

**AVOIDING PROBLEMS WITH PAIN MANAGEMENT:**  
**ETHICAL AND LEGAL GUIDELINES FOR PHYSICIANS**

**Joint Committee on Biomedical Ethics  
of the  
Los Angeles County Medical Association  
and  
Los Angeles County Bar Association**

**Approved by the Los Angeles County Medical Association May 9, 2012**  
**Approved by the Los Angeles County Bar Association June 27, 2012**

**AVOIDING PROBLEMS WITH PAIN MANAGEMENT:**  
**ETHICAL AND LEGAL GUIDELINES FOR PHYSICIANS**

**From the Joint Committee on Biomedical Ethics of the  
Los Angeles County Medical Association and Los Angeles County Bar Association**

**I. Introduction**

It is universally acknowledged that patients are entitled to adequate management of acute and chronic pain. Nevertheless, there is growing recognition that under-treatment of pain is common. Both the State of California and the United States government have officially recognized the under-treatment of pain as a serious problem.

Although there are a number of barriers to adequate pain management, one of the primary reasons physicians give for not treating pain aggressively, or for avoiding the use of controlled substances such as opioids, is fear of regulatory scrutiny. Many physicians may have inaccurate perceptions about regulatory oversight, and consequently fear that good medical practice in this area will not be enough to protect them from overzealous regulators. This misperception may result in less aggressive pain management than would be appropriate in individual cases.

Other barriers also may impede adequate treatment of patients who suffer from significant pain. For example, it may be difficult for physicians and patients to discuss and establish realistic expectations for pain relief and side effects. Additionally, cultural influences may cause some physicians to mistrust reports of pain from members of certain groups, or from patients who have abused substances in the past.

The purposes of this document are: (1) to identify common barriers to appropriate pain management; (2) to present a summary of federal and state drug enforcement law and policy; and (3) to reassure physicians that aggressive use of controlled substances, including opioids, when medically appropriate and properly documented, will not render them vulnerable to

governmental harassment.<sup>1</sup>

## **II. Barriers to Appropriate Pain Management**

### **A. No Reliable, Objective Measure**

There is no reliable, objective measure of pain, so physicians must rely on their patients' descriptions of their symptoms. Cultural and personal factors may influence how patients perceive pain, and how physicians react to certain patients' reports of pain. For example, studies have shown that children, individuals with cognitive impairments, and the elderly tend to be viewed as inaccurate reporters of pain, and also that racial and ethnic minorities and women appear to be at greater risk for under-treatment of pain. Factors such as patients' limited access to resources, fears of addiction, and mistrust of physicians or the medical system also contribute to under-treatment.

### **B. Potential for Abuse**

Although there is a significant potential for abuse and diversion of controlled substances, the risk of *addiction* from prescribed pain medication is widely misunderstood. While most patients treated with prolonged opioid therapy develop physical dependence and sometimes tolerance, they typically do *not* develop addictive behaviors. Nevertheless, the fear that prescribing pain medication may cause or exacerbate addiction understandably is heightened when the patient is known or suspected to have a history of addiction to drugs<sup>2</sup> or alcohol, and thus there may be a greater need in such a case to consult with an expert.

---

<sup>1</sup> This document is not directed toward medical management of pain, as multiple clinical guidelines on pain management already exist.

<sup>2</sup> The Controlled Substances Utilization Review and Evaluation System ("C.U.R.E.S.") established as part of the California Bureau of Narcotic Enforcement's Prescription Drug Monitoring Program enables registered prescribers, pharmacists, and authorized agencies to search a database of medications dispensed in California, to assist them in identifying patients who may be abusing controlled substances. See the link to the C.U.R.E.S. website in Appendix A.

**C. Fear of Regulatory Scrutiny and Malpractice Liability**

As noted above, a frequently reported reason why physicians are reluctant to prescribe controlled substances such as opioids is fear of regulatory scrutiny. In addition to perceiving government enforcement activity in this area as overzealous, physicians may believe it is inconsistent. A similar barrier to appropriate pain management may be fear of malpractice liability for either under-treatment or over-treatment of pain.

**D. Lack of Experience in Complex Pain Management**

Different clinical indications create different sets of problems for physicians prescribing pain medications, and chronic pain from non-malignant conditions poses the greatest challenges. Not all physicians have extensive training and experience in the management of pain, especially chronic pain. As noted above, both patients and physicians may be understandably concerned that pain medication, especially opioids, will lead to addiction—and this concern may be compounded if either the physician or the patient confuses addiction with the expected physiologic dependence and dose tolerance that may occur in the long-term treatment of pain. As in other areas of medical practice, physicians treating chronic pain should either possess or acquire the appropriate competence, or request pain management consultation. Due to the high risk of unintentional overdose with long-acting opiates such as methadone or transdermal Fentanyl, physicians treating chronic pain should seek consultation with physicians experienced in the use of these medications, or additional training, prior to prescribing these drugs.

**E. Lack of Recognition That Some Pain Patients Need Care from Other Types of Professionals**

The experience of pain, especially chronic pain, can diminish a patient's overall quality of life, and this effect may not be alleviated solely through pain medication. Additionally, psychological and social conditions affecting the patient may exacerbate pain. Thus, referrals to a variety of other professionals to address associated physical, psychological, social and vocational problems may be necessary to provide adequate care to some long-term pain patients.

**F. Lack of Readily Available Specialty Consultation in Some Settings**

In some instances, a physician may recognize that consultation with a pain management expert would be beneficial, but find that such expertise is not readily available in the physician's particular practice setting. Appendix B to this document lists some resources that may assist physicians in such circumstances.

**III. The Regulatory Landscape**

**A. Laws and Principles**

Both the federal government and California have recognized officially that the under-treatment of pain is a serious problem, and expressed concern about the unintended chilling effect that drug enforcement can have on effective pain management. Federal and California officials have articulated legal principles designed to create a better balance between the patient's right to adequate pain management and the government's duty to prevent illegal drug trafficking and substance abuse.<sup>3</sup>

These legal principles can be summarized as follows:

1. Federal and California law authorize physicians to prescribe controlled substances for legitimate medical purposes, in accordance with the standard of care.
2. California law specifically gives patients a right to certain kinds of pain medication, including opioids, where medically indicated. A physician who is unable or unwilling to provide this treatment option to a patient has a legal and ethical duty to refer the patient to a physician who will.
3. Neither prescribing opioids for pain nor treating pain aggressively should result in government scrutiny under federal or California law when done in accordance with good medical practices, including current, accessible recordkeeping that documents the following:

---

<sup>3</sup> Appendix A includes citations to federal and California statutes, regulations and guidelines relating to prescribing of controlled substances.

- a. relevant medical history;
  - b. physical examination;
  - c. diagnostic, therapeutic, and laboratory results;
  - d. evaluations and consultations;
  - e. treatment objectives;
  - f. discussion with the patient of (i) risks and benefits, (ii) treatment options, and (iii) current medications (date, type, dosage and quantity prescribed);
  - g. rationale for changes in treatment plan or medication;
  - h. instructions to and/or agreements with patients,<sup>4</sup> and
  - i. periodic reviews.
4. The frequency, amount, and duration of prescription medications, by themselves, are not indicative of abuse or an illicit purpose. Individual patient characteristics and medical need also must be considered to determine appropriate prescribing. A physician's intent and the medical practices followed are also very important in determining whether the physician had a legitimate or illegitimate purpose.
5. Federal and California laws prohibit a physician from giving controlled substances to someone the physician *knows* is selling the drugs or abusing them. If a physician is aware of prescribing controlled substances for a patient with a known or suspected addiction (or history of drug abuse), then the physician has a duty to try to minimize the risk of abuse while still adequately treating the patient's pain.
6. Physicians who provide inadequate pain treatment are vulnerable to tort liability and disciplinary action by medical boards. For example, in 2001, a physician was found liable for elder abuse and reckless conduct due to inadequate pain

---

<sup>4</sup> See Appendix C for links to pain management agreement resources.

management in the case of a patient who was dying of lung cancer. The jury awarded \$1.5 million to the patient's family. In 2003, the California Medical Board disciplined a physician for unprofessional conduct and incompetence because the physician failed to prescribe medications properly to relieve pain.

## **B. Enforcement Activity**

At the federal level, the U.S. Drug Enforcement Administration (DEA) is responsible for ensuring that controlled substances are prescribed, administered, and dispensed only for legitimate medical purposes. In California, the Medical Board of California (MBC) has authority to discipline physicians who fail to meet minimum standards of care or who violate the state's Medical Practice Act. These agencies have overlapping authority with respect to the prescribing of controlled substances.

Some regulatory officials have expressed concern that physician fear of government scrutiny interferes with the appropriate prescribing of pain medication. The DEA has tried to dispel the perception that it targets physicians merely for prescribing controlled substances for pain, and has stated that "the overwhelming majority of physicians who prescribe controlled substances do so in a legitimate manner that will never warrant scrutiny by Federal or State law enforcement officials. . . . In any given year, . . . fewer than one out of every 10,000 physicians in the United States (less than 0.01 percent) lose their controlled substance registration based on a DEA investigation of improper prescribing."<sup>5</sup> Similarly, criminal enforcement activity involving physician prescribing is rare, and typically occurs where there is substantial evidence of criminal activity or illicit motive. For example, some of the behaviors that have resulted in criminal prosecution or loss of DEA registration include:

- Issuing prescriptions for controlled substances without a *bona fide* physician-patient relationship, as evidenced by any of the following: no medical

---

<sup>5</sup> Dispensing Controlled Substances for the Treatment of Pain, 71 Federal Register 52716, 52719 (Sept. 6, 2006).

examination, no follow-up or monitoring, and/or no logical relationship between the drugs prescribed and the medical condition purportedly being treated—conduct often associated with Internet prescribing;

- Issuing prescriptions in exchange for sex;
- Issuing several prescriptions at once for a highly potent combination of controlled substances;
- Charging fees commensurate with drug dealing rather than providing medical services;
- Using street slang for drugs instead of medical terminology;
- Issuing prescriptions using fraudulent names;
- Selling blank pre-signed forms or allowing non-DEA registered individuals to issue pre-signed prescriptions;
- Abuse by the practitioner, such as using patients' or fictitious names to fill prescriptions for controlled substances that are actually for the physician's personal use, or inappropriate prescribing for the physician's family members;
- Splitting prescriptions, i.e., writing multiple prescriptions for the same drug for a patient, in order to try to avoid scrutiny based on drug quantity—especially where patients are instructed to visit specific pharmacies to fill the prescriptions so as to avoid detection; and
- Prescribing a large quantity of controlled substances for a patient or multiple patients, in combination with some other improper behavior or consequence, such as multiple deaths linked to such overprescribing, the physician's personal abuse of controlled substances, or reselling of drugs.

#### **IV. Conclusion**

In pain management, as in other aspects of medical practice, physicians should undertake whatever training is necessary to become and remain competent in those areas of pain management that are expected to arise in their individual practices, should provide care appropriate to their patients' needs, should thoroughly document that care and the reasons for it, and should seek help when they encounter problems beyond their capabilities.

Physicians who prescribe controlled substances responsibly and who follow and document good medical practices can be confident that the risk of governmental intervention and liability exposure will be minimal.

## **Appendix A**

### **Bibliography of Statutes, Regulations, Guidelines, Etc. Regarding Pain Management and Prescribing of Controlled Substances**

#### **Federal Statutes and Regulations**

Registration Requirements, Controlled Substances Act, 21 United States Code § 823 (2012)

Persons Entitled to Issue Prescriptions, 21 Code of Federal Regulations (C.F.R.) § 1306.03 (2012)

Purpose of Issue of Prescription, 21 C.F.R. § 1306.04 (2012)

Dispensing Controlled Substances for the Treatment of Pain, 71 Federal Register 52716 (Sept. 6, 2006)

#### **California Statutes and Regulations**

California Intractable Pain Treatment Act, California Business & Professions Code § 2241.5 (2012)

Responsibility and Liability for Prescribing Controlled Substances; Unlawful Prescriptions, California Health & Safety Code § 11153 (2012)

Legislative Findings and Declarations, California Health & Safety Code § 124960 (2012)

Pain Patient's Bill of Rights, California Health & Safety Code § 124961 (2012)

#### **Federal Guidelines**

Practitioner's Manual of the U.S. Drug Enforcement Administration,  
<http://www.dea.gov/divisions/cead/pubs/manuals/pract/index.html>

Model Policy for the Use of Controlled Substances for the Treatment of Pain (2004),  
<http://www.fsmb.org/index.html>

#### **California Guidelines**

Guidelines for Prescribing Controlled Substances for Pain,  
[http://www.medbd.ca.gov/pain\\_guidelines.html](http://www.medbd.ca.gov/pain_guidelines.html)

Medical Board's Guidebook to Laws Governing the Practice of Medicine by Physicians and Surgeons,  
[http://www.medbd.ca.gov/publications/laws\\_guide.html](http://www.medbd.ca.gov/publications/laws_guide.html)

#### **California Controlled Substances Utilization Review and Evaluation System (C.U.R.E.S.)**

<http://ag.ca.gov/bne/cures.php>

## Appendix B

### Organizational/Internet Resources

- Los Angeles County Medical Association (LACMA), <http://www.lacmanet.org/>
- California Medical Association (CMA): <http://www.cmanet.org/>
  - California Physician Legal Handbook (multi-volume reference available for purchase): <http://www.cmanet.org/resource-library/detail?item=california-physicians-legal-handbook>
  - Medical Legal Library, free to members, \$2 per page for non-members: <http://www.cmanet.org/resource-library/chapters?category=medical-legal-library>
  - Free service for members to ask legal questions: [legalinfo@cmanet.org](mailto:legalinfo@cmanet.org)
- Other Professional Organizations Providing Relevant Information
  - American Academy of Pain Medicine: <http://www.painmed.org/>
  - American Pain Society: <http://www.ampainsoc.org/>
  - California Society of Anesthesiologists: <http://www.csahq.org/>
  - American Society of Addiction Medicine: <http://www.asam.org/>
  - California Society of Addition Medicine: <http://www.csam-asam.org/>
  - Elder Law Organizations:  
[http://www.ncea.aoa.gov/ncearoot/Main\\_Site/index.aspx](http://www.ncea.aoa.gov/ncearoot/Main_Site/index.aspx)
  - Palliative Care Organizations/Information: <http://www.capc.org/about-capc;>  
[http://www.getpalliativecare.org/;](http://www.getpalliativecare.org/)  
<http://www.nlm.nih.gov/medlineplus/palliativecare.html>

## **Appendix C**

### **Internet Resources for Pain Management Agreements**

American Academy of Pain Management:

<http://www.aapainmanage.org/literature/Articles/OpioidAgreements.pdf>

Minnesota Prescription Monitoring Program:

<http://pmp.pharmacy.state.mn.us/assets/files/PDFs/Sample%20Pain%20Management%20Contract.pdf>

National Institutes of Health, National Library of Medicine:

<http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1829426/>