Vermont Board of Medical Practice

Policy for the Use of Controlled Substances for the Treatment of Pain

This policy is adapted from the *Model Policy for the Use of Controlled Substances for the Treatment of Pain* approved by the Federation of State Medical Boards of the U.S., Inc. in May 2004. The Introduction to that document may be found in Appendix A.

Section I: Preamble

The Vermont Board of Medical Practice recognizes that principles of quality medical practice dictate that patients have access to appropriate and effective pain relief. The appropriate application of up-to-date knowledge and treatment modalities can serve to improve the quality of life for those patients who suffer from pain as well as reduce the morbidity and costs associated with untreated or inappropriately treated pain. For the purposes of this policy, the inappropriate treatment of pain includes nontreatment, undertreatment, overtreatment, the continued use of ineffective treatments, and initiation or continuation of treatment without appropriate evaluation and assessment.

The diagnosis and treatment of pain is integral to the practice of medicine. The Board encourages physicians to view pain management as a part of quality medical practice for all patients with pain, acute or chronic, and it is especially urgent for patients who experience pain as a result of terminal illness. All physicians should become knowledgeable about assessing patients' pain and effective methods of pain treatment, as well as statutory requirements for prescribing controlled substances. Accordingly, this policy has been developed to clarify the Board's position on pain control, particularly as related to the use of controlled substances, to alleviate physician uncertainty and to encourage better pain management. Inappropriate pain treatment may result from physicians' lack of knowledge about pain management. Fears of investigation or sanction by federal, state and local agencies may also result in inappropriate treatment of pain. Appropriate pain management is the treating physician's responsibility. As such, the Board will consider the inappropriate treatment of pain to be a departure from standards of practice and will investigate such allegations, recognizing that some types of pain cannot be completely relieved, and taking into account whether the treatment is appropriate for the diagnosis.

The Board recognizes that controlled substances, including opioid analgesics, may be essential in the treatment of acute pain (due to trauma or surgery) and chronic pain (due to cancer or non-cancer origins). The Board will refer to current clinical practice guidelines and expert review in approaching cases involving management of pain. The medical management of pain should consider current clinical knowledge and scientific research and the use of pharmacologic and non-pharmacologic modalities according to the judgment of the physician. Pain should be assessed and treated promptly, and the quantity and frequency of doses should be adjusted according to the intensity, duration of the pain, and treatment outcomes. Physicians should recognize that tolerance and physical dependence are normal consequences of sustained use of opioid analgesics and are not the same as addiction.

The Vermont Board of Medical Practice is obligated under the laws of the State of Vermont to protect the public health and safety. The Board recognizes that the use of opioid analgesics for other than legitimate medical purposes poses a threat to the individual and society and that the inappropriate prescribing of controlled substances, including opioid analgesics, may lead to drug diversion and abuse by individuals who seek them for other than legitimate medical use. Accordingly, the Board expects that physicians will incorporate safeguards into their practices to minimize the potential for the abuse and diversion of controlled substances.

Physicians should not fear disciplinary action from the Board for ordering, prescribing, dispensing or administering controlled substances, including opioid analgesics, for a legitimate medical purpose and in the course of professional practice. The Board will consider prescribing, ordering, dispensing or administering controlled substances for pain to be for a legitimate medical purpose if based on sound clinical judgment. All such prescribing must be based on clear documentation of unrelieved pain. To be within the usual course of professional practice, a physician-patient relationship

must exist and be appropriately documented, and the prescribing should be based on a diagnosis and documentation of unrelieved pain. Compliance with applicable state and federal law is required.

The Board will judge the validity of the physician's treatment of the patient based on available documentation, rather than solely on the quantity and duration of medication administration. The goal is to control the patient's pain while effectively addressing other aspects of the patient's functioning, including physical, psychological, social, and work-related factors.

Allegations of inappropriate pain management will be evaluated on an individual basis. The board will not take disciplinary action against a physician for deviating from this policy when contemporaneous medical records document reasonable cause for deviation. The physician's conduct will be evaluated to a great extent by his or her documentation of the management and outcome of pain treatment, recognizing that some types of pain cannot be completely relieved, and by taking into account whether the drug used is appropriate for the diagnosis, as well as improvement in patient functioning and/or quality of life.

Section II: Guidelines

The Board has adopted the following criteria when evaluating the physician's treatment of pain, including the use of controlled substances:

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

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

Informed Consent and Agreement for Treatment—The physician should discuss the risks and benefits of the use of controlled substances with the patient, persons designated by the patient or with the patient's surrogate or guardian if the patient is without medical decision-making capacity. Physicians should consider whether to enter a formal written agreement with their patients that outlines the patients' responsibilities with respect to controlled substances. The following topics should be reviewed with patients orally and documented in the medical record or included in a written agreement (see Appendix B for samples of written agreements):

- prescriptions should be obtained from one physician and one pharmacy whenever possible;
- urine/serum or other types of toxicology/medication levels screening may be requested;
- number and frequency of and permissible methods for obtaining prescription refills;
- reasons for which drug therapy may be discontinued and other possible consequences of violating the agreement.

If discharge from the physician's practice is to be a potential consequence of violating the agreement, the physician must consider the clinical situation and must comply with the Board's policy on Termination of the Physician-Patient Relationship and all other applicable ethical, legal, and contractual obligations.

Periodic Review—The physician should periodically review the course of pain treatment and any new information about the etiology of the pain or the patient's state of health. Patients should be seen at least quarterly and as frequently as warranted by the clinical circumstances. **Continuation or modification of controlled substances for pain management therapy depends on the physician's evaluation of progress toward treatment objectives. Satisfactory response to**

treatment may be indicated by the patient's decreased pain, increased level of function, or improved quality of life. Adequate documentation of these factors is essential. Objective evidence of improved or diminished function should be monitored and information from family members or other caregivers should be considered in determining the patient's response to treatment. If the patient's progress is unsatisfactory, the physician should assess the appropriateness of continued use of the current treatment plan and consider the use of other therapeutic modalities.

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

Medical Records—The physician should keep accurate and complete records to include:

1. medical history and physical examination,
2. diagnostic, therapeutic and laboratory results,
3. evaluations and consultations,
4. treatment objectives,
5. discussion of risks and benefits,
6. informed consent,
7. treatments,
8. medications (including date, type, dosage and quantity prescribed, documented in a clear manner in a readily accessible section of the medical record. Some physicians keep copies of all scheduled drug prescriptions in one section of the medical record; others use a flow chart for this purpose, such as the sample in Appendix C),
9. instructions and agreements, and
10. periodic reviews.

Records should remain current and be maintained in an accessible manner and readily available for review.

Prescription Medication Abuse and Diversion

Behaviors such as multiple claims of prescriptions or medications having been lost or destroyed, multiple attempts to obtain prescriptions from other clinicians or emergency rooms, concurrent abuse of alcohol or other drugs, and other behaviors may indicate abuse or diversion of pain medication. Physicians should carefully and objectively evaluate behaviors that may indicate prescription medication abuse or diversion while taking care to avoid misinterpreting attempts to achieve adequate pain relief as drug-seeking behaviors. The physician should review and consider the sensitivity, specificity and marked limitations of toxicology screening methods used.

Compliance With Controlled Substances Laws and Regulations—To prescribe, dispense or administer controlled substances, the physician must be licensed in the state and comply with applicable federal and state laws and regulations. Physicians are referred to the Physicians Manual of the U.S. Drug Enforcement Administration for specific federal rules governing controlled substances.

Section III: Definitions

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

Acute Pain—Acute pain is the normal, predicted physiological response to a noxious chemical, thermal or mechanical stimulus and typically is associated with invasive procedures, trauma and disease. It is generally time-limited.

Addiction—Addiction is a primary, chronic, neurobiologic disease, with genetic, psychosocial, and environmental factors influencing its development and manifestations. It is characterized by behaviors that include the following:

impaired control over drug use, craving, compulsive use, and continued use despite harm. Physical dependence and tolerance are normal physiological consequences of extended opioid therapy for pain and are not the same as addiction.

Chronic Pain—Chronic pain is a state in which pain persists beyond the usual course of an acute disease or healing of an injury, or that may or may not be associated with an acute or chronic pathologic process that causes continuous or intermittent pain over months or years.

Pain—Pain is an unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage.

Physical Dependence—Physical dependence is a state of adaptation that is manifested by drug class-specific signs and symptoms that can be produced by abrupt cessation, rapid dose reduction, decreasing blood level of the drug, and/or administration of an antagonist. Physical dependence, by itself, does not equate with addiction.

Pseudoaddiction—Pseudoaddiction is the iatrogenic syndrome resulting from the misinterpretation of relief seeking behaviors as though they are drug-seeking behaviors that are commonly seen with addiction. The relief seeking behaviors resolve upon institution of effective analgesic therapy.

Substance Abuse—Substance abuse is the use of any substance(s) for non-therapeutic purposes or use of medication for purposes other than those for which it is prescribed.

Tolerance—Tolerance is a physiologic state resulting from regular use of a drug in which an increased dosage is needed to produce a specific effect, or a reduced effect is observed with a constant dose over time. Tolerance may or may not be evident during opioid treatment and does not equate with addiction.

Appendix A

Introduction from the Federation of State Medical Boards *Model Policy for the Use of Controlled Substances for the Treatment of Pain.*

The recommendations contained herein were adopted as policy by the House of Delegates of the Federation of State Medical Boards of the United States, Inc., May, 2004.

Introduction

The Federation of State Medical Boards (the Federation) is committed to assisting state medical boards in protecting the public and improving the quality and integrity of health care in the United States. In 1997, the Federation undertook an initiative to develop model guidelines and to encourage state medical boards and other health care regulatory agencies to adopt policy encouraging adequate treatment, including use of opioids when appropriate for patients with pain. The Federation thanks the Robert Wood Johnson Foundation for awarding a grant in support of the original project, and the American Academy of Pain Medicine, the American Pain Society, the American Society of Law, Medicine, & Ethics, and the University of Wisconsin Pain & Policy Studies Group for their contributions.

Since adoption in April 1998, the *Model Guidelines for the Use of Controlled Substances for the Treatment of Pain* have been widely distributed to state medical boards, medical professional organizations, other health care regulatory boards, patient advocacy groups, pharmaceutical companies, state and federal regulatory agencies, and practicing physicians and other health care providers. The *Model Guidelines* have been endorsed by the American Academy of Pain Medicine, the Drug Enforcement Administration, the American Pain Society, and the National Association of State Controlled Substances Authorities. Many states have adopted pain policy using all or part of the *Model Guidelines*. Despite increasing concern in recent years regarding the abuse and diversion of controlled substances, pain policies have improved due to the efforts of medical, pharmacy, and nursing regulatory boards committed to improving the quality of and access to appropriate pain care.

Notwithstanding progress to date in establishing state pain policies recognizing the legitimate uses of opioid analgesics, there is a significant body of evidence suggesting that both acute and chronic pain continue to be undertreated. Many terminally ill patients unnecessarily experience moderate to severe pain in the last weeks of life. The undertreatment of pain is recognized as a serious public health problem that results in a decrease in patients' functional status and quality of life and may be attributed to a myriad of social, economic, political, legal and educational factors, including inconsistencies and restrictions in state pain policies. Circumstances that contribute to the prevalence of undertreated pain include: (1) lack of knowledge of medical standards, current research, and clinical guidelines for appropriate pain treatment; (2) the perception that prescribing adequate amounts of controlled substances will result in unnecessary scrutiny by regulatory authorities; (3) misunderstanding of addiction and dependence; and (4) lack of understanding of regulatory policies and processes. Adding to this problem is the reality that the successful implementation of state medical board pain policy varies among jurisdictions.

In April 2003, the Federation membership called for an update to its *Model Guidelines* to assure currency and adequate attention to the undertreatment of pain. The goal of the revised model policy is to provide state medical boards with an updated template regarding the appropriate management of pain in compliance with applicable state and federal laws and regulations. The revised policy notes that the state medical board will consider inappropriate treatment, including the undertreatment of pain, a departure from an acceptable standard of practice. The title of the policy has been changed from *Model Guidelines* to *Model Policy* to better reflect the practical use of the document.

The Model Policy is designed to communicate certain messages to licensees: that the state medical board views pain management to be important and integral to the practice of medicine; that opioid analgesics may be necessary for the relief of pain; that the use of opioids for other than legitimate medical purposes poses a threat to the individual and society; that physicians have a responsibility to minimize the potential for the abuse and diversion of controlled substances; and that physicians will not be sanctioned solely for prescribing opioid analgesics for legitimate medical purposes. This policy is not meant to constrain or dictate medical decision-making.

Through this initiative, the Federation aims to achieve more consistent policy in promotion of adequate pain management and education of the medical community about treating pain within the bounds of professional practice and without fear of regulatory scrutiny. In promulgating this *Model Policy*, the Federation strives to encourage the legitimate medical uses of controlled substances for the treatment of pain while stressing the need to safeguard against abuse and diversion.

State medical boards are encouraged, in cooperation with their state's attorney general, to evaluate their state pain policies, rules, and regulations to identify any regulatory restrictions or barriers that may impede the effective use of opioids to relieve pain. Accordingly, this *Model Policy* has been revised to emphasize the professional and ethical responsibility of the physician to assess patients' pain as well as to update references and definitions of key terms used in pain management.

The Model Policy is not intended to establish clinical practice guidelines nor is it intended to be inconsistent with controlled substance laws and regulations.

1. As of January 2004, 22 of 70 state medical boards have policy, rules, regulations or statutes reflecting the Federation's *Model Guidelines for the Use of Controlled Substances for the Treatment of Pain* and two (2) states have formally endorsed the *Model Guidelines.*
2. SUPPORT Study Principal Investigators. A controlled trial to improve care for seriously ill hospitalized patients; *JAMA*, 274(20) (1995): p. 1591-1598.
3. AM. Gilson, I).E. Joranson, and MA. Mauer. Improving Medical Board Policies: Influence of a Model, *J. of Law, Medicine, and Ethics*, 31(2003): p. 128.

Appendix B

This Appendix contains samples of formal written agreements used by some physicians to outline their patients' responsibilities with respect to controlled substances. **Please note:**

- These samples are not endorsed by the Vermont Board of Medical Practice and are offered solely to illustrate how some physicians put these concepts into practice.
- **These samples are not intended to constitute legal advice or endorsement of any kind. Reliance on information provided in this Appendix is at user's risk. Your attorney should be consulted regarding legal matters.**
- The authors have granted permission for the Board to include the samples in this appendix.

  * Fletcher Allen Health Care (FAHC) has granted permission for Vermont physicians, should they choose to do so, to use the FAHC form in whole or in part as part of their practice.

  * Please contact the creator of the copyrighted sample included in this Appendix directly regarding adoption, adaptation or use of the sample: The American Academy of Pain Medicine, 4700 W. Lake Avenue, Glenview, IL 60025-1485, 847/375-4731 Fax 877/734-8750, E-mail aapm@amctec.com; Web site http://www.painmed.org/

Fletcher Allen HEALTH CARE

PRIMARY CARE INTERNAL MEDICINE

INFORMED CONSENT AND CONTRACT FOR LONG-TERM NARCOTIC THERAPY FOR NON-CANCER PAIN

There are potential risks and side effects of long-term narcotic treatment including but not limited to the following:

PHYSICAL SIDE EFFECTS

Common side effects include mood changes, drowsiness, dizziness, constipation, nausea, or confusion. Many of these side effects disappear over several days to weeks. Extreme caution must be used while driving or operating potentially harmful machinery.

Any other sedating medications or alcohol must be avoided.

PHYSICAL DEPENDENCE

Physical dependence is an expected side effect from long term use of narcotics when they are used on a regular basis. If the medication is stopped abruptly, you may experience a withdrawal syndrome. This may include sweating, diarrhea, irritability, runny nose, achiness, and craving for medication. Medication should be slowly tapered under the supervision of a physician.

TOLERANCE TO MEDICATION

With continued use, some patients will experience a tolerance to the medication, where increasing doses are required to control the same pain. This occurs rarely and may require tapering and discontinuation of the medication.

INCREASED PAIN

The long-term effects of narcotics on the body's own pain-fighting system are not well understood. There is some evidence that treatment may cause an increased sensitivity to pain. Come clinicians believe that narcotics reinforce or perpetuate the perception of pain.

ADDICTION

Addiction is present when an individual experiences loss of control over the use of medications, is constantly seeking drugs, or experiences adverse consequences as a result of drug use. Most pain patients who use long term narcotics are able to take medication as prescribed, do not seek other drugs when their pain is controlled, and experience improvement in the quality of life as a result of the treatment—they are therefore not addicted. Physical dependence on the medication does not indicate that someone is addicted.

Individuals with a history of alcoholism or other drug addiction may be at increased risk for the development of addiction while using narcotics. This is generally indicated by concurrent seeking and using other drugs, by the inability to take the medication on a scheduled basis as prescribed, and by decreasing quality of life.

PRESCRIPTION CONTRACT

Because of the potential for some of the adverse consequences noted above, prescribing narcotics must be done in the organized and carefully documented manner. Prescribing flexibility is limited by both state and federal law. Both the physician and patient have a responsibility for the safe and effective use of narcotics.

It is important that you review and agree to the following conditions:

- Prescriptions will only be filled by one physician, Dr. _____.
  If that physician is unavailable, the office will make appropriate arrangements.
- Prescriptions will only be filled at one pharmacy, _____.
- Your dose and frequency will be maintained in your chart with a specific date when the next refill of medication is due.
- Loss of theft of medication should be reported immediately to the police. Loss or theft of prescriptions will be grounds for discontinuation of treatment.
- Random urine drug testing may be used to document use of medication.
- Narcotic therapy may be continued if you experience decreased pain and improvement in quality of life and daily function.
- Narcotic therapy may be discontinued of you:
  Experience progressive tolerance that cannot be managed by adjustments to the medication
  Experience unacceptable side effects
  Experience a decline in daily functioning
  Exhibit addictive behavior
  Adjust your medication without consulting with the office
  Obtain narcotics from multiple physicians or from street sources
  Fill prescriptions at other pharmacies without explanation
  Sell, share, or lose medication
  Alter prescriptions

I have had the opportunity to review the above consent form and contract for long term narcotic therapy. I have been given the opportunity to ask questions about the risks and benefits of the proposed treatment. I accept the risks and conditions outlined above.

Patient Printed Name: _____ DOB: _____

Patient Signature _____ Date _____

Physician Signature _____ Date _____

SAMPLE FOR ADAPTATION AND REPRODUCTION ON PHYSICIAN LETTERHEAD

PLEASE CONSULT WITH YOUR ATTORNEY

Long-term Controlled Substances Therapy for Chronic Pain

SAMPLE AGREEMENT

*A consent form from the **American Academy of Pain Medicine***

The purpose of this agreement is to protect your access to controlled substances and to protect our ability to prescribe for you.

The long-term use of such substances as opioids (narcotic analgesics), benzodiazepine tranquilizers, and barbiturate sedatives is controversial because of uncertainty regarding the extent to which they provide long-term benefit. There is also the risk of an addictive disorder developing or of relapse occurring in a person with a prior addiction. The extent of this risk is not certain.

Because these drugs have potential for abuse or diversion, strict accountability is necessary when use is prolonged. For this reason the following policies are agreed to by you, the patient, as consideration for, and a condition of, the willingness of the physician whose signature appears below to consider the initial and/or continued prescription of controlled substances to treat your chronic pain.

1. All controlled substances must come from the physician whose signature appears below or, during his or her absence, by the covering physician, unless specific authorization is obtained for an exception. (Multiple sources can lead to untoward drug interactions or poor coordination of treatment.)

2. All controlled substances must be obtained at the same pharmacy, where possible. Should the need arise to change pharmacies, our office must be informed. The pharmacy that you have selected is:

   _____ phone: _____.

3. You are expected to inform our office of any new medications or medical conditions, and of any adverse effects you experience from any of the medications that you take.

4. The prescribing physician has permission to discuss all diagnostic and treatment details with dispensing pharmacists or other professionals who provide your health care for purposes of maintaining accountability.

5. You may not share, sell, or otherwise permit others to have access to these medications.

6. These drugs should not be stopped abruptly, as an abstinence syndrome will likely develop.

7. Unannounced urine or serum toxicology screens may be requested, and your cooperation is required. Presence of unauthorized substances may prompt referral for assessment for addictive disorder.

8. Prescriptions and bottles of these medications may be sought by other individuals with chemical dependency and should be closely safeguarded. It is expected that you will take the highest possible degree of care with your medication and prescription. They should not be left where others might see or otherwise have access to them.

9. Original containers of medications should be brought in to each office visit.

10. Since the drugs may be hazardous or lethal to a person who is not tolerant to their effects, especially a child, you must keep them out of reach of such people.

11. Medications may not be replaced if they are lost, get wet, are destroyed, left on an airplane, etc. If your medication has been stolen and you complete a police report regarding the theft, an exception may be made.

12. Early refills will generally not be given.

13. Prescriptions may be issued early if the physician or patient will be out of town when a refill is due. These prescriptions will contain instructions to the pharmacist that they not be filled prior to the appropriate date.

14. If the responsible legal authorities have questions concerning your treatment, as might occur, for example, if you were obtaining medications at several pharmacies, all confidentiality is waived and these authorities may be given full access to our records of controlled substances administration.

15. It is understood that failure to adhere to these policies may result in cessation of therapy with controlled substance prescribing by this physician or referral for further specialty assessment.

16. Renewals are contingent on keeping scheduled appointments. Please do not phone for prescriptions after hours or on weekends.

17. It should be understood that any medical treatment is initially a trial, and that continued prescription is contingent on evidence of benefit.

18. The risks and potential benefits of these therapies are explained elsewhere [and you acknowledge that you have received such explanation].

19. You affirm that you have full right and power to sign and be bound by this agreement, and that you have read, understand, and accept all of its terms.

Physician Signature	Patient Signature
Date	Patient Name (Printed)

Approved by the AAPM Executive Committee on April 2, 2001.

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Appendix C

This Appendix contains a sample of a flow chart used by some physicians to document medications (including date, type, dosage and quantity prescribed) in a clear manner in a readily accessible section of the medical record. **Please note:**

- This sample is not endorsed by the Vermont Board of Medical Practice and is offered solely to illustrate how some physicians put these concepts into practice.
- **This sample is not intended to constitute legal advice or endorsement of any kind. Reliance on information provided in this Appendix is at user's risk. Your attorney should be consulted regarding legal matters.**
- Fletcher Allen Health Care has granted permission for the Board to include this sample in this appendix and for Vermont physicians, should they choose to do so, to use the form in whole or in part as part of their practice.

PATIENT NAME: ______________________________ DOB: ____________

CHRONIC NARCOTIC AND BENZODIAZEPINE FLOW SHEET

GIVEN HEALTH CARE CENTERS

PROBLEM#: ____________ PHARMACY: ______________________ ___________

DATE	MEDICATION	# TABS	REFILL FREQUENCY IN WEEKS	NEXT REFILL DUE