



STATE OF MICHIGAN

DEPARTMENT OF COMMUNITY HEALTH
LANSING

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Michigan Board of Pharmacy Guidelines for the Use of Controlled Substances for the Treatment of Pain

Section I: Preamble

The Michigan Board of Pharmacy recognizes that principles of quality pharmacy practice dictate that the people of the State of Michigan 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. The Board encourages pharmacists to view effective pain management as a part of quality health care for all patients with pain, acute or chronic, and it is especially important for patients who experience pain as a result of terminal illness. All pharmacists should become knowledgeable about effective methods of pain treatment as well as statutory requirements for prescribing and dispensing controlled substances.

Inadequate pain control may result from a health care provider's lack of knowledge about pain management or from an inadequate understanding of addiction. Fears of investigation or sanction by federal, state and local regulatory agencies may also result in inappropriate or inadequate treatment of chronic pain patients. Accordingly, these guidelines have been developed to clarify the position of the Board on pain control, specifically as related to the use of controlled substances, in order to alleviate uncertainty of pharmacists and to encourage better pain management.

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 medical management of pain should be based on current knowledge and research and include the use of both pharmacologic and non-pharmacologic modalities. Pain should be assessed and treated promptly, and the quantity and frequency of doses should be adjusted according to the intensity and duration of the pain. Pharmacists should recognize that tolerance and physical dependence are normal consequences of sustained use of opioid analgesics and are not synonymous with addiction. Pharmacists should also be aware that pseudoaddiction may develop as a direct consequence of inadequate pain management.

The Board is obligated under the laws of the State of Michigan to protect the public health and safety. The Board recognizes that inappropriate prescribing and dispensing of controlled substances, including opioid analgesics, may lead to drug diversion and abuse by individuals who seek them for other than legitimate medical use. Pharmacists should be diligent in preventing the diversion of drugs for illegitimate purposes.

The following are reference sources that provide sound approaches to the management of pain:

1. Acute Pain Management Guideline Panel. Acute Pain Management: Operative or Medical Procedures and Trauma. *Clinical Practice Guideline*. AHCPR Publication No. 92-0032. Rockville, Md. Agency for Health Care Policy and Research. U.S. Department of Health and Human Resources, Public Health Service. February 1992.
2. Jacox A, Carr DB, Payne R, et al. Management of Cancer Pain. *Clinical Practice Guideline No. 9*. AHCPR Publication No. 94-0592. Rockville, Md. Agency for Health Care Policy and Research. U.S. Department of Health and Human Resources, Public Health Service. March 1994.

3. Lipman AG, *Pain Management for Primary Care Clinicians*. 1st ed. American Society of Health System Pharmacists: Bethesda. 2004.

Pharmacists should not fear disciplinary action from the Board or other state regulatory or enforcement agency for dispensing controlled substances, including opioid analgesics, for a legitimate medical purpose and in the usual course of professional practice. The Board will consider control of patients' pain to constitute a legitimate medical purpose when the prescribing and dispensing of controlled substances is based on accepted scientific knowledge of the treatment of pain and/or when based on sound clinical grounds.

The Board will not take disciplinary action against a pharmacist for failing to adhere strictly to the provisions of these guidelines, if good cause is shown for such deviation. In each case, the conduct of the pharmacist will be evaluated to a great extent by patient outcome, taking into account whether the drug used is medically and/or pharmacologically recognized to be appropriate for the patient's condition. In addition, the pharmacist will have taken steps in good faith to assure safe and effective medication use and to prevent possible drug diversion.

Section II: Guidelines

The following guidelines are not intended to define complete or best practices, but rather to communicate what the Board considers to be minimum standards of practice for pharmacists caring for patients requiring pain control and presenting with prescriptions for controlled substances.

Review of the Prescription

The pharmacist should exercise due diligence to verify that each prescription for a controlled substance has been issued for a legitimate medical purpose. The review should include, but not necessarily be limited to, a careful review of the prescription document for evidence of forgery or

alteration, a discussion with the patient regarding the signs and symptoms of the disorder or disease and the diagnosis, a review of the patient's prescription records, and/or a discussion with the prescriber. The pharmacist may also determine that a query to the Michigan Automated Prescription System (MAPS) is warranted if fraud is suspected. Each of these and/or other steps taken to assure the validity of a prescription should be documented and filed in a readily retrievable manner.

Fictitious or Possibly Fictitious Prescriptions

When a pharmacist is reasonably certain that a prescription is fictitious, he/she should contact the appropriate law enforcement agency. In cases where the pharmacist suspects, but cannot be certain, that a prescription is fictitious, he/she should take necessary steps to help assure that a patient's symptoms are managed during the time it takes to confirm the validity of the prescription. In these cases, the pharmacist should also be certain to obtain positive patient identification in case the event must later be reported to enforcement agencies. The pharmacist may also determine that a query to the Michigan Automated Prescription System (MAPS) is warranted.

Prescription Refills

The pharmacist should evaluate the patient at each refill of a controlled substance to help assure that positive, intended outcomes are achieved and that the patient is not experiencing untoward effects. This evaluation should include but not necessarily be limited to, a discussion with the patient regarding signs and symptoms of the condition being treated, a review of signs and symptoms of untoward effects, a review of the patient's prescription records, and/or a discussion with the prescriber regarding the need for continuation or modification of therapy.

Special attention should be given to those pain patients who are at risk for misusing their medications. The management of pain in patients with a history of substance abuse or with a co-morbid psychiatric disorder may require extra care, monitoring, documentation and consultation with or referral to an expert in the management of such patients.

The steps undertaken in the process of evaluation should be documented and filed in a readily retrievable manner.

Patient Referral

When a patient presents with a prescription for a controlled substance that is not stocked in the pharmacy, the pharmacist should make every effort to refer the patient to another proper source of care to help assure the patient finds access to medication required for symptom relief.

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 an adverse chemical, thermal or mechanical stimulus and is associated with surgery, trauma and acute illness. It is generally time-limited and is responsive to opioid therapy, among other therapies.

Addiction

Addiction is a neurobehavioral syndrome with genetic and environmental influences that results in psychological dependence on the use of substances for their psychic effects and is characterized by compulsive use despite harm. Addiction may also be referred to by terms such as "drug dependence" and "psychological dependence." Physical dependence and tolerance are normal physiological consequences of extended opioid therapy for pain and should not be considered addiction.

Analgesic Tolerance

Analgesic tolerance is the need to increase the dose of opioid to achieve the same level of analgesia. Analgesic tolerance may or may not be evident during opioid treatment and does not equate with addiction.

Chronic Pain

A state of pain which is persistent and in which the cause of the pain cannot be removed or otherwise treated. Chronic pain may be associated with a long-term incurable or intractable medical condition or disease.

Controlled Substance

A controlled substance is a drug, substance, or immediate precursor included in schedules 1 to 5 of Article 7, part 72, of Public Act 368 of 1978 as amended (the Michigan Public Health Code).

Dispense

Dispense means to deliver or issue a controlled substance to an ultimate user or research subject by or pursuant to the lawful order of a practitioner, including prescribing, administering, or compounding necessary to prepare the substance for the delivery or issuance.

Dispenser

Dispenser means a practitioner that dispenses.

Good Faith

The prescribing or dispensing of a controlled substance by a practitioner licensed under section 333.7303 of the Michigan Public Health Code, in the regular course of professional treatment to, or for, an individual who is under treatment by a practitioner for a pathology or condition other than that individual's physical or psychological dependence upon or addiction to a controlled substance, except as provided in this article. Application of good faith to a pharmacist is the dispensing of a controlled substance pursuant to a prescriber's order that, in the professional judgment of the pharmacist, is lawful. The pharmacist shall be guided by nationally accepted professional standards including, but not limited to, all of the following, in making the judgment:

- (a) Lack of consistency in the doctor-patient relationship
- (b) Frequency of prescriptions for the same drug by one prescriber for larger numbers of patients
- (c) Quantities beyond those normally prescribed for the same drug
- (d) Unusual dosages

- (e) Unusual geographic distances between patient, pharmacist, and prescriber.

Pain

An unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage.

Pharmacy Practice

Pharmacy practice means a health service, the clinical application of which includes the encouragement of safety and efficacy in the prescribing, dispensing, administering, and use of drugs and related articles for the prevention of illness, and the maintenance and management of health. Professional functions associated with the practice of pharmacy include:

- (a) The interpretation and evaluation of the prescription
- (b) Drug product selection
- (c) The compounding, dispensing, safe storage, and distribution of drugs and devices.

Physical Dependence

Physical dependence on a controlled substance is a physiologic state of neuro-adaptation which is characterized by the emergence of a withdrawal syndrome if drug use is stopped or decreased abruptly, or if an antagonist is administered. Physical dependence is an expected result of opioid use. Physical dependence, by itself, does not equate with addiction.

Positive Identification

Positive identification means identification that includes a photograph of an individual in addition to his or her date of birth. Positive identification shall include an identification card issued by a governmental agency provided the ID card meets these requirements.

Practitioner

A prescriber or pharmacist, a scientific investigator as defined by rule or the administrator, or other person, licensed, registered, or otherwise permitted to distribute, dispense, conduct research with respect to or administer a controlled substance in the course of the professional practice or research in this state.

A pharmacy, hospital, or other institution or place of professional practice licensed, registered, or otherwise permitted to distribute, prescribe, dispense, conduct research with respect to, administer a controlled substance in the course of professional practice or research in this state.

Pseudoaddiction

Pseudoaddiction is the term that describes patient drug-seeking behaviors that may develop as a direct consequence of inadequate pain management. Pseudoaddiction can be distinguished from true addiction in that the behaviors resolve when the pain is effectively treated.