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REPORT OF THE

MINNESOTA BOARD OF MEDICAL PRACTICE

WORK GROUP ON APPROPRIATE PRESCRIBING OF CONTROLLED SUBSTANCES FOR THE MANAGEMENT OF PAIN

Presented to the Board on
November 10, 2007

MINNESOTA BOARD OF MEDICAL PRACTICE
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MINNESOTA BOARD OF MEDICAL PRACTICE
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INTRODUCTION

The Minnesota Board of Medical Practice Work Group on the Appropriate Prescribing of Controlled Substances for the Management of Pain was mandated by the 2007 Legislature. (Statutory language in Attachment 1)

Members of the Work Group were appointed by the Board, and are listed in Attachment 2. The Group was staffed by Rob Leach and Dick Auld of the Board Staff. Mr. Peter Krieser of the Office of the Attorney General served as legal counsel for the Group. Meetings were held under the Open Meeting Law, and posted accordingly. Participating members of the public included representatives from Minnesota Board of Nursing, Minnesota Board of Pharmacy, Lockridge, Grindal and Nauen, P.L.L.P., Medtronic, Minnesota Medical Association, Medical Advanced Pain Specialists, and two private citizens.

The Work Group met on October 17th, 2007, and October 24th, 2007, at the offices of the Board of Medical Practice. (Minutes of the meetings are included in Attachments 3 and 4.)

Numerous background materials were provided and reviewed in detail by the Group. Key among them were model clinical methodologies for the prescription of controlled substances, including those published by: The American Medical Association, The Federation of State Medical Boards, the Institute for Clinical Systems Improvement, and The Minnesota Department of Labor and Industry, in its draft proposed rules for the use of controlled substances on the management of chronic pain in Workers Compensation Patients.

The Group agreed on the following principles:

1. Appropriate pain management is the treating provider's professional, legal, ethical and moral responsibility.
2. Controlled substances, especially opioid analgesics, are legitimate and necessary tools for the provider to use in carrying out this responsibility.
3. There is compelling evidence that acute pain due to trauma or surgery, and chronic pain, whether due to cancer or non-cancer origins remains either undertreated or untreated due to professional fear of legal and regulatory reprisals.
4. The prescribing of controlled substances for the management of pain must be done on a case by case basis, utilizing a thorough clinical methodology to determine the individual patient's cause and severity of pain, based on history, examination, appropriate testing, diagnosis, a treatment plan based on the diagnosis, appropriate follow-up to determine response to treatment, appropriate adjustment of treatment, and other clinical processes necessary to monitor and document the treatment.

5. Untreated pain or undertreated pain is as serious a departure from the standard of care, and as serious a violation of the Minnesota Medical Practice Act as is excessive prescribing of controlled substances or prescribing of controlled substances for non-therapeutic purposes.
6. Health care providers are insufficiently educated and trained in appropriate pain management, and professional schools should be required to work toward more adequate education and training curricula.
7. Recent Minnesota legislation requiring that Class II and III controlled substances be recorded and monitored in an electronic, real-time data base continues to have the potential to create a "chilling effect" on health care providers' willingness to use controlled substances when they are medically necessary, and thus should be monitored closely by the legislature.

After discussion, the Group decided that its work could best serve to further the Minnesota Practice Community's ability to carry out its professional, legal, ethical, and moral responsibility by issuing a report that focuses on the five areas outlined in the Minutes of the October 17th meeting of the Group. (See Attachment 3)

A

STATEMENT OF THE WORK GROUP'S CLINICAL METHODOLOGY FOR ACCEPTABLE PAIN MANAGEMENT

The Work Group reviewed models for clinical methodology for acceptable management of pain published by three major clinical organizations, and the Minnesota Department of Labor and Industry. After comparison of the models and discussion, the Work Group voted unanimously to adopt in its entirety the *Model Policy for the Use of Controlled Substances for the Treatment of Pain* adopted as policy by the House of Delegates of the Federation of State Medical Boards of the United states, Inc., May 2004. (A copy of the Model Policy is included in Attachment 5.)

B

STATEMENT REGARDING UNDERTREATMENT OF PAIN

Ethical treatment of a patient who is in pain requires the provider to use all reasonable efforts to alleviate the patient's pain. Treatment with controlled substances, including opioid analgesics, may be essential to the treatment of pain, acute or chronic, from whatever cause. Such uses of controlled substances are acceptable, provided that the provider uses appropriate clinical methodology in working up the patient and documenting the care.

The Minnesota Medical Practice Act, Minnesota Statutes 147.081, Subd. 3, part 3 includes the treatment of pain in the definition of the practice of medicine. The Preamble to the Federation of State Medical Boards' *Model Policy for the Use of Controlled Substances for the Treatment of Pain* states: "The diagnosis and treatment of pain is integral to the practice of medicine." It further states: ".....the principles of quality medical practice dictate that the people.....have access to appropriate and effective pain relief." It also recognizes: ".....that controlled substances, including opioid analgesics, may be essential in the treatment of acute pain due to trauma or surgery, and chronic pain, whether due to cancer or non-cancer origins."

The Work Group agrees with recommendations published in the Federation of State Medical Boards' *Model Policy for the Use of Controlled Substances of the Treatment of Pain,"* and in other sources, and further agrees with the findings of the Minnesota Board of Medical Practice in over two decades of investigation of inappropriate prescribing. These findings include: (a) That unacceptable excessive prescribing of controlled substances in the treatment of pain is a public harm, a serious departure from the prevailing standard of care, and a violation of the Medical Practice Act; (b) That undertreated or untreated pain when controlled substances are indicated is also a public harm, a serious departure from the prevailing standard of care, and a violation of the Medical Practice Act. Either of these departures constitute unethical and unprofessional conduct as well. The Work Group finds that this applies to all other prescribing health care professions in Minnesota.

C

RECOMMENDATION FOR LEGISLATIVE ACTION TO FURTHER PAIN MANAGEMENT EDUCATION

The Work Group's own experience coincides with that of the Minnesota Board of Medical Practice in investigating inappropriate prescribing of controlled substances for over two decades. We recognize that the professional schools for the prescribing professions in Minnesota do not sufficiently teach and train their students in the areas of pain and pain management.

Therefore, the Work Group recommends that the Legislature require the health care professional schools for the prescribing professions of Minnesota form a joint task force to explore how their students and residents can be better taught and trained to manage the volume and type of pain occurring in nearly every profession and specialty.

D

STATEMENT
RECOMMENDING THAT THE LEGISLATURE MONITOR CERTAIN ASPECTS OF PAIN MANAGEMENT AND DRUG DIVERSION ACTIVITIES IN MINNESOTA

Because of ongoing concerns regarding the impact of the Minnesota Controlled Substance Prescription Data Base incorporating the Federal NASPER requirements, the Work Group recommends that the Legislature monitor the practice of pain management and the diversion of controlled substances in Minnesota for at least five years after the implementation of the data base, including the following items:

A. Any shift or migration of volume of controlled substance prescriptions for pain management among the schedules of controlled substances. To avoid having their prescriptions entered into the data base, and hence, monitored providers may attempt to treat their pain patients with drugs which aren't covered by the data base.
Severe pain, whether acute or chronic, cannot be effectively managed with Schedule III, IV, or V analgesics. These medications are too weak and contain added compounds such as non-steroidal anti-inflamatories, acetaminophen, or aspirin. If these schedules of analgesics are given in large enough dosages to manage severe pain, the added compounds will be administered near or at toxic levels, potentially causing hemorrhage, organ damage or failure, and even death. Data regarding which drugs are prescribed for pain management is contained in third party payer records, including Medical Assistance and Minnesota's health plans.

B. Any shift or migration in referrals from primary care management of pain to specialty pain management clinics. Such a shift would indicate that primary care practitioners are abdicating their responsibility to manage pain patients within their practices out of fear of having their prescriptions monitored by the data base, and hence a deviation from acceptable standards.

C. Any increase in the use of interventional techniques to manage pain, as a substitute for medical (pharmaceutical) management. Interventional pain management techniques (injections, implants, and surgical oblations) are necessary and effective measures in a certain select subset of the total pain patient population. They are, however, improper substitutes for pharmaceutical pain management where pharmaceuticals are otherwise appropriate, because they carry a far higher dollar cost, and significantly higher risk of complications for the patient. Any attempt on the part of providers to avoid having their practice monitored by the controlled substance data base by using interventional techniques, or referring patients for interventional techniques instead of less costly and safer medical management would constitute a deviation from acceptable standards. Data showing any such shift would, again, be available from the same third party payers.

D. Any increase in the overall cost of pain management for the total field of pain patients. Any such increase in cost after the implementation of the data base should be examined carefully, since it not only will be an indicator of the cost effectiveness of the data base itself, but may be a significant indicator that the practice is migrating pain management to higher cost, and potentially higher risk techniques to avoid inclusion in the data base. Again, data for this parameter would be available from third party payers.

E. Monitor the flow of controlled substances to the street market, and end abuse of controlled substances by the public. Loss of controlled substances in the supply chain is monitored, and data, especially data regarding loss in transit, is available from the Minnesota Board of Pharmacy. The amount of transit loss of controlled substances in Minnesota should be compared pre and post implementation. This data would be useful in addressing whether the street market is, in fact, making up for any decrease which could be attributed to the effectiveness of the controlled substance data base, which is intended to reduce the diversion and misuse of these drugs. Likewise, Emergency Department admissions for overdose of Schedules II and III controlled substances should be monitored and compared, pre and post implementation of the data base. Again, this data would be useful in determining the effectiveness of the data base in reducing abuse and diversion of these drugs.

F. Monitor the incidences of theft and robberies of controlled substances from pharmacies in Minnesota which are reported to the DEA. No change in the incidences of these occurrences, taken with other data, can be an indication that the controlled substance data base is ineffective in removing pharmaceutical drugs from the street market.

E

STATEMENT OF BOARD'S EDUCATIONAL EFFORTS IN PAIN MANAGEMENT

Board of Medical Practice
Seminars That Have Been Presented

Seminars on Prescribing and Related Documentation

April 5, 1989	Austin, Austin Tech. Institute – 1900 8th Avenue NW
April 11, 1989	St. Paul, Holiday Inn East – I-94 and McKnight Road
April 12, 1989	Detroit Lakes, Holiday Inn – Highway 10 East
April 25, 1989	Plymouth, Holiday Inn – 1 – 494 and Highway 55
April 26, 1989	Grand Rapids, Sawmill Inn – Highway 169
May 3, 1989	Redwood Falls, Redwood Inn – Highway 71

Seminars on Cancer Pain Management

March 22, 1995	Winona, Winona State University – Kryzsko Commons
March 29, 1995	Mankato, Mankato State University – Centennial Student Union
April 5, 1995	St. Cloud, St. Cloud University – 740 – 4th Avenue South
April 19, 1995	Fergus Falls, Fergus Falls Community College – Public Service Room
April 26, 1995	Hibbing, Hibbing Community College – 1515 East 25th Street
May 2, 1995	St. Paul, Lakewood Community College – 3401 Century Avenue
May 4, 1995	Eden Prairie, Eden Prairie Campus – 9200 Flying Cloud Drive

Chronic Pain Management: Critical Issues and New Directions

March 27, 2001	Rochester, Marriott
March 28, 2001	Mankato, Holiday Inn
April 24, 2001	Hibbing, University Medical Center
April 25, 2001	Duluth, St. Mary's Clinic
May 1, 2001	Minneapolis, Sheraton Four Points
May 2, 2001	St. Paul, St. Paul Hotel
May 8, 2001	Thief River Falls, Best Western
May 9, 2001	Alexandria, Radisson Arrowwood
May 15, 2001	St. Cloud, Holiday Inn – Division Street
May 16, 2001	Willmar, Holiday Inn

Since September 29, 2003, Board members and staff have delivered in excess of one dozen speaker bureau presentations on behalf of the Minnesota Board of Medical Practice on the topic of the use of opioids in pain management throughout the state of Minnesota. They include the following:

April 2004	Duluth Medical Clinic
April 2004	Hibbing Medical Clinic
December 2004	Aspen Medical, Clinic Golden Valley
January 2005	Aspen Medical Clinic, Edina
March 2005	Aspen Medical Clinic, Burnsville
April 2005	Park Nicollet Clinic, St. Louis Park
April 2005	Wilmar Medical Clinic
June 2005	Professional Pharmacist Association
June 2005	CDI, St. Cloud
November 2005	Rochester Mayo Clinic
September 2006	North Memorial Medical Center
September 2006	Bush Fellowship Foundation
September 2006	St. John's Hospital Medical
September 2006	Minnesota Osteopathic Medical Association
April 2007	U of M Nurse Practitioners
June 2007	Minnesota Oncology, Burnsville
June 2007	Minnesota Oncology, Edina

The Web Site for the Board of Medical Practice www.bmp.state.mn.us contains numerous resources on the topic of pain management. These resources are continuously updated and improved.

Remedial Coursework for Physicians Disciplined for Inappropriate Prescribing 1987-Present

Pharmacology
Clinical methods for patient selection and management of chronic pain
Recognition and management of chemical addiction
Record keeping

Sec. 26. **BOARD OF MEDICAL PRACTICE.**

The Board of Medical Practice shall convene a work group to discuss the appropriate prescribing of controlled substances listed in Minnesota Statutes, section 152.02, subdivisions 3 and 4, and those substances defined by the Board of Pharmacy under Minnesota Statutes, section 152.02, subdivisions 7, 8, and 12, for pain management, and shall report to the legislature by December 15, 2007.

Work Study Group on
Controlled Substances on
Pain Management
Taskforce Members

Alfred V. Anderson, D.C., M.D., Chair
Medical Pain Management, LTD

Richard Auld, Ph.D.
Minnesota Board of Medical Practice

Miles Belgrade, M.D.
Fairview Pain Management Clinic

James Langland, M.D.
Dakota Clinic

Rob Leach, J.D.
Minnesota Board of Medical Practice

Richard D. Lentz, M.D.
Park Nicollet Clinic

Bill Lohman, M.D.
Department of Labor and Industry

Burton S. Schwartz, M.D.
Minnesota Oncology Hematology, P.A.

John Van Etta, M.D., FACP
St. Luke's Internal Medicine Associates

Meeting Minutes
October 17, 2007

The Work Group met the evening of October 17th and after a review of the legislative mandate requiring the Board to convene the Group (copy attached), and discussion and input from all members, guests, and staff, adopted, by consensus, the following as content for the Legislative Report:

A. A statement of clinical methodology applicable for determining appropriate patient selection for the use of controlled substance medication for pain management, and for determining the proper use of these medications in the management of pain in the selected patients, for both acute and chronic pain

B. A statement that under-management, or non-management of pain is as serious a departure from medical standards and as serious a violation of the Minnesota Medical Practice Act as is inappropriate prescribing of controlled substances

C. A statement that the Legislature should require the health professional schools for the prescribing professions of Minnesota to form a joint task force to explore how students and residents can be taught and trained to manage pain commensurately with the volume of pain complaints presented in nearly every profession and specialty

D. A statement that the legislature should monitor the effect of recent legislation requiring Minnesota to initiate a controlled substance prescription data bank under the Federal NASPER requirements over a five year period after implementation of the data bank, including the following parameters:
   a) Any shift in volume among the schedules of controlled substances prescribed for pain
   b) Any increased use of interventional techniques, as opposed to medical (pharmaceutical) techniques for the management of pain
   c) Any increase in the cost of pain management among pain patients of MA and the Minnesota health plans
   d) Any change in reports of transit loss of controlled substances in the pharmaceutical supply chain after the implementation of the data base; any change in Emergency Department admissions for controlled substance overdose after implementation of the data base; any change in the incidences of theft and robberies of controlled substances from pharmacies in Minnesota which are reported to the DEA.

E. A statement of the Minnesota Board of Medical Practice's efforts over the past two decades to educate the Minnesota practice community in the appropriate use of controlled substances in the management of pain.

The Group decided to circulate models of clinical methodology for pain management from the AMA and ICSI for use in drafting that portion of the report by the Group at subsequent meetings, and to delegate the drafting of sections B-E to staff.

Meeting Minutes
October 24, 2007

1. **The Work Group reviewed the Minutes of the October 17th meeting and approved them as written, with the re-wording of Item C to include all prescribing health care professions in Minnesota.**
2. **The Work Group reviewed staff drafts for Items B-E and approved them as written, with editorial additions, and added a further Item F.**
3. **The Work Group reviewed models for clinical methodology from three major clinical organizations, reviewed the legislative charge to the group, held a discussion based on their own clinical experiences, and voted unanimously to adopt the entirety of the *Model Policy for the Use of Controlled Substances for the Treatment of Pain* published by the Federation of State Medical Boards.**
4. **The Group instructed staff to revise existing documents as directed by the Group, and to prepare additional drafts as directed, and to circulate all electronically for revisions and approval by the Group.**

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

Federation of State Medical Boards of the United States, Inc.

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*.[1] 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.[2] 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.[3] 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. A.M. Gilson, D.E. Joranson, and M.A. Mauer, Improving Medical Board Policies: Influence of a Model, *J. of Law, Medicine, and Ethics*, 31 (2003): p. 128.

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

Section I: Preamble

The (name of board) recognizes that principles of quality medical practice dictate that the people of the State of (name of state) 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, and the continued use of ineffective treatments.

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 have 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, whether 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 (name of board) is obligated under the laws of the State of (name of state) to protect the public health and safety. The Board recognizes that the use of opioid analgesics for other than legitimate medical purposes pose 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 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 the prescribing should be based on a diagnosis and documentation of unrelieved pain. Compliance with applicable state or 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 the 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. The patient should receive prescriptions from one physician and one pharmacy whenever possible. If the patient is at high risk for medication abuse or has a history of substance abuse, the physician should consider the use of a written agreement between physician and patient outlining patient responsibilities, including

- urine/serum medication levels screening when requested;
- number and frequency of all prescription refills; and
- reasons for which drug therapy may be discontinued (e.g., violation of agreement).

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. 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. 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. the 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),
9. instructions and agreements and
10. periodic reviews.

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

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 regulations. Physicians are referred to the Physicians Manual of the U.S. Drug Enforcement Administration and (any relevant documents issued by the state medical board) for specific rules governing controlled substances as well as applicable state regulations.

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—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—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.