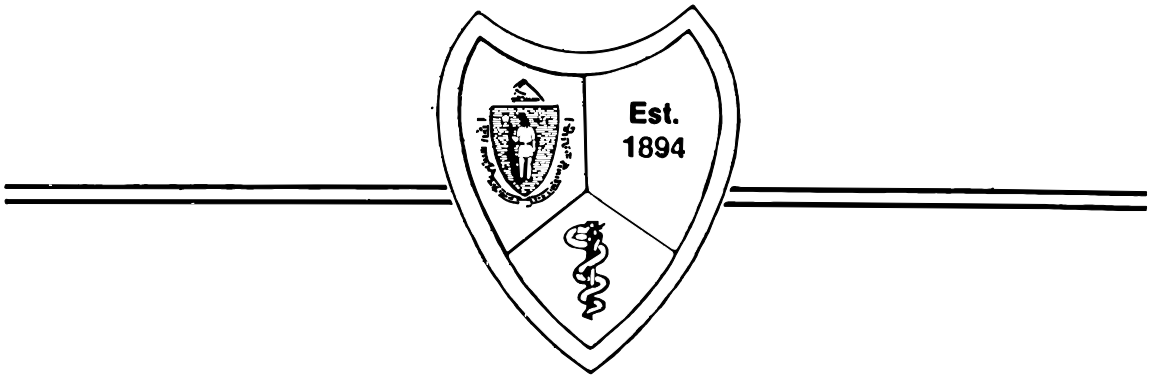
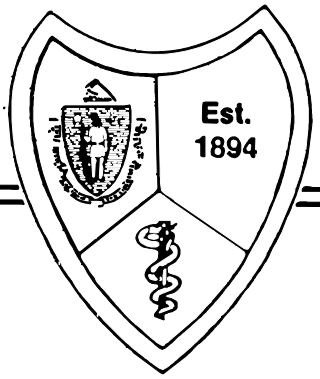
COMMONWEALTH OF MASSACHUSETTS
BOARD OF REGISTRATION IN MEDICINE



Prescribing Practices Policy and Guidelines

Adopted August 1, 1989
Amended December 12, 2001

COMMONWEALTH OF MASSACHUSETTS
BOARD OF REGISTRATION IN MEDICINE



Jane Swift
Governor

Jennifer Davis Carey
Director of Consumer Affairs and Business Regulation

Peter N. Madras, M.D.
Chair

Nancy Achin Sullivan
Executive Director

Members of the Board

Dorothy Keville, *Vice Chair*
Rafik Attia, M.D., *Secretary*
Mary Anna Sullivan, M.D., *Physician Member*
Martin Crane, M.D., *Physician Member*
Regis Anthony de Silva, M.D., *Physician Member*
Roscoe Trimmier, Jr., J.D., *Public Member*

Commonwealth of Massachusetts
Board of Registration in Medicine
Ten West Street, Third Floor
Boston, Massachusetts 02111
(617) 727-3086

TABLE OF CONTENTS

PART TWO

PRESCRIBING PRACTICES

Introduction

The Massachusetts Board of Registration in Medicine has prepared this publication to encourage proper prescribing practices by providing physicians with greater understanding of their responsibilities regarding controlled substances. This publication is available on the Board's website at www.massmedboard.org. Periodic updates of the policy will be placed on the website, and all physicians are encouraged to check the website and the policy regularly to ensure that they are aware of the latest revisions.

The consequences of improper prescribing practices are matters of grave concern to the public, the medical community, law enforcement personnel, state and federal agencies and licensing boards that license and oversee health care professionals. Indeed, physicians who engage in improper prescribing practices, including direct diversion of drugs for non-medical use and indirectly contributing to such diversion by imprudent prescribing, account for a high percentage of Board investigations and disciplinary actions.[1]

The overall mission of the Board is to foster the delivery of competent, high quality health care in Massachusetts, rather than merely sanction improper prescribing.[2]

---

[1] Drug diversion by physicians for their own use to support a dependency is a major area of concern for the Board. On June 15, 1988, the Board adopted a "Chemically Dependent Physician Policy" which sets forth a series of options available to the Board when confronted with a physician who is dependent on drugs and/or alcohol. Copies of the entire Policy or a digest of the policy can be obtained upon written request.

[2] The Board believes that the delivery of optimal care also requires that physicians remain abreast of pharmaceutical developments. Many of the drugs prescribed by practicing physicians today were not developed when they were taught pharmacology in medical school. Not only do physicians require continuing education to remain current but patients, as the consumers of health care services, should share in the educational process by receiving full and fair information on the drugs they are prescribed, to make them partners in their health care.

The Board believes that this Guide will advance that goal by informing physicians as to the legal requirements upon them and the standards the Board applies in reviewing their prescribing practices.

The first part of this Guide summarizes applicable federal and state laws regarding the prescribing of drugs, as well as interpretations of the law by the Board and by the courts. The second part of this Guide deals with specific topics of concern, such as treating drug dependent persons, prescribing anorectics, self-prescribing, prescribing for family members, misuse of anabolic steroids, and the management of pain.

The Board is also aware of the rapidly developing issues surrounding the practice of "telemedicine," including obtaining prescription medications on-line, sometimes across state or even national borders.[3] The Board will continue to study these issues and will update this policy as appropriate to reflect changes brought about by advances in technology. Again, the Board urges physicians to check the Board's website periodically, at www.massmedboard.org., to ensure that they have timely information.

The Board hopes that this information will help physicians maintain a high level of quality in their daily prescribing practices.

[3] The Board does not regard such prescriptions as legally valid. As discussed in detail below at pp. 12-16, a prescription is invalid if the physician has not conformed to minimum professional norms and standards, such as conducting an appropriate physical (or mental status) examination.

PART ONE

Dual Registration Requirements[4]

Physicians who prescribe controlled substances[5] must be registered with the Massachusetts Department of Public Health (DPH) pursuant to the Controlled Substances Act of 1971 (Chapter 94C of the Massachusetts General Laws) and with the federal Drug Enforcement Administration (DEA), pursuant to the federal Controlled Substances Act of 1970.[6]

1. *Registration with the Drug Enforcement Administration*

DEA registration requirements are set forth in 21 CFR 1301.

Under federal law, the requirement for individual DEA registration is waived for some specific medical practitioners, such as interns and residents.

If a physician has more than one office in which he or she administers and/or dispenses controlled substances, the physician is then required to register at each office. However, if a physician administers and/or dispenses only at his or her principal office and only writes prescription orders at the other office or offices, the physician is only

[4] Copies of all the state regulations (CMR) referred to in this Guide may be obtained from the State Bookstore, State House, Room 116, Boston, MA 02133. Telephone: (617) 727-2834. Copies of federal regulations (CFR) may be obtained from the U.S. Government Bookstore, Thomas P. O'Neill, Jr. Federal Building, Room 169, 10 Causeway Street, Boston, MA 02222. Telephone: (617) 720-5753.

[5] Under Massachusetts law, all prescription drugs are deemed to be controlled substances whereas only drugs within Schedules II through V are "controlled substances" for purposes of federal law. Substances in Schedule I may not be prescribed in the United States. Federal law classifies substances from Schedule II through Schedule V. Massachusetts law adopts the five federal schedules and then adds Schedule VI to cover all remaining prescription drugs.

[6] A small number of physicians issue prescriptions for Schedule VI drugs only, in which case only a Massachusetts controlled substances registration number is required. A DEA registration number is required to prescribe for controlled substances in Schedules II - V. Separate registration with the DEA and DPH is required to possess Schedule I drugs.

required to register at the principal office where he or she administers and/or dispenses, provided each office is within the same state.

A physician may transfer the certificate if he or she moves to another address. Requests for transfer must be in writing and accompanied by photocopies of the physician's Massachusetts Medical License, Massachusetts Controlled Substances Registration Certificate and DEA Registration Certificate. Applications for DEA registration (Form DEA-224) can be obtained from any DEA Regional Office or by writing to the Drug Enforcement Administration, 15 New Sudbury Street, Boston, MA 02203-0402. Telephone: (617) 557-2100. The DEA has a registration system whereby registration has to be renewed every three years, instead of annually. To obtain a federal DEA number, a physician must first obtain a Massachusetts Controlled Substance Registration number from the Department of Public Health.

2. *Registration with the Department of Public Health*

The Massachusetts registration requirements are set forth in Chapter 94C, section 7 of the Massachusetts General Laws and Chapter 105, part 700.000 of the Code of Massachusetts Regulations. Interns, fellows, medical officers and other authorized persons may administer, prescribe or otherwise dispense[7] controlled substances without separate registration under the registration of the hospital or other registered health facility by which they are employed, provided that they act only within the scope of their employment in the facility and the facility authorizes the person to dispense controlled

[7] Under Massachusetts law, the term "dispense" means "to deliver a controlled substance to an ultimate user or research subject by a practitioner or pursuant to the order of a practitioner, including the prescribing and administering of a controlled substance and the packaging, labeling, or compounding necessary for such delivery." M.G.L. c. 94C, § 1.

substances under its registration number and assigns a specific code number for each physician so authorized.[8]

Physicians must register separately for each of their business professional activities (such as physician, researcher, chemical analyst), as listed in 105 CMR 700.004(A)(2) and are registered only for the group of activities for that business or professional activity as set forth in 105 CMR 700.004(C). Physicians may not manufacture controlled substances unless they are specifically registered to do so.

Similar to federal law, Massachusetts has separate registration requirements for separate locations.[9] Massachusetts requires separate registration at each principal place of business or professional practice at one general physical location where the physician manufactures, distributes, administers or prescribes controlled substances, or uses controlled substances in research, teaching, or chemical analysis. An office or registered hospital or other registered health care facility which is used by a physician, who is registered at another location that is his principal place of professional practice, is deemed not to be a place where controlled substances are manufactured, distributed or dispensed, provided that no controlled substances are maintained by such practitioner at that place where he or she is not registered.

Pursuant to 105 CMR 700.004(J), termination of registration occurs when a registrant dies, discontinues business or professional practice in Massachusetts, changes his or her name or address as shown on the registration, or has his registration revoked by the Commissioner. In the case of a change in name or address, a physician may apply for a new registration in advance of the effective date of such change. There is no fee to

[8] 105 CMR 700.004(B)(5).
[9] M.G.L c. 94C, § 10 and 105 CMR 700.004(F).

obtain a new registration for a change of name or address. Thirty days notice to the Commissioner is required for any registrant who discontinues business or professional practice, or changes his name or address as shown on the certificate.

Physicians should note that there is no provision for physicians who discontinue their business or professional practice in Massachusetts to remain registered in the state, even if they maintain a home in the state or maintain other contacts with the state. Controlled substances registrations of physicians who discontinue their business or professional practice in Massachusetts are deemed terminated, and such physicians must re-register with the Department of Public Health if they return to Massachusetts to practice. Unless terminated, registration with the Department of Public Health does not have to be renewed.

Applications for registration with the Department of Public Health can be obtained from the Department of Public Heath, Division of Food and Drugs, 305 South Street, Jamaica Plain, MA 02130. Telephone: (617) 983-6700.

Formal Requirements of Prescriptions

Physicians should be familiar with the legal requirements for approved prescription forms in Massachusetts.[10] Every prescription written in the Commonwealth must be written on a form that contains:

- A signature line for the physician's signature. Prescriptions are not valid without a signature. A rubber signature stamp may not be used. Physicians who prescribe

[10] The contents of a valid prescription are specified in 105 CMR 721.000 and in M.G.L. c. 94C, § 22(a).

- using the prescription blank of a hospital or other clinic must print or type their name directly below their signature;
- Below the signature line there must be a space of one-half inch to one inch in which the physician may write in his or her own handwriting the words "no substitution." Below this space shall be printed the words "Interchange is mandated unless the practitioner writes the words 'no substitution' in this space." No other procedure is to be deemed the equivalent of a practitioner's handwritten statement "no substitution;"
- The name and address of the practitioner (or, in the case of a hospital or clinic prescription form, the name and address of the hospital or clinic) must be printed or typed on the form.

Also, there must be space for the practitioner to enter:

- The registration number of the physician;[11]
- The date of issuance of the prescription;
- The name, dosage and strength per dosage unit of the controlled substance prescribed, and the quantity of the dosage units;
- The name and address of the patient;
- Directions for use, including any cautionary statements required; and
- A statement indicating the number of times to be refilled. For further discussion, see page 18.

[11] The DEA registration number and the Massachusetts registration number are not identical. The Drug Enforcement Administration and the Department of Public Health require that the DEA number be on prescriptions for controlled substances in Schedules II - V. The Massachusetts registration number or the DEA registration number may be on prescriptions in Schedule VI.

To reduce forged prescriptions, the Board of Registration in Pharmacy has asked pharmacists to pass on the following recommendations[12] to physicians to reduce the number of forged prescription orders:

1) Treat prescription pads similar to your personal checkbook;
2) Stock only the minimum amount of prescription pads necessary;
3) Do not leave prescription pads unattended;
4) Keep prescription pads in your possession when you are actively using them;
5) Store any surplus prescription pads in a locked drawer or safe or appropriate area; and
6) Report any prescription pad theft to local pharmacies, local law enforcement and to the Board of Registration in Pharmacy, 239 Causeway Street, Suite 500, Boston, MA 02114. Telephone: (617) 727-9953.

Verbal Prescriptions

Schedule II controlled substances may not be prescribed without a written prescription except in emergency situations.[13] A verbal prescription for a Schedule II

---

[12] 6:1 Massachusetts Board of Registration in Pharmacy News 4 (1988).

[13] "Emergency situations" are defined by 247 CMR 5.03(1) as "situations in which the practitioner who proposes to prescribe a controlled substance in Schedule II determines: (a) that the immediate administration of the controlled substance is necessary for the proper treatment of the intended ultimate user, and (b) that no appropriate alternative treatment is available, including administration of a controlled substance which is not in Schedule II, and (c) that it is not reasonably possible for the practitioner to provide a written prescription to be presented to the person dispensing the controlled substance prior to the dispensing." A definition of "emergency situations" from which the Massachusetts regulation was derived, can also be found in 21 CFR 290.10. Pharmacists are not permitted to fill verbal prescriptions for Schedule II substances in a quantity exceeding that which is "adequate to treat the patient during the emergency period." 21 CFR 1306.11(d)(1).

drug must be reduced to writing and filed with the pharmacy within seven (7) days[14] and the prescription should have written on its face the notation "Authorization for Emergency Dispensing."[15]

Drugs in Schedules III - VI may be prescribed by verbal prescription in the absence of an emergency[16] but the prescription must be reduced to writing and filed with the pharmacy within seven days.[17] Verbal prescriptions may be communicated to a pharmacist by an expressly authorized employee or agent of the physician.[18]

Faxed Prescriptions

For ambulatory patients, Scheduled II substances may be faxed to pharmacies but a hard copy prescription must accompany the patient before the medication can actually be dispensed.[19] However, a hard copy follow-up prescription is not required for residential patients in either long-term care facilities or federally supported or state licensed hospice care programs. Nor is a hard copy follow-up prescription required when the facsimile prescription calls for a narcotic to be compounded for direct administration by injection to the patient.[20]

Facsimile prescriptions for Schedules III, IV, V, and VI drugs do not require the filing of a hard copy in follow-up with the pharmacy.

[14] The regulations of the Board of Registration in Pharmacy require that the physician deliver a written prescription for the emergency quantity prescribed orally within seven (7) days. 247 CMR 5.03(3). This corresponds to M.G.L c. 94C, § 17, which requires that the written prescription be delivered "promptly."
[15] 21 CFR § 1306.11(d)(4).
[16] M.G.L. c. 94C, § 17(c).
[17] M.G.L c. 94C, § 20(c).
[18] M.G.L c. 94C, § 18(b).
[19] 21 CFR 1306.11(a).
[20] 21 CFR 1306.11(e), (f) and (g).

Other Electronically Transmitted Prescriptions

As of the time of publication, federal law does not permit any form of electronically transmitted prescriptions for Schedule II through V controlled substances other than by facsimile transmission. However, change may be imminent as federal authorities are currently studying the issue of electronically transmitted prescriptions and may proceed to formulate regulatory standards and requirements.

State law, however, does currently permit Schedule VI prescriptions to be electronically transmitted by computer modem or similar electronic devices subject to requirements analogous to those pertaining to facsimile prescriptions. Such a prescription must either bear the physician's electronic signature or employ some other secure method of validation.[21]

Internet Prescriptions

As discussed in detail below, a prescription to be legally valid must be issued within the context of a physician-patient relationship under circumstances in which the physician has conformed to certain minimum norms and standards for the care of patients, such as taking an adequate medical history and conducting an appropriate physical examination. Prescribing over the internet while deviating from these requirements is therefore unlawful.

[21] 247 CMR 5.02(1)(b).

Dispensing Controlled Substances Without a Prescription

Under Massachusetts law, physicians may not dispense controlled substances without a prescription except where the drug is being delivered or administered to the patient for immediate treatment.[22] This prohibition applies to free samples of controlled substances that physicians keep in stock in their offices.

A physician registered with the proper agencies may deliver or administer controlled substances without a prescription to patients in a single dose or in such quantity as is, in the opinion of the physician, essential for the proper treatment of the patient. However, that amount or quantity of controlled substance shall not exceed the amount needed for the immediate treatment of the patient and all further controlled substances required must be dispensed by prescription. "Immediate treatment" is defined as "that quantity of a controlled substance which is necessary for the proper treatment of the patient until it is possible for him to have a prescription filled by a pharmacy."[23]

A physician may not issue prescriptions to obtain controlled substances for the physician's supply for the purpose of giving out or selling those drugs to patients.[24]

Where the physician does deliver controlled substances to a patient (and the substance is not administered by the physician or ingested in the physician's presence) the physician must package the controlled substance in a container and affix a label to the

[22] Under Massachusetts law, the term "dispense" means "to deliver a controlled substance to an ultimate user or research subject by a practitioner or pursuant to the order of a practitioner, including the prescribing and administering of a controlled substance and the packaging, labeling, or compounding necessary for such delivery." M.G.L c. 94C, § 1.

[23] M.G.L. c. 94C, § 9(b). There is an exception to this prohibition. A physician who is acting in good faith and providing care under a program funded in whole or in part by 42 U.S.C. 300, The Family Planning and Population Research Act, or in a clinic licensed by the Department of Public Health to provide comparable medical services, may dispense Schedule VI controlled substances to recipients of these services in such quantity as is needed for treatment. They are exempt from the requirement that such dispensing be in a single dose or as necessary for immediate treatment. M.G.L c. 94C, § 9(e).

[24] M.G.L. c. 94C, § 19(b).

container that includes the following information: the physician's name and address; the date of dispensing; the name of the patient; the name, dosage and strength of the drug; directions for use; and, any necessary cautionary statements.[25]

Physicians who stock sample controlled substances should be aware that the Prescription Drug Marketing Act of 1987 imposes strict record-keeping requirements on physicians, restricts the manner in which drug samples may be acquired and authorizes heavy fines and prison sentences for violations of its provisions.[26]

NOTE: A chart outlining the varying technical provisions regarding the filling of prescriptions applicable to each of the controlled substance schedules can be found at Attachment A.

Prescriptions Must Be Issued In the Usual Course of Professional Practice and for a Legitimate Medical Purpose

> *A prescription for a controlled substance to be valid shall be issued for a legitimate medical purpose by a practitioner acting in the usual course of his professional practice…An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent [of this act].*
>
> *M.G.L. c. 94C, § 19(a)*

This statutory language sets forth the minimum requirements that must be met in order for a prescription to be valid in the Commonwealth. In sum, the standard of

[25] M.G.L. c. 94C, § 22(b).
[26] See Title 21 U.S.C. §331(t), 333(b) and 353(c)-(d).

conduct proposed by Chapter 94C can be broken down into two requirements. To be valid:

1) A prescription must be issued for a legitimate medical purpose; and
2) By a practitioner in the usual course of his professional practice.

The Board discussed these standards in depth in the disciplinary case *In the Matter of Arthur E. Baer, M.D.,* Adjudicatory Case No. 205, Final Decision and Order, (July 14, 1978). The following two sections summarize the standards established in the *Baer* decision.

1. *Legitimate Medical Purpose*

The general standard for whether a prescription is issued for a legitimate medical purpose is often regarded as a question of whether the physician was acting in good faith in issuing the prescription.[27]

Several indications of the lack of good faith are furnished by case law. They are:

a) Failure to follow at least minimum professional procedures (see discussion below of the requirement that a prescription be issued by a practitioner in the usual course of his professional practice);
b) The physician permitting the patient to name the drug he desires;[28]
c) The physician expressing concern during a patient encounter as to how and where a prescription would be filled in a manner that does not indicate a good faith concern for his patient;

[27] *Commonwealth v. Noble*, 230 Mass. 83 (1918); *Commonwealth v. Miller*, 361 Mass. 644 (1972); and *Commonwealth v. Pike*, 430 Mass. 317 (1999).
[28] The fact that a patient has named the drug he is eventually prescribed obviously does not by itself necessarily make the prescription of that drug inappropriate.

d) Repeated refills over relatively short periods;[29]

e) General remarks of the physician indicating his or her experience with non-therapeutic uses of the drug and of drug enforcement actions and procedures;

f) Failure to schedule appropriate additional appointments for return visits and other factors indicating a lack of interest in follow-up care; and

g) Conversations and other circumstances that demonstrate that the physician knew that the drugs were not to be used for a therapeutic or medical purpose.

Physicians should remember that these are merely indications of a lack of good faith that state or federal authorities might look for in scrutinizing a physician's prescribing practices.

2. *In the Usual Course of a Practitioner's Practice*

To satisfy the requirement that a prescription be issued by a practitioner in the usual course of his professional practice, there must be a physician-patient relationship that is for the purpose of maintaining the patient's well being and the physician must conform to certain minimum norms and standards for the care of patients.

A minimum standard of proper medical practice requires that the physician establish a proper diagnosis and regimen of treatment. At a minimum, on first encounter with a patient, a physician must:

1) Take and record an appropriate medical history; and

2) Carry out an appropriate physical and/or mental status exam and record the results.

[29] The Board realizes that there are many situations where repeated refills over short periods are perfectly appropriate. Whether this indicates bad faith depends on the context in which the refills are given.

The paramount importance of a complete medical history is well established.[30] The importance of the physical examination in making a correct diagnosis and establishing a course of treatment is also well documented.[31]

The observance of these procedures as a function of the "usual course of professional practice" is of particular importance when controlled substances are to play a part in the course of treatment. It is the responsibility of the physician to prescribe drugs with proper regard for their action and potential dangers. Such procedures not only ensure that the patient obtains correct treatment but they may also prevent adverse reactions to drugs, which are a common cause of morbidity, and less commonly, mortality.

Failure to obtain an appropriate medical history and conduct an appropriate examination may not only have serious consequences for the patient, but it can also lead to difficulties for the physician as well, including malpractice claims and Board investigations.[32] Careless diagnosis is as serious as careless treatment and frequently leads to allegations of misconduct. Physicians who have been disciplined by the Board for prescription practice violations have written prescriptions for potentially dangerous

[30] "The written history of an illness should embody all the facts of medical significance in the life of the patient up to the time that he consults the physician...the mind of the physician must be constantly alert to the possibility that any event related by the patient, any symptom however trivial or apparently remote, may be the key to the solution of the puzzle." HARRISON, PRINCIPLES OF INTERNAL MEDICINE, 3-6 (1977).

[31] "The importance of a thorough and accurate physical examination in establishing a medical diagnosis cannot be overemphasized...[N]eglect of any portion thereof may result in the physician missing some important sign. In this regard, it should be emphasized that not infrequently patients may have disease states which are pre-symptomatic or controlled. Thus, every patient who seeks medical advice is deserving of a complete examination." P.J. TALSO & P.R. ALEXANDER, THE PRINCIPLES & PRACTICE OF MEDICINE 12 (1972).

[32] The Board recognizes that covering and cross-covering for fellow physicians is part of the good practice of medicine and in such situations it may be perfectly appropriate to prescribe drugs to a patient who the covering physician has never seen or examined. In these circumstances, the covering physician is relying on the treating physician's examination and diagnosis and this is permissible as long as the reliance is reasonable. For further discussion, see page 24.

controlled substances without conducting any physical examinations or after conducting only cursory examinations.[33]

Beyond documenting appropriate medical histories and physical examinations, physicians must maintain medical records that are detailed enough in nature that the physician's clinical reasoning is implicit in his or her documentation. Treatment plans should be explicitly recorded. All patient visits and telephone calls relating to treatment should be documented. Prescriptions should be documented and changes in medications or dosage should be explained. These are, of course, just some of the rudiments of complete medical records.

DEA Prescription Guidelines

The Drug Enforcement Administration has issued these general guidelines for prescribers of controlled substances (i.e., Schedules II-V). These guidelines have been endorsed by the American Medical Association.[34] The Board endorses these general guidelines.

1) Controlled substances have legitimate clinical usefulness and the prescriber should not hesitate to consider prescribing them when they are indicated for the comfort and well being of patients.

[33] Some specialists, such as psychiatrists in a private office setting, are permitted to prescribe drugs for mental ailments without conducting a physical examination where the general standards of good medical care indicate that a physical examination is not appropriate. Medical doctors, including psychiatrists, are permitted to treat illnesses outside their specialized area of practice where they have adequate training and the proper facilities to do so. However, a psychiatrist in a private office setting who does not have the facilities to conduct a proper physical examination should not be treating physical illnesses (such as back pain) where a physical examination is required.

[34] American Medical Association, Prescribing Controlled Drugs Source Book 90 (1986).

2) Prescribing controlled substances for legitimate medical uses requires special caution because of their potential for abuse and dependence.
3) Good judgment should be exercised in administering and prescribing controlled substances so that diversion to illicit uses is avoided and the development of drug dependence is minimized or prevented.
4) Physicians should guard against contributing to drug abuse through injudicious prescription writing practices or by acquiescing to unwarranted demands of some patients.
5) Each prescriber should examine his or her individual prescribing practices to ensure that all prescriptions for controlled substances are written with caution.
6) Physicians should make a specific effort to ensure that patients are not obtaining multiple prescription orders from different prescribers. For further discussion, see page 22-23.

Further Prescription Guidelines

The following, more specific guidelines are based upon either the DEA's guidelines; principles the Board articulated in the *Baer* decision or derived from other Board decisions; and, Massachusetts law.

1) *The Prescription Must Be Manually Signed When Written.* The prescription order must be signed by the prescriber when it is written. A rubber stamp signature may not be used.

2) *The Prescription Must Be Legible.* The written prescription order should be precise and distinctly legible to enhance exact and effective communications between prescriber and dispenser.

3) *Refills Must Be Indicated.* The prescription order should indicate whether or not it may be refilled and, if so, the number of times or the duration for which refill is authorized. Unlike practice in other states, the term "PRN" (Pro Re Nata) has no meaning with respect to refills in Massachusetts. If no refills are permitted the physician should indicate "no refills" to prevent patients from adding refills in their own hand. Prescription orders for Schedule III and IV drugs may be refilled if so authorized on the prescription order. However, prescriptions for Schedule III and IV drugs may only be refilled up to five times within six months after the date of issue.[35] The refilling of Schedule II prescription orders is prohibited.[36] Controlled substances that are prescribed without an indication for refills cannot be refilled without authorization by the prescriber.

4) *Prescriptions Should Be Made Alteration-Proof.* When prescribing a drug, the actual amount should be written out as well as given in Arabic numbers or Roman numerals, with the number enclosed in parentheses or brackets to prevent the number from being altered. Prescribers should consider placing a number of check-off boxes on their prescription blanks to show amounts within which range the prescribed amount falls, such as 1-25, 26-50, 51-100, and over 100.

5) *DEA Numbers Should Be Hand-Written or Stamped.* The Board discourages physicians from using prescription pads with a pre-printed DEA registration

[35] 21 C.F.R. ch. II, § 1306.22(a) (1987).
[36] M.G.L. c. 94C, § 23(b).

number. Pre-printing makes it easier for someone in possession of a stolen or forged prescription pad to write a falsified prescription. Physicians might want to consider using prescription pads with carbon copies or numbered prescription pads.

6) *Write Indications on Prescription.* The Board suggests that the indications be written directly on prescriptions for stronger drugs. While this may not always be appropriate or necessary, putting the indications on the prescription provides additional documentation of the physician's care.

7) *Information on the Prescription Must Be Truthful.* It is illegal for a prescription to be issued by a physician using the name of another physician or in the name of a person who is not the ultimate user of the drug. Problems of this nature usually arise when a physician is purposefully attempting to self-prescribe to conceal a chemical dependency. A physician should also be careful that his or her name is not being signed by colleagues on prescriptions and should be alert to the possibility that a patient might be obtaining drugs for ultimate use by other persons.

8) *Separate Blanks Are Required for Separate Substances.* A separate prescription blank must be used for each controlled substance prescribed. 105 CMR 721.035 states that practitioners who wish to prescribe more than one drug product, with the same or different dispensing instructions, shall place each prescription on a separate prescription form. More than one drug product may be prescribed on a single form in a hospital setting for the treatment of diseases specified on a list

established by the Department of Public Health, provided that the prescription form sufficiently permits clear direction for use and interchange.

9) *Beware of Fake Medical Records.* Physicians should be aware that patients sometimes alter their prior medical records, acquired from another physician, to obtain drugs from a new physician. Physicians can avoid this problem by speaking with the prior physician to verify the prior care claimed by the patient orally or through a medical record.

10) *Put Identifying Information on Institutional Prescription Blanks*. When institutional prescription blanks are used, the prescriber must print his or her name under his or her signature. The physician's address and DEA registration number (or hospital DEA number with assigned suffix) should also be on such blanks.

11) *Pre-Dating and Post-Dating Are Prohibited.* The date of issuance must appear on the prescription and no other date may appear.[37] This means that pre-dating or post-dating prescriptions is prohibited. Keep in mind that a prescription does not have to be filled on the date it is issued. Schedule II prescriptions may be filled within thirty day of issuance. Schedule III and IV prescriptions are valid for six months. Schedules V and VI prescriptions may be filled for an unspecified period after the date of issuance.[38]

[37] M.G.L c. 94C, § 22(a) states that a prescription must include the date of delivery. 105 CMR 721.030(A)(3)(b) provides that the prescription must have space for the date of issuance. The date of delivery or the date of issuance is the date the prescription is written. Furthermore, M.G.L c. 94C, § 19 implies that a prescription is valid when "issued."

[38] Prescriptions for controlled substances in all schedules should be prescribed and filled pursuant to the professional judgment of the practitioner and the pharmacist, in good faith, and in the usual course of professional practice and treatment.

12) *Do Not Overprescribe.* Physicians should prescribe no greater quantity of a drug than is needed until the next check-up. Physicians may prescribe no more than a 30 day supply of Schedule II or III controlled substances upon any single filling.[39]

13) *Patient Contact Must Be Maintained.* The Board has interpreted "proper medical practice" to require that physicians remain in close contact with patients to whom they prescribe stronger drugs. In general, the Board believes that where a physician is prescribing controlled substances over a long period of time to a patient whose disease process is stable, proper medical practice requires that:

- The physician see the patient at least once every six months; or
- The physician write a note in his or her records explaining why it is impossible, impractical or inappropriate to see the patient at least once every six months.[40] Those occasions when it is all right to go more than six months without seeing a patient who is receiving controlled substances, even if a note is made in the record, should be extremely rare.

The Board strongly urges physicians to see as frequently as possible patients who are using Schedule II drugs and suggests that they be clinically re-evaluated at least every four months. At a minimum, the physician should speak with the patient or the patient's primary care physician by telephone before issuing a new Schedule II prescription.

[39] M.G.L c. 94C, § 23(d). There are two exceptions to this restriction. Dextro amphetamine sulphate or methyl phenidate hydrochloride, when prescribed for minimal brain dysfunction or narcolepsy, may be prescribed in a 60-day supply.

[40] The Board is particularly concerned with physicians who prescribe Schedule II and III substances to patients who they do not see for extended periods of time because these drugs have a greater potential for abuse and are, therefore the most dangerous controlled substances.

14) *Make Reasonable Efforts to Coordinate Treatment.* When a physician knows or has reason to know that a patient is receiving treatment from another physician, the Board strongly encourages the physician to make reasonable efforts to coordinate treatment so that a patient is not independently receiving prescriptions for similar, potentially dangerous controlled substances from more than one physician. It is the Board's position that when a primary care physician and a specialist are both treating a patient, it is the specialist who is obligated to inform the primary physician as to any treatment rendered to a mutual patient.

Physicians should also note that M.G.L. c. 94C, § 33(b) prohibits patients from obtaining controlled substances by deception or subterfuge through the nondisclosure of a material fact. Physicians should encourage all patients to disclose if they are receiving drugs from another physician before prescribing additional drugs to them. At a minimum, a physician should ask whether a patient is seeing, or has recently seen, another physician and, if so, whether the other physician has prescribed medication for the patient. In the event that the patient is seeing another doctor, the physician, before prescribing Schedule II and III drugs, may want to contact the other doctor to verify that the patient is not already being treated with drugs that would be incompatible with the prescription of certain controlled substances. Phone verification may be particularly appropriate where the patient is unfamiliar to the physician or the physician has reason to question the patient's candor. Such coordination of treatment may be critical to preventing serious drug interactions, in addition to preventing drug addiction or diversion. When a physician consults with another doctor concerning a common patient, the

conversation should be documented in the patient's medical records. It may be wise in some circumstances to write a note to the other doctor that says, “We are both treating Patient A and I am prescribing drugs X, Y and Z.”

15) *Prescribing on Request May Be Improper.* Physicians must exercise independent judgment when prescribing and not prescribe simply on demand. Patient requests for specific drugs, especially Schedule II and III controlled substances, should be regarded as potential warning signals by the physician, particularly when the physician is not familiar with the patient or the patient's history. In such a situation, the physician should be especially cautious to ascertain that the patient is not seeking the drug for illegitimate uses. Obviously, the patient is often the best and only source of what alleviates his or her pain or other symptoms and the Board does not wish to suggest that using the patient as a source of information is in any way improper.

16) *Avoid Cursory Examinations.* Patient examinations, particularly initial examinations, should be thorough and should include the taking of an appropriate medical history. As part of any initial examination, the physician or his staff should document the patient's social situation, as social factors often contribute to drug diversion.

Because each patient is unique, there are no universal examination requirements that govern every patient visit. In general, the accepted standards of professional conduct should guide the physician when examining a patient. For further information, refer to the discussion of the *Baer* decision on pages 12-16.

17) *Exercise Care When Covering for other Physicians.* The Board recognizes that covering and cross-covering for other physicians is part of good medical practice, and often the covering physician will write a prescription for a patient who the covering physician has neither seen nor examined. In these situations the covering physician is acting in reliance on the treating physician's examination. As long as the covering physician's reliance is reasonable, this practice is perfectly permissible. The covering physician's reliance on another physician's examination will be presumed to be reasonable if the covering physician verifies the identity of the treating physician,[41] discusses the patient's case with the treating physician, prescribes only that amount of medication necessary until the treating physician can again assume control of the patient's treatment, and documents his or her coverage accurately. Particular care must be taken when the covering physician is prescribing Schedule II substances to a patient who the covering physician has not personally examined.

18) *Record Accurately Examination Results and Prescriptions Written.* The appearance of impropriety can result if a physician prescribes a controlled substance based upon an examination that is not properly and accurately recorded. In addition, all prescriptions written should be accurately recorded in the patient's record.

19) *Phone in First Prescription if Suspicious of New Patient.* On a patient's initial visit, the physician may want to inquire what pharmacy the patient uses and call

[41] Verification should include checking the telephone number and calling the physician back, where the coverage is arranged by telephone and the treating physician is not personally known by the covering physician.

in the prescription personally if the physician has reason to be suspicious of the patient.[42] This permits the physician to determine whether the patient is being truthful about actually using the pharmacy and may enable the physician to discover what other drugs, if any, the patient is being prescribed by other physicians.

Enhancing Patient Compliance

Surveys of patient compliance with prescription instructions are not encouraging. As many as half of all patients may be deviating from the physician's directions for use by:

- Never obtaining the drug;
- Never taking the prescribed drug;
- Taking the prescribed drug improperly.
- Self-medicating by taking non-prescribed drugs and alcohol in addition to or in place of a prescribed drug.

Open avenues of communication between the physician and the patient can enhance patient compliance. Physicians should carefully describe to patients the purpose and use of the drug, as well as any significant side effects that the patient may experience. This is especially important where psychoactive drugs are involved.

Where the physician has reason to suspect the patient's motives, but the physical examination and patient history indicate that the patient's complaint may be based upon a legitimate physical or psychological condition, the physician can lessen problems of non-

[42] Schedule II substances, of course, cannot be communicated over the telephone in Massachusetts in non-emergency situations.

compliance by prescribing the smallest possible amount of the drug pending confirmation of the patient's ailment.[43]

NOTE: Patient Medication Information sheets that describe individual prescription drugs in easy to understand terms are available for a nominal charge from the American Medical Association. The Board encourages physicians to provide this type of written information to patients to help patients become more informed participants in their own health care.

[43] *See* American Medical Association, Prescribing Controlled Drugs Source Book 91-92 (1986).

PART TWO

Treating Drug Dependent Persons

1. *Legal Requirements*

Physicians who use drugs to treat drug dependent persons for dependency are subject to special reporting requirements under Massachusetts law[44] and must be aware of the limitations imposed by federal law.[45] Physicians who are not specially registered with the DEA are not prohibited from administering narcotics to a person for the purpose of relieving acute withdrawal symptoms when necessary while arrangements are being made for referral for treatment. However, in such cases, not more than one day's medication may be administered at a time and such treatment may not continue for more than three days.[46] It should be emphasized that patients who legitimately take controlled substances for extreme pain can become tolerant to their medications. Such patients should not be considered "drug dependent."

Physicians who administer or otherwise deliver controlled substances in Schedules I, II, or III to treat a drug dependent person for his or her dependency must report to the Department of Public Health giving identifying information and the address

[44] A drug dependent person is defined as "a person who is unable to function effectively and whose inability to do so causes, or results from, the use of a drug other than alcohol, tobacco or lawful beverages containing caffeine, and other than from a medically prescribed drug when such drug is medically indicated and the intake is proportioned to the medical need." M.G.L. c. 111E, § 1.

[45] 21 C.F.R. ch. II, § 1306.07 (1987).

[46] 21 C.F.R. ch. II, § 1306.07(b). The limitation in § 1306.07(a) also "is not intended to impose any limitations on a physician or authorized hospital staff to administer or dispense narcotic drugs in a hospital to maintain or detoxify a person as an incidental adjunct to medical or surgical treatment of conditions other than addiction, or to administer or dispense narcotic drugs to persons with intractable pain in which no relief or cure is possible or none has been found after reasonable efforts." 21 C.F.R. ch. II, § 1306.07(c).

of each patient to whom such controlled substance is dispensed, and the name, dosage and strength per dosage unit of the substance used.[47] Physicians who wish to treat drug dependent persons must also obtain separate registration from the Drug Enforcement Administration. In addition, federal regulations impose strict limits on the treatment of drug dependent persons with narcotic drugs. A physician may administer or dispense directly (but not prescribe) narcotic drugs in any schedule to a narcotic drug dependent person for "detoxification treatment" or "maintenance treatment" provided the physician is separately registered and complies with all other regulatory standards.[48]

Treating patients for drug dependency usually requires specialized knowledge beyond the typical substance abuse training that is taught in medical school. Physicians should not undertake to treat patients for drug dependency or the psychological underpinnings of an addictive personality unless they have sufficient training to do so. Where the treating physician lacks specialized knowledge, patients should be referred to experts in drug dependency.

Drug dependent persons, of course, often suffer from other medical illnesses that require prescription medication. Physicians who are not treating a patient for drug dependency may prescribe drugs for the separate condition to the drug dependent patient and are not generally subject to the above requirements. Questions about using controlled substances and other drugs to treat drug dependent persons should be directed

[47] M.G.L c. 94C, § 24(a).

[48] 21 C.F.R. ch. II, § 1306.07(a). "Detoxification treatment" is defined as "the dispensing, for a period not in excess of twenty-one days, of a narcotic drug in decreasing doses to an individual in order to alleviate adverse physiological or psychological effects incident to withdrawal from the continuous or sustained use of a narcotic drug and as a method of bringing the individual to a narcotic drug-free state within such period." 21 U.S.C. 802(30). "Maintenance treatment" is defined as "the dispensing, for a period not in excess of twenty-one days, of a narcotic drug in the treatment of an individual for dependence upon heroin or other morphine-like drugs." 21 U.S.C. 802(29).

to the Drug Enforcement Administration (Telephone: (617) 557-2100) and the Department of Public Health Division of Food & Drug (Telephone: (617) 983-6700).

2. *Identifying the Deceptive Patient*

Drug dependent persons frequently approach honest physicians for the specific purpose of securing drugs to support their dependency. The AMA has identified the following approaches used by such patients:

- *Feigning Physical Problems.* Many physical problems can be convincingly simulated by patients.
- *Feigning Psychological Problems.* The psychological complaints most often presented include anxiety, insomnia, fatigue and depression.
- *Other Deceptions.* In addition to prescription theft, forgery and alterations, other manipulative tactics include concealing or pretending to take medications, and using the excuse that the medication was lost or stolen to get refills within a shorter period of time than was originally prescribed.
- *Pressuring the Physician* by eliciting sympathy or guilt, or even through direct threats or offering bribes.

Many physicians have been victimized by drug dependent persons when these tactics are employed skillfully. Drug dependent persons seeking controlled substances can be any age and often do not “look” suspicious. Physicians should beware of transient patients, patients who study the physician's own responses too carefully, extremely persuasive patients and patients who show little interest in the diagnosis and resist

attempts to verify their medical history. These are common behaviors among deceptive patients.

Physicians who feel that they have been threatened into writing a prescription should immediately notify the police once the patient has left the office.

Inactive Physicians

Physicians whose licenses are on "inactive status" are not permitted to prescribe drugs. A physician who is inactive can no longer engage in the practice of medicine in Massachusetts. Prescribing drugs is part of the practice of medicine.

Management of Pain

> *Pain is one of the most common reasons people consult a physician, yet it frequently is inadequately treated, leading to enormous social cost in the form of lost productivity, needless suffering and excessive healthcare expenditures.*
>
> American Pain Society
> *The Use of Opioids for the Treatment of Chronic Pain*

The Board does not wish to discourage physicians from prescribing strong analgesics to relieve the suffering of patients who are in severe pain, both acute and chronic. Opiates and opioids have legitimate clinical usefulness, and physicians should not hesitate to prescribe them when they are indicated for the comfort and well-being of patients who require relief that cannot be provided by non-opiate analgesics and alternative forms of therapy.

When faced with a patient who is in acute or chronic pain physicians should complete a history and physical that addresses the nature of the patient's pain and

includes an assessment of the patient's risk of addiction. Physicians should consider and explore appropriate alternatives to drug therapy and referral to an established pain clinic. Neuropathic pain is usually not relieved by the use of narcotic analgesics and physicians should look for drugs that have been shown to be effective for that particular symptom. The treatment plan should be individualized to the patient. The medical record should include documented, careful informed consent and possibly a written agreement signed by the patient. Periodic reassessment and review of the treatment plan should be well-documented.

The Board also recognizes that there is a distinction between prescribing solely to maintain a dependency and prescribing to chronic pain patients who are tolerant to the pain medications they require. All patients will probably develop tolerance and physical dependence with sustained use of narcotic and analgesics. When patients are receiving these drugs for the treatment of legitimate pain, this rarely presents a problem.

Beyond these basic principles of pain management, the Board has specifically endorsed the *Model Guidelines for the Use of Controlled Substances for the Treatment of Pain* that were developed and adopted as policy by the House of Delegates of the Federation of State Medical Boards of the United States, in May 1998. These Guidelines are appended as Attachment B.

Prescribing for Immediate Family Members

Prescribing to immediate family members is frequently associated with problems of self-medication and chemical dependency by physicians and is therefore carefully scrutinized by the Board. Treatment of immediate family members with controlled

substances over a substantial period of time may indicate a lack of objectivity and clinical detachment on the part of the physician. Physicians who prescribe controlled substances for family members must take extra precautions to insure that this privilege is not abused.

The same examination requirements applicable to patients who are not related to the physician apply when the physician is prescribing controlled substances to the physician's immediate family members. Physicians should document examination results carefully and accurately. Schedule II controlled substances, because of their extremely high potential for abuse, may not be prescribed to a member of a licensee's immediate family, including a parent, child, sibling, parent-in-law, son/daughter-in-law, brother/sister-in-law, step-parent, step-child, step-sibling, or spouse or equivalent, except in an emergency. This prohibition includes other relatives permanently residing in the same residence as the licensee. The Board suggests that physicians consider refraining from prescribing all controlled substances for family members and significant others in non-emergency situations.

Self-Prescribing by Physicians

Physician self-prescribing presents even deeper concerns than prescribing to family members. The prescription of drugs to oneself creates an enormous potential for abuse and places a difficult burden on the pharmacist, who is equally responsible under the law to determine whether a prescription is valid. The Board has concluded that the potential for abuse of lower schedule drugs far outweighs the relatively minor inconvenience that is caused by requiring physicians to obtain prescriptions for their own

use from other physicians. For this reason, the Board has prohibited physicians from prescribing controlled substances in Schedules II through IV for their own use.

Prescription of Anorectics

The questionable effectiveness of anorectics is troublesome because anorectics have a substantial potential for inducing dependence and are frequently the subject of misuse. Given the narrow usefulness, dubious effectiveness, and clear dangers of anorectics, the Board has concluded that the prescription of Schedule II medications as anorectics for weight control can never be justified and has therefore prohibited this use.

Prescription of Anabolic Steroids for Athletic Purposes

The use and distribution of steroids is illegal in the United States, except through authorized prescriptions. While there are many positive uses for steroids that are clearly medically appropriate, the practice of prescribing anabolic steroids for the sole purpose of increasing a patient's body muscle and/or athletic performance is a questionable one and something that the Board feels compelled to address.

Anabolic steroids are apparently effective. They can hasten the growth of muscle tissue, increase strength and add bulk. These benefits, however, may come at a significant price. The potential side effects from the use of anabolic steroids are extremely severe. Liver cancer, high blood pressure, clogging of the arteries, hypertension, prostate cancer, breast cancer and sterility are just some of the negative side effects associated with anabolic steroids. The Board has therefore prohibited prescribing anabolic steroids to enhance a patient's athletic ability or performance.

The Importance of Continuing Education

Many physicians engage in improper and uninformed prescribing practices simply because they have not kept abreast of new developments in pharmacology and drug therapy. The Board urges all physicians to keep up-to-date on current information that affects the proper prescribing of controlled substances by taking Continuing Medical Education Courses.

Adverse Drug Reactions

Physicians are encouraged to report adverse drug reactions to assist the Food and Drug Administration in identifying drug risks quickly, so that accurate information can be passed along to physicians, patients and health care officials. The FDA relies on voluntary reporting to discover safety problems that do not show up in drug trials that are conducted prior to the drug's approval.

MedWatch, a Medical Products Reporting Program sponsored by the Food and Drug Administration, was created to promote and facilitate the reporting of adverse drug reactions. Adverse drug reactions may be reported by calling the FDA at: 1-800-FDA-1088. Otherwise, you may download the voluntary FDA Form 3500 from the FDA's web site (www.fda.gov/medwatch/report/hcp.htm) and mail it to MedWatch, 5600 Fishers Lane, Rockville, MD 200852-9787.

ATTACHMENTS

ATTACHMENT A

SUMMARY OF PRESCRIPTION FILLING LAWS AND REGULATIONS

Schedule	CII	CIII	CIV	CV	CVI
Examples	Morphine Percodan	Tylenol/Codeine Fiorinal	Valium Phenobarbital	Cough Syrups /Codeine,Lomotil	All other Rx medications
Time valid for Rx filling	30 days after date of issue	180 days from date of issue	180 days from date of issue	None	None
Max days supply per fill	30 days[1]	30 days[1]	180 days	None	None
Max refills allowed	no refills allowed	5 refills	5 refills	None	None
Oral Rx allowed	Emergency only	Yes	Yes	Yes	Yes
Faxing	Yes[2]	Yes[3]	Yes[3]	Yes[3]	Yes[3]

Complied by: Douglas J. Pisano, Ph.D., R.Ph.,
Dean, Massachusetts College of Pharmacy and Health Sciences - Worcester

1 - Methylphenidate and dextroamphetamine may be dispensed in 60-day supply for narcolepsy or minimal brain dysfunction. Implantable infusion pumps consisting of C-II or C-III may be filed for a maximum of 90-days.

2 - C-II prescriptions may be faxed to pharmacies for ambulatory patients based on patient convenience only. A hard-copy prescription must accompany the patient before the medication can be dispensed. Patients in institution, long-term care facilities, hospice or those on injectable medications may have prescriptions faxed to pharmacies as well, HOWEVER, hard-copy follow-up is not required.

3 - Prescriptions for C-III, IV, V and VI do not require a hard-copy follow-up when faxed to a pharmacy.

ATTACHMENT B

Model Guidelines 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 1998.

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. The Board encourages physicians to view effective pain management as a part of quality medical practice 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 physicians should become knowledgeable about effective methods of pain treatment as well as statutory requirements for prescribing controlled substances.

Inadequate pain control may result from physicians' lack of knowledge about pain management or 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 Board's position on pain control, specifically as related to the use of controlled substances, to alleviate physician uncertainty 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. Physicians are referred to the *U.S. Agency for Health Care and Research Clinical Practice Guidelines* for a sound approach to the management of acute[1] and cancer-related pain.[2] 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. Physicians should recognize that tolerance and physical dependence are normal consequences of sustained use of opioid analgesics and are not synonymous with 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 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. Physicians should be diligent in preventing the diversion of drugs for illegitimate purposes.

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.

Physicians should not fear disciplinary action from the Board or other state regulatory or enforcement agency for prescribing, dispensing or administering controlled substances, including opioid analgesics, for a legitimate medical purpose and in the usual course of professional practice. The Board will consider prescribing, ordering, administering or dispensing controlled substances for pain to be for a legitimate medical purpose if based on accepted scientific knowledge of the treatment of pain or if based on sound clinical grounds. All such prescribing must be based on clear documentation of unrelieved pain and in compliance with applicable state or federal law.

Each case of prescribing for pain will be evaluated on an individual basis. The board will not take disciplinary action against a physician for failing to adhere strictly to the provisions of these guidelines, if good cause is shown for such deviation. The physician's conduct will be evaluated to a great extent by the treatment outcome, taking into account whether the drug used is medically and/or pharmacologically recognized to be appropriate for the diagnosis, the patient's individual needs—including any improvement in functioning—and recognizing that some types of pain cannot be completely relieved.

The Board will judge the validity of prescribing based on the physician's treatment of the patient and on available documentation, rather than on the quantity and chronicity of prescribing. The goal is to control the patient's pain for its duration while effectively addressing other aspects of the patient's functioning, including physical, psychological, social and work-related factors. The following guidelines are not intended to define complete or best practice, but rather to communicate what the Board considers to be within the boundaries of professional practice.

Section II: Guidelines

The Board has adopted the following guidelines when evaluating the use of controlled substances for pain control:

1. Evaluation of the Patient

A complete medical history and physical examination must be conducted 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.

2. 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.

3. 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 incompetent. The patient should receive prescriptions from one physician and one pharmacy where possible. If the patient is determined to be at high risk for medication abuse or have a history of substance abuse, the physician may employ 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 (i.e., violation of agreement).

4. Periodic Review

At reasonable intervals based on the individual circumstances of the patient, the physician should review the course of treatment and any new information about the etiology of the pain. Continuation or modification of therapy should depend on the physician's evaluation of progress toward stated treatment objectives, such as improvement in patient's pain intensity and improved physical and/or psychosocial function, i.e., ability to work, need of health care resources, activities of daily living and quality of social life. If treatment goals are not being achieved, despite medication adjustments, the physician should reevaluate the appropriateness of continued treatment. The physician should monitor patient compliance in medication usage and related treatment plans.

5. 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 pain patients who are at risk for misusing their medications and those whose living arrangement pose a risk for medication misuse 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.

6. Medical Records

The physician should keep accurate and complete records to include

- the medical history and physical examination;
- diagnostic, therapeutic and laboratory results;
- evaluations and consultations;
- treatment objectives;
- discussion of risks and benefits;
- treatments;
- medications (including date, type, dosage and quantity prescribed);
- instructions and agreements; and
- periodic reviews.

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

7. 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 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 pain state 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.

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 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.

Pseudoaddiction

Pattern of drug-seeking behavior of pain patients who are receiving inadequate pain management that can be mistaken for addiction.

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 the same effect, or a reduced effect is observed with a constant dose.