substances with the advanced approval by a supervising physician for a specific patient unless a physician assistant completes an approved education course in controlled substances and if delegated by the supervising physician. To ensure that a PA's actions involving the prescribing, administration, or dispensing of drugs is in strict accordance with the directions of the physician, every time a PA administers or dispenses a drug or transmits a drug order, the physician supervisor must sign and date the patient's medical record or drug chart within seven days. (Section 1399.545(f) of Title 16, California Code of Regulations)

NP's are allowed to furnish Schedule III-V controlled substances under written protocols.

*Postscript*

While it is lawful under both federal and California law to prescribe controlled substances for the treatment of pain - including intractable pain - there are limitations on the prescribing of controlled substances to or for patients for the treatment of chemical dependency (see Sections 11215-11222 of the California Health and Safety Code). In summary, a physician and surgeon must follow the same standard of care when prescribing and/or administering a narcotic controlled substance to a "known addict" patient as he or she would for any other patient.

The physician and surgeon must:

- perform an appropriate prior medical examination;
- identify a medical indication;
• keep accurate and complete medical records, including treatments, medications, periodic reviews of treatment plans, etc;

• provide ongoing and follow-up medical care as appropriate and necessary.

The Medical Board emphasizes the above issues, both to ensure physicians and surgeons know that a patient in pain who is also chemically dependent should not be deprived of appropriate pain relief, and to recognize the special issues and difficulties associated with patients who suffer both from drug addiction and pain. The Medical Board expects that the acute pain from trauma or surgery will be addressed regardless of the patient's current or prior history of substance abuse. This postscript should not be interpreted as a deterrent for appropriate treatment of pain.