

Ethical Issues in the Treatment of Chronic Non-Malignant Pain: A Focus on the Legal Side

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Target Audience: This continuing medical education activity is intended for members of the American Academy of Pain Management, primary care physicians, and other healthcare professionals who can take advantage of AMA PRA Category 1 Credit™.

Statement of Need: The National Center for Health Statistics estimates that 32.8% of the US general population has persistent or chronic pain symptoms. The reluctance to use certain classes of analgesics for nonmalignant pain has resulted in ineffective relief for a large group of patients. Unlike the risks of most other classes of medications, the risks of opioid pain medications also include the potential for abuse and diversion to illicit channels of distribution for illegal use. Over the years, increasing media attention to the risks of opioids has clouded objectivity and has helped perpetuate misunderstandings of the actual benefits and risks of prescription analgesics. Without globally accepted guidelines, chronic pain management remains burdened with debate that centers around the appropriate role of prescription medications for moderate to severe pain.

When treating chronic pain, physicians must walk a fine line between adhering to state, federal, and professional guidelines and providing the best possible care for their patients. Whereas guidelines are often an agency's current position statement and are not clinical care standards, deviations from guidelines are often used during review of board cases and may result in administrative sanctions. This contributes to the fear and reluctance among many clinicians to prescribe certain opioids, which may be in conflict with the physicians' responsibility to provide the best possible care for their chronic pain patients.

An annual needs assessment conducted by the American Academy of Pain Management in the second quarter of 2007 found that 75% of members surveyed requested more educational opportunities in medico-legal aspects of clinical practice. Similarly, 65% of members indicated that they would like more information on the

role of appropriate documentation. This assessment, plus the fears and hesitations which members often express, demonstrate that there is a clear need to educate the frontline clinician on 1. the controversies surrounding prescribing pain medication, 2. the impact of laws and regulations on providing adequate pain relief, and 3. the implementation a comprehensive policy that promotes both adherence to legal and professional guidelines and effective treatment of the chronic pain patient. This activity will address these educational gaps by focusing on the legal aspects of treating chronic non-malignant pain. At the end of this activity, clinicians will be able to confidently and effectively intervene and improve the quality of life for the patient with chronic pain.

Learning Objectives:

At the conclusion of this session, participants should be able to:

- Describe the barriers associated with clinician reluctance to treat chronic non-malignant pain
- Explain the federal regulations regarding prescription pain medications

Accreditation Statement: This activity has been planned and implemented in accordance with the Essential Areas and policies of the Accreditation Council for Continuing Medical Education (ACCME) through the joint sponsorship of the American Academy of Pain Management and SynerMed® Communications. The American Academy of Pain Management is accredited by the ACCME to provide continuing medical education for physicians and takes responsibility for the content, quality, and scientific integrity of this CME activity.

Credit Designation: The American Academy of Pain Management designates this educational activity for a maximum of .5 hour in Category 1 credit toward the AMA Physician's Recognition Award. Each physician should claim only those hours of credit that he/she actually spent on the activity.

Faculty Information: As a sponsor accredited by the Accreditation Council for Continuing Medical Education, the American Academy of Pain Management must insure fair balance, independence, objectivity, and

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Jennifer Bolen served as an Assistant U.S. Attorney with the U.S. Department of Justice for nearly fourteen years. In 2002, Ms. Bolen founded The Legal Side of Pain® and entered private practice in 2003 to educate health care providers on medico-legal issues on the use of controlled substances to treat pain. Ms. Bolen serves on several national advisory boards and committees dedicated to improving legal and regulatory educational efforts for health care providers. She is the Legal Editor for *Pain Medicine News* and publishes a regular column in both *Pain Medicine News* and *Anesthesiology News*. Ms. Bolen serves on the editorial board for the American Academy of Pain Medicine's journal, *Pain Medicine*, and for the *Journal of Opioid Management*. Ms. Bolen's most recent efforts include a new mentoring effort to help pain management practitioners improve medical record documentation of controlled substance prescribing practices through the Chronic Pain Network and her Pain Law Mentor™ training series.

Disclosures: Jennifer E. Bolen, JD, is on the speakers' bureau for AIT Laboratories, Alpharma Inc., Ortho-McNeil, Inc., and Purdue Pharma L.P. She is on the speakers' bureau and is a consultant for Dominion Diagnostics and King Pharmaceuticals, Inc. She is on the speakers' bureau for, is a consultant for, and has received grant support from Ligand Pharmaceuticals, Inc. She is a

consultant for Abbott Laboratories. She is Legal Editor of *Pain Medicine News*, is Special Counsel to the American Academy of Pain Medicine, and has written on occasion for Cephalon, Inc.

Instructions: To receive credit for this activity, you must read the entire article and successfully complete the post-test, answering 4 of the 5 questions correctly. It is estimated that this activity will take approximately one half hour to complete.

Fee: There is no charge for members of the American Academy of Pain Management.

Commercial Support: This activity is supported by an educational grant from PriCara™, unit of Ortho-McNeil, Inc.

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Ethical Issues in the Treatment of Chronic Non-Malignant Pain: *A Focus on the Legal Side*

BY JENNIFER BOLEN, JD

Physicians treating chronic pain sufferers must walk a fine line between adhering to the guidelines and regulations set forth by state, federal, and professional authorities and providing the best possible care for their patients. As a former U.S. attorney with the Justice Department, a legal and educational consultant, and sufferer of chronic non-malignant pain, I am fully aware of the day-to-day intricacies healthcare providers face when balancing these contractual and covenantal relationships.

Clearly, physicians have a contractual relationship with the varying regulatory and healthcare agencies such as the U.S. Drug Enforcement Agency (DEA), various licensing boards, and managed care organizations (See Figure 1). As healthcare professionals, they are obligated to provide a certain level of care to patients while staying within the parameters designated by regulatory and healthcare agencies. While these contractual relationships exist for good reason, they may sometimes be viewed as restrictive to practical practice. Therefore, clinicians should

Factors Cited by DEA Regarding Recurring Concomitance of Condemned Behavior (1)

1. An inordinately large quantity of controlled substances prescribed.
2. Large numbers of prescriptions issued.
3. No physical examination given.
4. Physician warned the patient to fill prescriptions at different drug stores.
5. Physician issued prescriptions to a patient known to be delivering the drugs to others.
6. Physician prescribed controlled drugs at intervals inconsistent with legitimate medical treatment
7. Physician involved used street slang rather than medical terminology for the drugs prescribed.
8. There was no logical relationship between the drugs prescribed and treatment of the condition allegedly existing.
9. Physician wrote more than one prescription on occasions in order to spread them out.

approach these boundaries as limitations that can be used proactively to further guide physician/patient relationships regarding pain management and the use of controlled substances.

The covenantal relationship between clinician and patient is the commitment to provide the utmost care for that person while doing no harm (2). Unlike a contractual relationship, the covenantal relationship is not based on rigid boundaries or obligations, but is based on empathy, understanding, and the commitment to work with patients to improve their health. Physicians are obligated to find a way to protect a patient's legitimate access to controlled substances, while demonstrating compliance with legal/regulatory guidelines. Clinicians should read and learn all applicable federal and state regulatory material on using controlled substances in pain management, stay current on clinical standards of care, and implement a compliance program to minimize the potential for abuse and diversion of controlled substances. Appropriate use of pertinent regulations can protect both the physician and patient and strengthen the covenantal relationship. Three general rules for proper medical decision making are summarized below.

Three General Rules in Medical Decision Making

Rule 1: Read all applicable federal and state laws, regulations, and guidelines relating to the use of controlled substances, particularly, the use of controlled substances in pain medicine. Maintain records and routinely update copies of these laws, regulations, and guidelines in the office.

Rule 2: Stay current on the accepted clinical care standards by educating yourself. Read the most current journals, take continuing medical education courses, and attend the appropriate conferences where legal/regulatory issues are taught by qualified instructors.

Rule 3: Keep updated records that focus on patient monitoring and assessment for all patients taking opioids for pain management. Before you incorporate a new form into your practice (or modify existing forms), make sure the language in the form is consistent with federal and state regulatory materials and current clinical standards of care. Your entire documentation and practice system should incorporate, and be consistent with, current legal/regulatory guidelines identified through *Rule 1*.

It is important to remember that guidelines are nothing more than an agency's current position statement on a particular subject. Guidelines are not clinical care standards. In fact, in most instances, they represent the minimal expectations of the agency. Guidelines are not laws, and do not carry any legal sanctions or penalties.

However, deviations from guidelines may result in administrative sanctions and licensing board experts often use these guidelines during review of board cases. In the absence of state legal/regulatory guidelines regarding opioid therapy or the use of controlled substances in pain management, clinicians should consider the Federation of State Medical Boards' Model Policy for the Use of Controlled Substances for the Treatment of Pain (3). The seven elements from the policy include:

- 1. History and physical examination.** The process begins with clear and detailed documentation of the nature and intensity of pain, any past and current treatments for pain, and the effect the pain has on the patient's physical and psychosocial function. Any underlying or coexisting diseases or conditions, history of substance abuse, and the medical implications for the use of a controlled substance should be documented. Physicians should confirm the patient's history with previous healthcare providers and review all medical documents regarding the patient. In addition, an initial drug screen may be used to verify the patient's self-reports.
- 2. Treatment plan.** A written treatment plan is critical to the covenantal relationship. The plan should outline what medications will be used, the parameters that will be used to determine treatment success, as well as outline any further diagnostic evaluations or treatments planned. The plan should also outline the frequency of treatment assessment, and, if determined necessary, how it will be altered.
- 3. Informed consent and treatment agreement.** Informed consent is the physician's ethical, and in most states, legal obligation to discuss the treatment's risk and benefits with the patient. When prescribing controlled substances, the physician is also obligated to discuss any treatment alternatives that may be available to the patient. On the other hand, the treatment agreement outlines the physician's policy regarding controlled substances. These documents will be discussed in more detail later.
- 4. Periodic review.** Most licensing boards give physicians discretion on the timing of periodic

review. However, physicians should use current clinical care standards to determine the appropriate follow-up period and what criteria will be used in the review process.

- 5. Consultations (and referrals).** Physicians should be willing to refer patients to pain specialists or psychologists for evaluation and treatment alternatives in order to achieve treatment objectives; this is especially true for patients who are at risk for medication misuse, abuse, or diversion.
- 6. Medical records.** Physicians should check with state regulatory authorities to make sure appropriate records are being kept; however, medical records should include information regarding physical examinations; clinical, diagnostic, and laboratory results; treatment objectives; informed consent agreements; medications; and periodic reviews.
- 7. Compliance with controlled substance laws and regulations.** Physicians must be licensed in the state in which they practice, and comply with all applicable federal and state regulations regarding the prescribing, dispensing, and administering of controlled substances.

Informed Consent and Treatment Agreement

Perhaps no other area illustrates the convergence of the covenantal and contractual relationships better than the Informed Consent and Treatment Agreement. Informed Consent is more than just a document outlining the treatment that a patient agrees to undergo. Informed Consent represents two ethical, and in some cases legal, obligations. First, the practitioner must give the patient sufficient information about the recommended treatment plan, including the use of any medication and its related risks, expected benefits, treatment alternatives, and special issues so that the patient can make an informed decision about the treatment. The discussion of risks should also include frank language regarding the risks of addiction or abuse with opioid use.

Second, the patient must be provided an opportunity to ask questions. Once the practitioner provides the patient the information and an opportunity to ask questions, a patient's consent to treatment is more likely

to withstand legal scrutiny and be considered “informed.” Failure to accomplish informed consent can lead to a negligence action against a practitioner (4). Treatment Agreements set boundaries and expectations concerning the physician-patient relationship as it relates to the use of controlled substances to treat pain. Most state guidelines suggest the use of Treatment Agreements with “high risk” patients or those with a history of substance abuse. Few state guidelines require them with all patients. In the courtroom (or in a licensing board context), it is through these documents and the practitioner’s method of handling the patient’s response (or lack thereof) to treatment and compliance issues, that treatment shortcomings are challenged and probably most evident.

In the Model Policy and in pain policy in general, the informed consent and treatment agreement appear to be treated as one concept. However, in law these are two distinct concepts and practitioners should take care to cover the formal elements of each concept after a careful review of their practice, existing ethical and clinical standards, and federal and state regulatory materials. Many state and professional medical organizations have blended informed consent elements with treatment agreements and created forms (5) that may fall short of ethical obligations and regulatory standards if challenged in a board hearing or the courtroom.

The Treatment Agreement sets up boundaries for both physician and patients and sets forth the office policy regarding the prescription of controlled substances. This document can be modified to meet a specific patient’s needs outlining what the physician will do to treat the patient and what is expected from the patient in return. Beware that inconsistencies between state terminology and the office form, and/or the use of multiple terms to refer to controlled substances can cause confusion. These inconsistencies may cause problems over the long-run, especially if the patient’s treatment is ever called into question.

Establishing Treatment Parameters

Unfortunately, treatment shortcomings resulting from a fear of regulatory scrutiny or a misunderstanding of legal or regulatory terms are often established in the creation of these documents. For example, physicians may discuss the risks and benefits of certain medications but not adequately address the risks of addiction or abuse of

those treatments or alternative options. Failing to do so may not allow the patient to make an informed decision regarding treatment nor establish realistic expectations of the medication. Failing to communicate the parameters of prescribing controlled substances, such as a single prescribing physician, a single pharmacy, or periodic drug testing, may put the patient at odds with the physician or create a lack of trust between the two. Parameters that go too far or not far enough may create a situation where patients wind up exhibiting what appears to be drug-seeking behavior and physicians may react harshly, terminating treatment for fear of regulatory reprisals and leaving patients with inadequate treatment.

Because physicians’ obligations differ somewhat from state to state, physicians must review their state’s guidelines or position statements regarding the use of controlled substances for pain. Through these guidelines medical licensing boards often attempt to define minimal licensing expectations through a “board’s-eye view” of a state law or regulation that governs medical practice in the state. Most state regulatory material contains directive language, such as the use of “shall” versus “should” or “must” versus “may.” Practitioners should make a checklist of these directives and use the checklist to perform a self-audit of their medical practice. Directive language provides guidance regarding the state’s boundaries around the prescribing of controlled-substances and documentation that must be generated in order to maintain medical licensing and registration.

The covenantal relationship between physician and patients may, at times, seem like it comes in direct contrast to the contractual one. Every patient is different, including his or her response to pain and treatment, so physicians often must be willing and able to think outside of the practice norms. The contractual relationships physicians engage in are not meant to hinder this. State, federal, and board restrictions and guidelines do not tell physicians how to practice medicine. All they do is set forth boundaries on prescribing controlled substances for legitimate medical purposes in the usual course of professional practice (3, 6). It is those two phrases, “legitimate medical purpose” and “usual course of professional practice” that impact the ethics of medicine. Using that as guidance will help clinicians find language in these guidelines that

can be used to set boundaries with patients in that initial discussion of the roles and responsibilities of the physician and patient.

Physicians must learn the delicate balance of pain management. With every patient they are juggling the science and medicine of pain management; the reality of treating a patient suffering from chronic pain; and the ethics, legal and regulatory materials governing this treatment. No amount of documentation, including an informed consent or agreement to treat, can prevent a lawsuit or licensing board investigation. However, proper documentation can impact how a deciding body, be it a jury or board reviewer, perceives a physician and the practice as a whole. Physicians should understand that the law can work for them and their patients.

REFERENCES

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(Figure 1)



GENERAL SUMMARY OF KEY DEA EXPECTATIONS THE USE OF CONTROLLED SUBSTANCES TO TREAT PAIN DECEMBER 2007 VERSION

Code of Federal Regulations

21 CFR § 1306.04 (purpose of issue of prescriptions)

To be valid, a prescription must be issued for a legitimate medical purpose by a provider acting in the usual course of professional practice. **NOTE:** There are several more federal regulations relating to controlled substance prescribing. Practitioners should read all of

Interim Policy Statement

Federal Register, Vol. 69, No. 220 (pages 67170-67172), Nov. 16, 2004

Responsibility to Minimize the Potential for Abuse and Diversion of Controlled Substances

Seriously Consider any Sincerely Expressed Concerns Made by Family Members or Friends about a Patient's Potential Abuse of CS

NOTE: This policy statements was finalized in Sept. 2006. Also, this policy statement prohibited the use of Multiple Prescriptions for Schedule II Controlled Substances, but this prohibition was lifted effective December 19, 2007, through the DEA's Final Rule on Multiple Prescriptions for Schedule II CS (released on Nov. 19, 2007).

Clarification Statement on Issuance of Multiple Prescriptions for Schedule II Controlled Substances

Federal Register, Vol. 70, No. 165 (50408-50409), Aug. 26, 2005

Continues prohibition against "DNF" prescriptions. Reiterates requirement of legitimate medical purpose & usual course of professional practice. Clearly states patients do not have to "see" their practitioners every 30 days to get cs prescriptions. HOWEVER, practitioners should consider whether a patient should be seen more or less frequently based on individual circumstances. DEA repeated this caution in its November 19, 2007, release of its final rule on multiple prescriptions for schedule II controlled substances. DEA also said that mailing and faxing Schedule II cs prescriptions *may* be an option for some practitioners, depending on state law. Finally, DEA made clear there is no federal quantity limit for the dosing of schedule II controlled substances, but state law and health plans may set quantity limits.

Final Policy Statement on Use of Controlled Substances to Treat Pain

Federal Register, Vol. 71, No. 172 (52716-52723), Sept. 6, 2006

Practitioners have a legal obligation to ensure that each prescription for a controlled substance must be issued for a legitimate medical purpose by a practitioner acting in the usual course of professional practice.

DEA registrants have an obligation to take reasonable measures to prevent diversion..

Each patient's situation is unique and the nature and degree of physician oversight should be tailored accordingly, based on the physician's sound medical judgment and consistent with established medical standards.

If a patient has a history of drug abuse, then DEA registrants have a responsibility to exercise a much greater degree of oversight to prevent diversion and abuse in the case of a known or suspected addict than in the case of a patient for whom there are no indicators of drug abuse. "Under no circumstances may a physician dispense controlled substances with the knowledge they will be used for a nonmedical purpose or that they will be resold by the patient. Some physicians who treat patients having a history of drug abuse require each patient to sign a contract agreeing to certain terms designed to prevent diversion and abuse, such as periodic urinalysis. While such measures are not mandated by the CSA or DEA regulations, they can be very useful."

Final Rule on the Issuance of Multiple Prescriptions for Schedule II Controlled Substance

Effective December 19, 2007; subject to state law approval on final usage.

Federal Register, Vol. 72, No. 222 (64921-64930), Nov. 19, 2007

Allows up to a 90-day supply of a schedule II controlled substance, using prescriptions dated and signed on the date issued to the patient with proper instructions to fill one or more of the prescriptions at a later date. **Key requirements:** (1) this is not effective until 12/19/07; (2) state law will control as to whether these prescriptions are ultimately permitted in each state; (3) if allowed in state, practitioner must conclude "the patient with multiple prescriptions in this manner does not create an undue risk of diversion or abuse"; (4) practitioner must properly indicate the "do not fill before [date]"; and (5) the practitioner must follow other applicable federal and state laws relating to controlled substance prescribing. Pharmacists shall not fill any prescription written under this rule before the date indicated in the "do not fill before [date]" instructions.

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Instructions: This activity should take approximately 1/2 hour to complete. The participant should read both the learning objectives and the monograph, and answer the 5-question multiple-choice post-test below by circling the single-letter responses that best answer the questions. The completed test should be faxed to (212) 532-5397 or sent via US mail to the following address:

**American Academy of Pain Management
Education Department
77 Park Avenue
New York, NY 10016**

1. Physicians have a contractual relationship with:
 - a. Licensing boards
 - b. Managed care organizations
 - c. State and federal regulatory agencies
 - d. All of the above

2. Which of the following is NOT the basis of the covenantal relationship between clinician and patient?
 - a. Rigid boundaries or obligations
 - b. Empathy and understanding
 - c. Commitment to work with the patient to improve their health
 - d. Protecting a patient's legitimate access to controlled substances

3. Guidelines are
 - a. Clinical care standards
 - b. Nothing more than an agency's current position statement on a particular subject
 - c. Minimal expectations of an agency
 - d. Tantamount to laws with legal sanctions and/or penalties

4. As part of the Model Policy, the treatment plan includes:
 - a. Types and frequency of any medications used
 - b. The parameters used to determine treatment success
 - c. Any planned diagnostic or treatment evaluations
 - d. All of the above

5. Which of the following is true of an informed consent?
 - a. It is a physician's ethical, but not legal obligation
 - b. It is the physician's ethical, and in most states, legal obligation
 - c. It legally protects the physician from any regulatory scrutiny
 - d. A and C

Participant information:

Name: _____

Degree and specialty: _____

Street Address: _____

City: _____ State: _____ Zip: _____

Phone: (____) _____ Fax: (____) _____ Email: _____