

**COMMONWEALTH OF MASSACHUSETTS  
BOARD OF REGISTRATION IN MEDICINE**

**PRESCRIBING PRACTICES  
POLICY AND GUIDELINES**



**Policy 15-05  
Adopted October 8, 2015**

## COMMONWEALTH OF MASSACHUSETTS BOARD OF REGISTRATION IN MEDICINE

*“Prescribing Practices Policy and Guidelines” (Prescribing Policy) was first adopted on August 1, 1989 as Board Policy 89-01. The Policy was amended on November 17, 2010. The November 17, 2010 amendment superseded all previous versions of this Prescribing Policy.*

*“Prescribing Practices Policy and Guidelines” is amended on October 8, 2015. This amendment supersedes all previous versions. “Prescribing Practices Policy and Guidelines” is hereby renumbered as Board Policy 15-05.*

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# COMMONWEALTH OF MASSACHUSETTS BOARD OF REGISTRATION IN MEDICINE

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## INTRODUCTION

The Massachusetts Board of Registration in Medicine has prepared these “Prescribing Practices Policy and Guidelines” to provide physicians with greater understanding of their responsibilities and the standards the Board applies in reviewing their prescribing practices. The Board believes that, by providing a comprehensive overview of the physician’s responsibilities related to prescribing, this publication will help further its overall mission to foster the delivery of competent, high quality health care in Massachusetts. The Board also believes that this information will help physicians maintain a high level of quality in their prescribing practices.

Scientific and legal developments in the area of prescribing occur frequently. It is the obligation of the physician to stay abreast of this rapidly-changing subject matter. The Board encourages all physicians who prescribe to educate themselves on the drugs they prescribe, and to continuously reevaluate prescribing practices in the light of clinical outcomes.

This publication is available on the Board’s website at [www.mass.gov/massmedboard](http://www.mass.gov/massmedboard). Physicians should check the website regularly. In addition to this publication, the Board has issued other policies and guidelines that are available on the Board’s website. Policies related to prescribing are attached to this publication as Appendices.

### **2015 UPDATE**

In 2015, Governor Charles Baker announced that Massachusetts was in the midst of an opioid epidemic. According to the Massachusetts Department of Public Health, there were over 1,000 estimated unintentional opioid-related deaths in 2014. There were 312 opioid-related deaths in the first three months of 2015. In February 2015, Governor Baker convened an Opioid Working Group, an 18-member statewide, expert panel.

On June 22, 2015, Governor Charles Baker announced the findings of his Opioid Working Group. The task force issued 65 recommendations to address the opioid epidemic in Massachusetts.) These recommendations include plans to establish 100 new addiction-treatment beds within one year. The task force called for access to evidence-based medication-assisted therapy and for greater availability of medication that can treat opioid overdose. *See* <http://www.mass.gov/eohhs/gov/departments/dph/stop-addiction/recommendations-from-the-governors-opioid-addiction-working-group.html>

One key element of the Governor’s plan is public education – for parents, about the hazards of prescription painkillers in the home, for students, on the dangers of opioids, and for health care professionals. Education is seen as the way to change the stigma against substance use disorder and to redefine addiction as a public health issue. Primary care practitioners are called upon to screen for and treat addiction as they would any other medical condition, in order to expedite interventions and treatment referrals.

Also in 2015, the Massachusetts Medical Society issued opioid prescribing guidelines for physicians. These guidelines are included in this Policy in Part 1, Section 5.

## **EXECUTIVE SUMMARY**

This Executive Summary is a short review of the material contained in the Guidelines. Please refer to each individual section for more comprehensive information.

### **Part I - Boundaries of Acceptable Medical Practice**

Part I of this publication provides guidance on the legal standards and boundaries applicable to prescribing in medical practices.

#### **Section 1: Basic Requirements of Acceptable Medical Practice**

To be valid, a prescription must be issued for a legitimate medical purpose, by a practitioner in the usual course of his or her professional practice. As with every aspect of medical care, a physician's prescription practices should be guided by medical knowledge, best-practices, professional guidelines and consensus standards. The Board encourages physicians to understand their roles and responsibilities in preventing medication errors.

#### Section 2: Prescribing to Immediate Family Members

Board regulations prohibit physicians, except in an emergency, from prescribing Schedule II controlled substances to a member of their immediate family.

#### Section 3: Prescribing to Self

Physicians are prohibited from prescribing controlled substances in Schedules II through IV for their own use.

#### Section 4: Internet Prescribing

To be valid, a prescription must be issued in the usual course of the physician's professional practice, and within a physician-patient relationship that is for the purpose of maintaining the patient's well-being. In addition, the physician must conform to certain minimum standards of patient care, such as taking an adequate medical history, doing a physical and/or mental status examination and documenting the findings. This rule applies to any prescription, issued by any means, including the Internet or other electronic process. Prescribing that does not meet these requirements is unlawful.

#### Section 5: Prescribing for the Treatment of Chronic Pain

Chronic pain is a major public health problem. At the same time, however, opioid misuse and overdoses have also become very serious public health problems. Physicians must be aware of the legitimate medical uses of controlled substances for the treatment of pain, while safeguarding against opioid misuse and diversion. The MMS Opioid Therapy and Physician

Communication Guidelines are included as a useful tool for physicians, especially primary care physicians.

#### Section 6: Treating Drug-Dependent Persons

Treating patients for drug dependency usually requires specialized knowledge beyond the substance abuse training that is received in medical school. Physicians should not undertake to treat patients for addiction unless they have sufficient training to do so. Where the treating physician lacks specialized knowledge, patients should be referred to an addiction medicine specialist or to another qualified physician.

Physicians who use drugs to treat drug dependency are subject to special requirements under Massachusetts and federal laws. Physicians interested in operating an opioid treatment program to provide Schedule II controlled substances for the treatment of opioid (narcotic) addiction should review Part I, Section 1, “Special Authorizations Required to Treat Addiction,” and Part II, Section 7, “Medication-Assisted Treatment of Opioid Addiction.”

Physicians who are not specially registered with the DEA are permitted to administer buprenorphine or methadone 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.

#### Section 7: Medication-Assisted Treatment of Opioid Addiction

Before any physician can treat opioid addicted patients in an office-based setting, the physician must apply for a waiver. *See* Part I, Section 1, “Special Authorizations Required to Treat Addiction.” Once a physician has received that waiver, the Board expects that the



physician will work within the boundaries of accepted professional practice for medication-assisted treatment of opioid addiction.

#### Section 8: Enhancing Patient Adherence

This section discusses means for enhancing patient adherence to their prescription medicine regimens. To help prevent the potential misuse of medications, physicians should talk with their patients about safely storing and disposing of prescription medications.

#### Section 9: The Importance of Continuing Professional Development

Some physicians may inadvertently engage in improper and uninformed prescribing practices 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 Professional Development (CPD) courses. Pursuant to M.G.L. c. 94C, § 19(6)(e), the Board requires active licensees who prescribe controlled substances to complete three (3) credits in opioid education and pain management training on a biennial basis as a prerequisite to licensure, renewal or revival of a license.

### **Part II – Technical Requirements**

Part II of this publication summarizes the practical and technical requirements related to prescribing in Massachusetts.

#### Section 1: Registration

Prior to prescribing any controlled substance in Massachusetts, physicians should:

- Have an active Massachusetts license to practice medicine; and
- Register with the United States Drug Enforcement Agency (DEA) to prescribe substances in Schedules II-V; and

- Obtain a Massachusetts Controlled Substance Registration (MCSR) number to prescribe substances in Schedules II-VI.<sup>1</sup>

The Board expects physicians to be aware of and comply with the registration requirements of both the DEA and the DPH. These requirements are summarized in Part I, Section 1 of these Guidelines.

Special authorization from the DEA is necessary to be considered a narcotic treatment program. Physicians who wish to run a narcotic treatment program must:

- Be separately registered with the DEA as a narcotic treatment program;
- Comply with all DEA regulations regarding drug addiction treatment;
- Be licensed by the Massachusetts DPH as a substance abuse treatment program; and
- Obtain a DEA waiver to treat opioid addiction outside a treatment program, if the physician wants to prescribe in the office setting.

## Section 2: Drug Schedules

In Massachusetts, all prescription medications are “controlled substances.” This section describes each of the six schedules, and lists examples of the drugs in each Schedule.

## Section 3: Prescriptions

This section sets out the requirements for issuing prescriptions, including verbal, faxed, and electronic prescriptions. It discusses the elements of a written prescription.

## Section 4: Dispensing

This section sets out the requirements for dispensing controlled substances.

## Section 5: The Prescription Monitoring Program.

The Prescription Monitoring Program (PMP) is a repository for a patient’s prescription history for Schedule II-V prescriptions. The PMP is administered by the Department of Public

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<sup>1</sup> All physicians registered with the MCSR are automatically enrolled in the Massachusetts Prescription Monitoring Program, *see* Section 5, *infra*.

Health. All Massachusetts pharmacies and out-of-state pharmacies delivering to people in Massachusetts provide prescription data to the PMP.

#### Section 6: The Medical Marijuana Law

Effective January 1, 2013, Massachusetts voters passed a Medical Marijuana law through the initiative petition process. The law allows physicians to advise a qualifying patient about the risks and benefits of the medical use of marijuana. The physician may provide a qualifying patient with written certification that the medical use of marijuana may benefit that particular patient. The physician's written certification must be based on a full assessment of the qualifying patient's medical history and condition.

Marijuana is a Schedule I substance under federal law. The Massachusetts law does not give immunity under federal law or prevent the federal government from enforcing federal law.

#### Section 7: Supervision of Healthcare Practitioners with Prescriptive Authority

Practitioners with Prescriptive Authority, including Advanced Practice Registered Nurses (APRN), Physician Assistants (PA) and Pharmacists may issue orders for a controlled substance in the course of professional practice. All PAs who have prescriptive authority must be in written guidelines with and supervised by a Massachusetts licensed physician. Some APRNs with prescriptive authority, i.e., certified nurse practitioners (CNP), psychiatric clinical nurse specialists (PCNS) and certified registered nurse anesthetists (CRNA), must be in written guidelines with a supervising physician. Certified nurse midwives (CNM) must practice within a healthcare system and be in a clinical relationship with an obstetrician-gynecologist.

Pharmacists may have prescriptive authority under the Collaborative Drug Therapy Management Act, which permits certain pharmacists and physicians to enter into a collaborative

practice agreement, under which the pharmacist may then initiate, monitor, modify or discontinue a patient's drug therapy.

Additionally, pharmacists with appropriate training may administer vaccines.

#### Section 8: Gifts Or Inducements From The Pharmaceutical Industry

The Commonwealth takes seriously the potential for impropriety or the appearance of impropriety which may occur when pharmaceutical companies or medical device manufacturers give gifts to physicians. This section discusses the AMA's ethical opinion on gifts from those industries and reviews the Massachusetts law that prohibits certain gifts to physicians from pharmaceutical and medical device manufacturing companies.

## **PART I - BOUNDARIES OF ACCEPTABLE MEDICAL PRACTICE**

### **1. BASIC REQUIREMENTS OF ACCEPTABLE PRESCRIPTIVE PRACTICE**

#### **Valid Prescriptions**

To be valid, a prescription must be issued for a legitimate medical purpose, by a practitioner in the usual course of his or her professional practice.<sup>2</sup>

#### **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.<sup>3</sup> There are several factors the Board looks at as indicia of the lack of good faith, including the following:

- Failure to follow at least minimum professional procedure;
- Permitting the patient to name the drug he desires;<sup>4</sup>
- 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 the patient;
- Repeated refills over relatively short periods;<sup>5</sup>
- General remarks of the physician indicating his or her experience with nontherapeutic uses of the drug and of drug enforcement actions and procedures;
- Failure to schedule appropriate additional appointments for return visits and other factors indicating a lack of interest in follow-up care; and
- Conversations and other circumstances that demonstrate that the physician knew that the drugs were not intended to be used for a therapeutic or medical purpose.<sup>6</sup>

#### **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 or her professional practice, there must be a physician-patient relationship that is

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<sup>2</sup> Mass. Gen.Laws c. 94C, §19(a).

<sup>3</sup> *Commonwealth v. Noble*, 230 Mass. 83 (1918); *Commonwealth v. Miller*, 361 Mass. 644 (1972) and *Commonwealth v. Pike*, 430 Mass. 317 (1999).

<sup>4</sup> The fact that a patient has named the drug he or she is eventually prescribed does not, by itself, make the prescription of that drug inappropriate.

<sup>5</sup> The Board realizes that there are situations where repeated refills over short periods may be appropriate. Whether this indicates bad faith depends on the context in which the refills are given.

<sup>6</sup> See *In the Matter of Arthur E. Baer, M.D.*, Board of Registration in Medicine, Adjudicatory Case No. 205 (Final Decision and Order, July 14, 1978).

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.<sup>7</sup> 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 take and record an appropriate medical history and carry out an appropriate physical or mental status exam and record the results. The paramount importance of a complete medical history and a thorough and accurate physical examination is well established. The observance of these procedures as a function of the "usual course of professional practice" is of particular importance when controlled substances are part 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 or mortality.

The Board recognizes that covering and cross-covering for fellow physicians is part of the practice of medicine and in such situations it may be appropriate to prescribe drugs to a patient whom the covering physician has not seen or examined. In these circumstances, the covering physician is relying on the treating physician's examination and diagnosis, This is permissible so long as the reliance is reasonable.

Failure to obtain an appropriate medical history and conduct an appropriate examination may have serious consequences for both the patient and the physician. Careless diagnosis and careless treatment lead to allegations of misconduct. Physicians who have been disciplined by the Board for prescription practice violations have written prescriptions for potentially dangerous

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<sup>7</sup> Id.

controlled substances without conducting any physical examinations or after conducting only cursory examinations.<sup>8</sup>

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 discernible from 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 just some of the rudiments of complete medical records.

#### Expedited Partner Therapy for the Treatment of Chlamydia

In order to combat the risk to the public health of untreated Chlamydia, the Massachusetts Legislature passed a law permitting the prescribing and dispensing of prescription medication without a physical examination, in certain limited circumstances. Physicians, physician assistants, nurse practitioners, and certified nurse midwives who are authorized to prescribe and dispense prescription drugs, and who diagnose infections due to Chlamydia trachomatis in individual patients, may prescribe and dispense prescription drugs to a patient's sexual partners for the presumptive treatment of Chlamydia infection without an examination of the patient's sexual partners.<sup>9</sup> Such prescribing practices are referred to as "Expedited Partner Therapy." In Massachusetts, Expedited Partner Therapy is permitted only for the treatment of Chlamydia.<sup>10</sup>

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<sup>8</sup> Some specialists, such as psychiatrists in private office settings, 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 when 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.

<sup>9</sup> St. 2010, c. 131, § 62, codified at M.G.L. c. 111, §121B (effective July 1, 2010).

<sup>10</sup> See Policy No. 2015-03: *Guidance for Filling Expedited Partner Therapy Prescriptions*, Appendix H.

M.G.L. c. 111, § 121B applies to physicians' prescribing practices, and the prescribing practices of any healthcare practitioner with prescriptive authority whom a physician is supervising.

Regulations governing Expedited Partner Therapy (EPT) for the treatment of Chlamydia are located at 105 CMR 700.003(J) and 105 CMR 721.000. The Board recognizes that the Legislature has authorized Expedited Partner Therapy in order to address a serious public health concern, but notes that it should not be interpreted as an abandonment of the Board's long-held position that the act of prescribing medication must be performed only in the context of a bona fide provider-patient relationship, and after the physician has taken and recorded an appropriate medical history and an appropriate physical examination.

### **General Medical Standards and Preventing Medication Errors**

As with every aspect of medical care, a physician's prescription practices should be guided by medical knowledge, best-practices, guidelines and consensus standards. Physicians should involve patients in decisions about treatment and adhere to requirements for informed consent. Physicians are expected to prescribe only within their scope of practice or expertise. Physicians must regularly review their prescribing practices and must have a system in place that enables them to stay up-to-date with drug information.

According to the Centers for Disease Control and Prevention, 48.5% of U.S. citizens have used at least one prescription drug in the past 30 days.<sup>11</sup> Establishing and maintaining a strong provider-patient partnership is essential to reducing medication errors. In addition, decreasing errors requires a comprehensive approach that includes participation by physicians,

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<sup>11</sup> Centers for Disease Control and Prevention, *Fast Stats*, accessible at: <http://www.cdc.gov/nchs/faststats/drug-use-therapeutic.htm>.



nurses, pharmacists, and others in the health care community.<sup>12</sup> The Board encourages physicians to understand their roles and responsibilities in preventing medication errors.

## **2. PRESCRIBING TO IMMEDIATE FAMILY MEMBERS**

Board regulations prohibit physicians, “[e]xcept in an emergency, . . . from prescribing Schedule II controlled substances to a member of his immediate family, including a spouse (or equivalent), parent, child, sibling, parent-in-law, son/daughter-in-law, brother/sister-in-law, step-parent, step-child, step-sibling, or other relative permanently residing in the same residence as the licensee.”<sup>13</sup>

The American Medical Association (AMA) has issued an ethical opinion on self-treatment and the treatment of families, and in that opinion states that physicians generally should not treat members of their immediate families.<sup>14</sup> The AMA notes that, among the risks that arise when a physician establishes a physician-patient relationship with an immediate family member are: professional objectivity may be compromised; the physician may fail to probe sensitive areas when taking the medical history or may fail to perform intimate parts of the physical examination; patients may feel uncomfortable disclosing sensitive information or undergoing an intimate examination when the physician is an immediate family member, and physicians may be tempted to treat problems that are beyond their expertise or training.

Accordingly, the Board suggests that physicians consider refraining from prescribing all controlled substances for family members and significant others in non-emergency situations. Physicians who do choose to prescribe controlled substances for family members must take extra

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<sup>12</sup> Institute of Medicine, *Preventing Medication Errors*, ed. Aspden, Wolcott, *et al.*, (2006).

<sup>13</sup> 243 Code Mass. Regs 2.07(19).

<sup>14</sup> American Medical Assn., *Code of Medical Ethics*, “Opinion 8.19 – Self-Treatment or Treatment of Immediate Family Members.” The AMA does recognize that “It would not always be inappropriate to undertake . . . treatment of immediate family members. In emergency settings or isolated settings where there is no other qualified physician available, physicians should not hesitate to treat . . . family members until another physician becomes available. In addition . . .there are situations in which routine care is acceptable for short-term, minor problems.”

precautions to insure that this privilege is not abused. The same documentation and 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, diagnosis and treatment plans carefully and accurately.

### **3. PRESCRIBING TO SELF**

Physicians are prohibited from prescribing controlled substances in Schedules II through IV for their own use.<sup>15</sup>

Physician self-prescribing presents even deeper concerns than prescribing to family members. The prescription of drugs to oneself creates an enormous potential for abuse. The Board has concluded that the potential for misuse of drugs in Schedules II through IV far outweighs the relatively minor inconvenience that is caused by requiring physicians to obtain prescriptions for their own use from other physicians.

### **4. INTERNET PRESCRIBING**

To be valid, a prescription for a controlled substance must be issued for a legitimate medical purpose by a practitioner acting in the usual course of his professional practice.<sup>16</sup> This standard applies to any prescriptions issued or dispensed via the Internet. The Board has interpreted M.G.L. c. 94C, §19A in issuing Policy No. 03-06: "Internet Prescribing."<sup>17</sup> The policy states that to be valid, a prescription must be issued in the usual course of the physician's professional practice and within a physician-patient relationship that is for the purpose of maintaining the patient's well-being. In addition, the physician must conform to certain minimum norms and standards for the care of patients, such as taking an adequate medical history and conducting an appropriate physical and/or mental status examination and recording the results. "Issuance of a

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<sup>15</sup> 243 CMR 2.07(19).

<sup>16</sup> M.G.L. c. 94C, §19A.

<sup>17</sup> See Appendix B.

prescription, by any means, including the Internet or other electronic process, that does not meet these requirements is therefore unlawful.”<sup>18</sup>

The federal standards for distributing or dispensing controlled substances by means of the Internet are defined at 21 C.F.R. 1300.04. While pharmacies are permitted to dispense controlled substances via orders made on the Internet, the original prescriptions must be issued for a legitimate medical purpose by a physician in the usual course of his or her professional practice.<sup>19</sup>

In April 2002, the Federation of State Medical Boards (FSMB) issued “Model Guidelines for the Appropriate Use of the Internet in Medical Practice,” which states, in part: “Treatment, including issuing a prescription, based solely on an online questionnaire or consultation does not constitute an acceptable standard of care.”

In 2003, the AMA adopted a policy on Internet Prescribing.<sup>20</sup> This policy calls for physicians who prescribe medications via the Internet to establish a valid patient-physician relationship. The AMA cautioned, “A physician prescribing medication across state lines must possess appropriate licensure in all jurisdictions where patients reside.”<sup>21</sup> The AMA further stated, “Physicians who practice medicine via the Internet, including prescribing, should clearly disclose physician-identifying information on the web site, including (but not necessarily limited to) name, practice location (address and contact information), and all states in which licensure is held.”<sup>22</sup> Both the AMA and FSMB policies caution that physicians using Internet Prescribing should transmit prescriptions over secured networks.

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<sup>18</sup> Mass. Board of Reg. in Medicine, Policy No. 03-06: “*Internet Prescribing*,” Appendix B.

<sup>19</sup> 21 Code Fed. Reg. § 1300.04(l)(1).

<sup>20</sup> AMA Policy H-120.949, *Guidance for Physicians on Internet Prescribing*.

<sup>21</sup> *Id.*

<sup>22</sup> *Id.*

In April 2014, the FSMB issued a “Model Policy for the Appropriate Use of Telemedicine Technologies in the Practice of Medicine,” wherein it addressed again the issue of Internet prescribing.<sup>23</sup> Specifically, the FSMB noted that measures should be employed to “uphold patient safety in the absence of traditional physical examination” and that the use of telemedicine to prescribe be “in accordance with current standards of practice and consequently carry the same professional accountability as prescriptions delivered during an encounter in person.” The Board has recognized telemedicine as the “practice of medicine.”<sup>24</sup>

## **5. PRESCRIBING OPIOIDS FOR THE TREATMENT OF CHRONIC PAIN**

Chronic pain is a major public health problem in the United States. One estimate is that 30% of the U.S. population suffers from chronic pain.<sup>25</sup> Opioid therapy is a common treatment for chronic pain and its use has been increasing over the past 15 years. Opioid therapy for use in the treatment of chronic pain differs from opioid therapy used to treat cancer pain or at the end of life, which are not discussed herein.

It should be emphasized that patients who legitimately take controlled substances for extreme pain can become tolerant to their medications. Physicians should be aware of the following criteria for problematic opioid use:

- “The patient displays an overwhelming focus on opiate issues during pain clinic visits that occupies a significant proportion of the pain clinic visit and impedes progress with other issues regarding the patient’s pain. This behavior must persist beyond the third clinic treatment session.
- The patient has a pattern of early refills (3 or more) or escalating drug use in the absence of an acute change in his or her medical condition.

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<sup>23</sup> “FSMB Model Policy for the Appropriate Use of Telemedicine Technologies,” accessible at: [http://www.fsmb.org/Media/Default/PDF/FSMB/Advocacy/FSMB\\_Telemedicine\\_Policy.pdf](http://www.fsmb.org/Media/Default/PDF/FSMB/Advocacy/FSMB_Telemedicine_Policy.pdf).

<sup>24</sup> 243 CMR 2.01(4), (effective 2/1/2012).

<sup>25</sup> Johannes CB, Le TK, Zhou X, Johnston, JA, Dworkin RH. “The prevalence of chronic pain in United States adults: results of an Internet-based survey.” *The Journal of Pain*; 2010; 11:1230-9.

- The patient generates multiple telephone calls or visits to the administrative office to request more opiates, requests early refills, or has problems associated with the opiate prescription. A patient may qualify with fewer visits if he or she creates a disturbance with the office staff.
- There is a pattern of prescription problems for a variety of reasons that may include lost medications, spilled medications or stolen medications.
- The patient has supplemental sources of opiates obtained from multiple providers, emergency rooms, or illegal sources.”<sup>26</sup>

In 2013, the Federation of State Medical Boards (FSMB) adopted a “Model Policy on the Use of Opioid Analgesics in the Treatment of Chronic Pain.”

“There is a significant body of evidence suggesting that many Americans suffer from chronic pain and much of that pain is inadequately or ineffectively treated. Since the 2004 [FSMB Pain Policy] revision, evidence for risk associated with opioids has surged, while evidence for benefits has remained controversial and insufficient. Over the last decade, there has been a parallel increase in opioid sales and an increase in morbidity and mortality associated with these drugs. At the same time, approximately one in four patients seen in primary care settings suffer from pain so intense as to interfere with the activities of daily living.”<sup>27</sup>

Recent scientific studies have provided new information on opioid use for chronic pain, and the FSMB has indicated it intends to revise its 2013 Model Policy so that it more closely align with the latest scientific information.<sup>28</sup> When the FSMB finalizes its revisions, the Board will review the Model Policy and consider whether to adopt it, in whole or in part.<sup>29</sup>

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<sup>26</sup> These criteria are set out in the AMA Council on Science and Public Health Report 2 (I-08) “Improving Medical Practice and Patient/Family Education to Reverse the Epidemic of Nonmedical Prescription Drug Use and Addiction.”

<sup>27</sup> Federation of State Medical Boards, “*Model Policy on the Use of Opioid Analgesics in the Treatment of Chronic Pain*” (July 2013) is accessible at: [http://www.fsmb.org/Media/Default/PDF/FSMB/Advocacy/pain\\_policy\\_july2013.pdf](http://www.fsmb.org/Media/Default/PDF/FSMB/Advocacy/pain_policy_july2013.pdf)

<sup>28</sup> Resolution 15-4, FSMB House of Delegates Meeting, Approved April 25, 2015. “*Resolved*: that the Federation of State Medical Boards will establish a workgroup ... to review the current science and revise the *Model Policy on the Use of Opioid Analgesics in the Treatment of Chronic Pain*.”

<sup>29</sup> “*Guideline for the Use of Controlled Substances for the Treatment of Pain*,” was adopted by the Board in December 2004.

## **The Massachusetts Medical Society Guidelines**

On May 21, 2015, the Massachusetts Medical Society (MMS) issued Guidelines related to the prescribing of opioids. (Appendix G.) The MMS issued two sets of Guidelines: Acute Care Guidelines and Chronic Pain Guidelines.

- The Chronic Pain Guidelines apply to patients who receive opioids for more than 90 days, including transferred patients with opioid histories.
- The MMS Guidelines are intended to have general applicability and are most relevant in primary care. Physicians should also review existing guidelines for their individual specialties.
- The Guidelines do not apply to patients with cancer, patients in hospice or palliative care, and inpatients at a hospital or a nursing home.

## **6. TREATING DRUG-DEPENDENT PERSONS**

The American Society of Addiction Medicine defines “addiction” as follows:

“Addiction is a primary, chronic disease of brain reward, motivation, memory and related circuitry. Dysfunction in these circuits leads to characteristic biological, psychological, social and spiritual manifestations. This is reflected in an individual pathologically pursuing reward and/or relief by substance use and other behaviors.

Addiction is characterized by inability to consistently abstain, impairment in behavioral control, and craving, diminished recognition of significant problems with one’s behaviors and interpersonal relationships, and a dysfunctional emotional response. Like other chronic diseases, addiction often involves cycles of relapse and remission. Without treatment or engagement in recovery activities, addiction is progressive and can result in disability or premature death.”<sup>30</sup>

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<sup>30</sup> “Standards of Care: For the Addiction Specialist Physician,” American Society of Addiction Medicine, 2014.

Treating patients for drug dependency may require specialized knowledge beyond the substance abuse education that is received in medical school. Physicians should not undertake to treat patients for addiction unless they have sufficient training to do so. Where the treating physician lacks specialized knowledge, patients should be referred to addiction medicine specialists or another qualified physician. The American Society of Addiction Medicine (ASAM) has published standards of care for treating patients with addiction.<sup>31</sup> These standards apply to physicians with addiction specialty certification and to any physician assuming the responsibility for caring for a patient with addiction.

Physicians who use drugs to treat addiction are subject to special requirements under Massachusetts and federal laws.<sup>32</sup> Physicians interested in operating an opioid treatment program to provide Schedule II controlled substances for the treatment of opioid addiction should review Part I, Section 1, “Special Authorizations Required to Treat Addiction,” and Part II, Section 7, “Medication-Assisted Treatment of Opioid Addiction.” To obtain the necessary applications for waivers and detailed information regarding opioid treatment program requirements, physicians should contact the DEA and the Massachusetts Drug Control Program. *See* Appendix A “Contact Information.”

Physicians who are not specially registered with the DEA are permitted to administer buprenorphine or methadone to a person for the purpose of relieving acute withdrawal symptoms when necessary while arrangements are being made for referral for treatment.<sup>33</sup> However, in

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<sup>31</sup> ASAM, accessible at <http://www.asam.org/docs/default-source/publications/standards-of-care-final-design-document.pdf>

<sup>32</sup> 21 C.F.R. § 1306.07(a); M.G.L. c. 111B, §§6, 6A, 6B; M.G.L. c 111E § 7; and 105 CMR 164.000

<sup>33</sup> 21 C.F.R. § 1306.07(b).

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.<sup>34</sup>

Physicians may be approached by patients for the specific purpose of securing drugs to support their addiction. Drug dependent persons seeking controlled substances can be any age and often do not look "suspicious." Physicians should beware of transient patients, 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.

## **7. MEDICATION-ASSISTED TREATMENT OF OPIOID ADDICTION IN THE MEDICAL OFFICE**

### **A. Buprenorphine-containing Products**

Before any physician can prescribe buprenorphine for the medication-assisted treatment of opioid addiction, the physician must apply for a waiver from the U.S. Department of Health and Human Services, Substance Abuse and Mental Health Services Administration (SAMHSA). SAMHSA will notify the DEA if the waiver is granted and the DEA will issue an Identification Number. The Identification Number must appear on all prescriptions for buprenorphine. *See infra* Part I, Section 1, "Special Authorizations Required to Treat Addiction."

Once a physician has received that waiver, the Board expects that the physician will work within the boundaries of accepted professional practice for office-based treatment of opioid addiction. Physicians should note that they are not permitted to delegate the prescribing of buprenorphine to non-physicians.

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<sup>34</sup> *Id.*



The Federation of State Medical Boards issued a Model Policy on DATA 2000 and Treatment of Opioid Addiction in the Medical Office.<sup>35</sup> The Board encourages physicians who are engaged in office-based treatment of opioid addiction to review the FSMB’s Model Policy. Physicians are also encouraged to review the materials published by SAMHSA, which administers the Buprenorphine program. *See e.g., SAMHSA’s Clinical Guidelines for the Use of Buprenorphine in the Treatment of Opioid Addiction: a Treatment Improvement Protocol TIP 40, which is available through the SAMHSA website.*<sup>36</sup>

## **B. Naltrexone**

In 2010, the Food and Drug Administration approved the use of Naltrexone for the treatment of people with opioid dependence. Naltrexone can be prescribed by any physician who is licensed to prescribe medications. While no special training is required, as with any drug, the Board expects physicians to familiarize themselves with risks and benefits of the naltrexone, and advise their patients accordingly.<sup>37</sup>

## **8. ENHANCING PATIENT ADHERENCE**

“Drugs don’t work in patients who don’t take them.”  
- Former U.S. Surgeon General C. Everett Koop, M.D.

Adherence to prescription medication regimens is a critical factor in achieving optimal patient outcomes; however, many patients do not realize the full benefits of treatment because of a failure to take their medication as prescribed. Non-adherence to medication regimens can lead

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<sup>35</sup> “*FSMB Model Policy on DATA 2000 and Treatment of Opioid Addiction in the Medical Office*,” (2013).  
Accessible at: [http://library.fsmb.org/pdf/2013\\_model\\_policy\\_treatment\\_opioid\\_addiction.pdf](http://library.fsmb.org/pdf/2013_model_policy_treatment_opioid_addiction.pdf).

<sup>36</sup> [http://buprenorphine.samhsa.gov/Bup\\_Guidelines.pdf](http://buprenorphine.samhsa.gov/Bup_Guidelines.pdf).

<sup>37</sup> “An Introduction to Extended-Release Injectable Naltrexone for the Treatment of People with Opioid Dependence,” accessible at: <https://store.samhsa.gov/shin/content/SMA12-4682/SMA12-4682.pdf>.

to poor clinical outcomes, high rates of hospitalization, high utilization of medical services and an overall increase in healthcare costs.<sup>38</sup>

Physicians can have a decisive impact on medication adherence by following a patient-centered approach to care that promotes open avenues of communication between the physician and the patient. Prior to prescribing new medications, physicians should carefully describe to patients the purpose and use of the drug, the benefits, as well as any significant side effects that the patient may experience, and basic information on how to take the medication correctly. Physicians should encourage patients to ask questions, and should provide written information about medication. 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.

Physicians can also assist patients in overcoming barriers to medication adherence by reducing the complexity of the prescribed medication regimens wherever clinically appropriate.<sup>39</sup> Patients should be provided ongoing support and follow-up care throughout their course of therapy to help ensure adherence and optimal treatment outcomes.

Patient non-adherence can also have effects on prescription drug diversion and misuse. SAMHSA's 2009 National Survey on Drug Use and Health showed that the scale of prescription drug misuse is vast, with more than 7 million Americans reporting use of a prescription medication for non-medical purposes in the past 30 days.<sup>40</sup> The Board encourages physicians to talk with patients about the importance of taking medications as directed along with the dangers associated with prescription drug diversion and misuse. Physicians can help alleviate the risk of

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<sup>38</sup> Viswanathan M, Golin CE, Jones CD, *et al*, "Interventions to improve adherence to self-administered medications for chronic diseases in the United States: a systematic review." 157 *Ann. Intern. Med.* 785-795 (2012).

<sup>39</sup> Matchin, R, M.D., "An Rx For Better Outcomes, Lower Costs," *American Medical News Opinion*, December 7, 2009.

<sup>40</sup> SAMHSA, *Results from the 2009 National Survey on Drug Use and Health (NSDUH): National Findings*, (2010), accessible at <http://oas.samhsa.gov/NSDUH/2k9NSDUH/2k9ResultsP.pdf>.

diversion and misuse by prescribing only the quantity of medication needed based on the patient's clinical presentation and by not over-prescribing, especially in the case of prescription pain medications such as opioids.

A large source of the prescription drug problem is what is stored in America's medicine cabinets.<sup>41</sup> Patients who fail to properly secure medication in their homes create a risk of drug diversion and misuse within their own household and community. To help prevent the potential misuse of medications, physicians should talk with their patients about safely storing and disposing of prescription medications.<sup>42</sup> Throughout Massachusetts, residents can dispose of prescription and over-the-counter drugs in permanent medication collection kiosks located at many community police stations.<sup>43</sup> Medication collection kiosks offer residents a free and confidential way to dispose of unused or expired medications to help prevent diversion and abuse.

The National Transportation Safety Board has asked that all state guidelines on prescribing controlled substances for pain include a recommendation that health care providers discuss with their patients the effect their medical condition and medication use may have on their ability to safely operate a vehicle, in any mode of transportation.<sup>44</sup>

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<sup>41</sup> Office of National Drug Control Policy, (2011). "*Epidemic: Responding to America's prescription drug abuse crisis.*" Retrieved from [https://www.whitehouse.gov/sites/default/files/ondep/issues-content/prescription-drugs/rx\\_abuse\\_plan.pdf](https://www.whitehouse.gov/sites/default/files/ondep/issues-content/prescription-drugs/rx_abuse_plan.pdf).

<sup>42</sup> Information on the proper storage and disposal of medications can be found at the Centers for Disease Control and Prevention website; <http://www.cdc.gov/HomeandRecreationalSafety/Poisoning/preventiontips.htm>. Information regarding the safe disposal of medications at private residences can be found at the Massachusetts Energy and Environmental Affairs website: <http://www.mass.gov/eea/agencies/massdep/toxics/sources/disposal-of-waste-medications-at-private-residences.html>.

<sup>43</sup> A list of permanent resident waste medication kiosks in Massachusetts is located on the Massachusetts Energy and Environmental Affairs website: [www.mass.gov/eea/docs/dep/toxics/stypes/kiosklist.pdf](http://www.mass.gov/eea/docs/dep/toxics/stypes/kiosklist.pdf).

<sup>44</sup> "Joint Alert on NTSB Study," Appendix F.

## 9. THE IMPORTANCE OF CONTINUING PROFESSIONAL DEVELOPMENT

Some physicians may inadvertently engage in improper and uninformed prescribing practices 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 Professional Development Courses.

In 2010, the Massachusetts Legislature amended the controlled substances law, M.G.L. c. 94C, § 18,<sup>45</sup> to require that all physicians who prescribe controlled substances complete training in effective pain management, identification of patients at high risk of substance abuse and counseling patients about the side effects, addictive nature and proper storage and disposal of controlled substances. M.G.L. c. 94C, § 18 requires that the boards of registration of each professional license that requires such training must develop the standards for appropriate training programs.

In response to this legislation, the Board promulgated a regulation at 243 CMR 2.06(6)(d), effective February 1, 2012. These regulations require that applicants for licensure and licensees seeking to renew their licenses complete three credits in opioid education and pain management training. These three credits must be earned each renewal cycle and count towards a licensee's required risk management credits. Information in regard to meeting this requirement can be found on the Board's website, [www.mass.gov/eohhs/gov/departments/borim](http://www.mass.gov/eohhs/gov/departments/borim).

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<sup>45</sup> St. 2010, c. 283.

## **PART II – TECHNICAL REQUIREMENTS**

### **1. REGISTRATION REQUIREMENTS**

In Massachusetts, all prescription drugs are “controlled substances.”<sup>46</sup> Therefore, to prescribe or dispense any type of prescription drug, physicians who practice medicine in Massachusetts must obtain a Massachusetts Controlled Substances Registration (MCSR) number from the Massachusetts Department of Public Health (DPH).<sup>47</sup> The DPH Drug Control Program is responsible for issuing MCSR numbers. To obtain an application for an MCSR number and information about the application process, contact the DPH Drug Control Program. *See* Appendix A: “Contact Information.”

All physicians who prescribe any controlled substance in Schedules II through V must also have a registration certificate from the United States Drug Enforcement Administration (DEA).<sup>48</sup> To obtain an application for a certificate of registration from DEA, instructions and a copy of the “DEA Practitioner’s Manual,” physicians should contact the DEA Boston Field Office. *See* Appendix A: “Contact Information.”

Massachusetts physicians who issue prescriptions only for Schedule VI drugs must have a MCSR number but are not required to register with the DEA.

Physicians in Massachusetts may not prescribe Schedule I controlled substances, which have no current accepted medical use, with the exception of medical marijuana.<sup>49</sup> Physicians are permitted to provide written certification to patients who qualify for the medical use of

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<sup>46</sup> M.G.L. c. 94C, § 2(a); 105 CMR § 700.002.

<sup>47</sup> M.G.L. c. 94C, § 7; 105 CMR § 700.004(M).

<sup>48</sup> 21 U.S.C. § 823 and 21 C.F.R. § 1301.

<sup>49</sup> M.G.L. c. 94C, § 3. *See infra* Part II, Section 2, “Drug Schedules.”

marijuana, as long as the physician follows the legal requirements for providing such certification.<sup>50</sup> See, Part II, Section 6, “Medical Marijuana” section.

In order to prescribe a Schedule II controlled substance (e.g., methadone) or a Schedule III controlled substance containing buprenorphine for the medication-assisted treatment of opioid addiction, physicians must obtain additional specific authorization from the DEA, the U.S. Substance Abuse and Mental Health Services Administration (SAMHSA), and the Massachusetts Bureau of Substance Abuse Services (BSAS).

#### Basic Requirements

The DEA and DPH require separate registrations for each practice location at which a physician dispenses or administers controlled substances.<sup>51</sup>

Physicians must obtain separate MCSR numbers for each of their professional activities. For example, separate Massachusetts registrations would be required for work as a researcher and as a practicing physician or chemical analyst.<sup>52</sup> The DEA does not require separate registrations for each professional activity.<sup>53</sup>

#### Change of Address

Because DEA certificates of registration and MCSR numbers are location-specific, physicians must notify the DEA and DPH Drug Control Program when they move from their registered address.<sup>54</sup>

A physician’s DEA registration may be transferred to a new location, if approved by the DEA.<sup>55</sup> A physician’s request for transfer must be made to the DEA in writing and must be

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<sup>50</sup> St. 2012, c. 369; 105 CMR § 725.000 *et seq.*

<sup>51</sup> 21 U.S.C. § 822(e); 21 C.F.R. § 1301.12; M.G.L c. 94C, § 10; 105 CMR § 700.004(F).

<sup>52</sup> 105 CMR § 700.004(A)(2) and 105 CMR § 700.004(C).

<sup>53</sup> 21 U.S.C. § 823(f).

<sup>54</sup> 105 CMR § 700.004(J); 105 CMR § 700.004(K); 21 U.S.C. § 827(g); 21 C.F.R. § 1301.51.

<sup>55</sup> 21 C.F.R. § 1309.63.

accompanied by photocopies of the physician's medical license, MCSR number, and DEA registration certificate.

A physician's MCSR is not transferrable to a new location; a physician must apply for a new registration prior to moving.<sup>56</sup> Physicians must also notify the DPH Commissioner 30 days in advance of their discontinuation of business or professional practice.<sup>57</sup>

#### Registration Renewal and Termination

DEA registration must be renewed every three years.<sup>58</sup> The DEA notifies registrants in advance of the renewal date.

The Commissioner of DPH periodically recalls MCSR numbers. Currently, the Commissioner recalls numbers every three years.<sup>59</sup>

The following conditions will result in termination of the MCSR number:

- A change of name or address as shown on the registration,
- Discontinuation of business or professional practice in Massachusetts,
- Revocation of registration by the DPH Commissioner, or
- Death of the registrant.<sup>60</sup>

Physicians should note, 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. Physicians must apply for a new MCSR number if they return to Massachusetts to practice.<sup>61</sup>

#### Physicians Exempt from Registration Requirements

##### **Limited Licensees**

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<sup>56</sup> 105 CMR 700.004(J)(1) and (K).

<sup>57</sup> 105 CMR 700.004(J)(2).

<sup>58</sup> 21 U.S.C. § 822(a)(2).

<sup>59</sup> M.G.L. c. 94C, § 7(f); 105 CMR § 700.004(D).

<sup>60</sup> 105 CMR § 700.004(J).

<sup>61</sup> *Id.*

Limited licensees (residents and clinical fellows) do not need a MCSR number or their own individual DEA registration number.<sup>62</sup> Limited licensees may “administer, prescribe or otherwise dispense controlled substances . . . under the registration of the hospital or other registered health facility by which they are employed.”<sup>63</sup> Limited licensees may only do so, however, if the dispensing, administering or prescribing is done in the usual course of professional practice and only within the scope of their employment in the facility; and they are specifically authorized by the facility to do so.<sup>64</sup> The hospital or facility designates a specific internal code consisting of a numeric suffix to the hospital’s or health facility’s registration number, preceded by a hyphen for each person so authorized. The hospital or facility must maintain a current list of internal codes and must make such codes available at all times to other registrants, the DPH Commissioner and authorized law enforcement agencies.<sup>65</sup>

### **Physicians in the Employ of the Federal Government**

The DEA registration requirements are waived for physicians who work exclusively for a branch of the U.S. Military, the U.S. Public Health Service, or the U.S. Bureau of Prisons.<sup>66</sup> Such physicians must put their service identification number on all prescriptions, however, and should consult with their agency’s administrators regarding other requirements.<sup>67</sup>

### **Special Authorizations Required to Treat Addiction**

Federal law defines a narcotic treatment program as “a program engaged in maintenance and/or detoxification treatment with narcotic drugs.”<sup>68</sup>

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<sup>62</sup> 21 U.S.C. § 822(c)(1); 21 C.F.R. § 1301.22; 105 CMR § 700.004(B)(5).

<sup>63</sup> 105 CMR 700.004(B)(5).

<sup>64</sup> *Id.*

<sup>65</sup> *Id.*

<sup>66</sup> 21 C.F.R. 1301.23

<sup>67</sup> 21 C.F.R. 1306.01 *et seq.*

<sup>68</sup> 21 C.F.R. 1300.01(31).



### Prescribing Schedule II Controlled Substances to Treat Opioid Addiction

An individual physician may only prescribe methadone or any other Schedule II controlled substance for purposes of treating opioid addiction if the physician is registered with the DEA as a narcotic treatment program and the physician is in compliance with DEA regulations regarding treatment.<sup>69</sup>

All substance abuse treatment programs operating in Massachusetts must be licensed by the Department of Public Health.<sup>70</sup> Physicians interested in operating an opioid treatment program to provide Schedule II controlled substances for the treatment of opioid (narcotic) addiction should contact the DEA, SAMHSA, and DPH to obtain the necessary applications and detailed information regarding opioid treatment program requirements. *See* Appendix A, “Contact Information.”

### Prescribing Schedule III – V Controlled Substances to Treat Opioid Addiction

Physicians who have specific expertise and meet the qualifications set by DEA and the Substance Abuse and Mental Health Services Administration (SAMHSA), may obtain a waiver permitting them to provide medication-assisted treatment of opioid addiction in their offices. Physicians who have been approved for such a waiver may use certain narcotic medications in Schedules III, IV, and V, which have been approved by the U.S. Food and Drug Administration (FDA) for opioid addiction treatment.<sup>71</sup> Currently, a waiver is necessary before a physician can prescribe FDA-approved medications that contain buprenorphine for use in opioid addiction treatment. During their first year under such a waiver, physicians are permitted to treat no more

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<sup>69</sup> 21 C.F.R. 1306.07(a).

<sup>70</sup> M.G.L. c. 111B, §§6, 6A, 6B; M.G.L. c 111E § 7; and 105 CMR § 164.000

<sup>71</sup> The Drug Addiction Treatment Act of 2000 (DATA 2000), 21 U.S.C. § 801. *See also* 21 C.F.R. § 1306.67(d).

than 30 patients. After one year, physicians may submit a notification of the need and intent to treat up to 100 patients.<sup>72</sup>

Physicians do not need a waiver to use extended-release injectable naltrexone to treat opioid addiction.<sup>73</sup> Unless exempted, physicians need to use the Prescription Monitoring Program before prescribing Schedule II or Schedule III narcotic drugs for the first time.<sup>74</sup>

## **2. DRUG SCHEDULES**

The general rule is that a prescription must be issued in the usual course of a practitioner's practice and for a legitimate medical purpose; this rule applies to all controlled substances.<sup>75</sup> There must be a physician-patient relationship that is for the purpose of maintaining the patient's health and the physician must conform to generally accepted standards of patient care, including documentation of the patient's current complaint, medical history, physical examination, appropriate diagnosis and treatment plan.<sup>76</sup>

### **Schedule I**

Schedule I controlled substances<sup>77</sup> have no current accepted medical use, lack safety standards for use under medical supervision, and have a high potential for abuse.<sup>78</sup> Although marijuana is a Schedule I controlled substance, Massachusetts physicians are permitted to provide written certification to patients who qualify for the medical use of marijuana, as long as the physician follows the legal requirements for providing such certification.<sup>79</sup>

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<sup>72</sup> 21 U.S.C. § 823(g)(2).

<sup>73</sup> SAMHSA, *Clinical Use of Extended-Release Injectable Naltrexone in the Treatment of Opioid Use Disorder: A Brief Guide* (February 2015).

<sup>74</sup> See *infra*, "Prescription Drug Monitoring Program," pp. 38-42.

<sup>75</sup> M.G.L. c. 94C, §19(a).

<sup>76</sup> See Part I, Section 1, "Basic Requirements of Acceptable Prescriptive Practice."

<sup>77</sup> 21 U.S.C. 812(c), M.G.L. c. 94C, §3(1).

<sup>78</sup> 21 U.S.C. 812(b)(1); M.G.L. c. 94C, §3(1).

<sup>79</sup> See Part II, Section 6, "Medical Marijuana Law;" St. 2012, c. 369; 105 CMR § 725.000 *et seq.*

Physicians may conduct bona fide research with Schedule I controlled substances with the approval of the Secretary of Health and Human Services, the Attorney General of the United States and the DPH Commissioner.<sup>80</sup> The requirements for using Schedule I controlled substances for research are quite restrictive and any physician who is interested in such research should consult with both the DEA and DPH for further information.

Some examples of Schedule I controlled substances include: heroin, lysergic acid diethylamide (LSD), marijuana,<sup>81</sup> and gamma hydroxybutyrate (GHB), and 3, 4-methylenedioxymethamphetamine (“Ecstasy”).<sup>82</sup>

## **Schedule II**

Schedule II controlled substances are considered to have a high potential for abuse, which may lead to severe psychological or physical dependence.<sup>83</sup>

Schedule II prescriptions may only be issued for a 30-day supply of medication.<sup>84</sup> There are two exceptions to this law:

- Prescriptions for methylphenidate and single entity drug products containing dextroamphetamine sulphate and methylphenidate hydrochloride may be issued for up to a 60-day supply when used for the treatment of inattention, impulsivity-hyperactivity disorder or narcolepsy; and
- Prescriptions for implantable infusion pumps containing a Schedule II controlled substance may be issued for a 90-day supply.<sup>85</sup>

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<sup>80</sup> 21 U.S.C. § 823(f); 105 CMR § 700.004(G).

<sup>81</sup> See Part II, Section 6, “Medical Marijuana Law.”

<sup>82</sup> 21 U.S.C. § 812(c).

<sup>83</sup> 21 U.S.C. § 812(b)(2); M.G.L. c. 94C, §3(2).

<sup>84</sup> M.G.L. c. 94C, §23.

<sup>85</sup> M.G.L. c. 94C, §23(d).

Refills of Schedule II drugs are not permitted.<sup>86</sup> Physicians may provide a patient with multiple prescriptions for the same Schedule II controlled substance for a total of up to a 90-day supply.<sup>87</sup> To comply with this federal law, the DPH Drug Control Program, the Board of Registration in Pharmacy, and the Board of Registration in Medicine have adopted a “Joint Policy Regarding Issuance of Multiple Prescriptions for Schedule II Controlled Substances; and Joint Policy on Prescribing and Dispensing of Dextro- and Levo- Amphetamines.”<sup>88</sup> Under this policy, physicians must date the prescriptions so they must be filled sequentially, with the patient receiving no more than a 30-day supply per prescription. The physician must indicate on subsequent prescriptions a “Do Not Fill Before” date, and must indicate the actual date that the prescription is signed.

Schedule II controlled substances may not be prescribed without a written prescription except in emergency situations. “Emergency situations” are defined as “situations in which the practitioner who intends 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.”<sup>89</sup> Pharmacists may not fill verbal prescriptions for Schedule II substances in a quantity exceeding that which is “adequate to treat the patient during the emergency period.”<sup>90</sup> A verbal prescription for a

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<sup>86</sup> 21 U.S.C. § 829; M.G.L. c. 94C, § 23(b).

<sup>87</sup> 21 C.F.R. § 1306.

<sup>88</sup> This policy is attached at Appendix C.

<sup>89</sup> 247 CMR 5.03(1). The federal definition of “emergency situations,” from which the Massachusetts regulation was derived, can be found in 21 C.F.R. § 290.10.

<sup>90</sup> 21 C.F.R. § 1306.11(d)(1).

Schedule II drug must be written and filed with the pharmacy within seven days of the event and the prescription should have written on its face, “Authorization for Emergency Dispensing.”<sup>91</sup>

For ambulatory patients, Schedule II substances may be faxed to pharmacies, but a hard copy prescription must accompany the patient before the medication can actually be dispensed.<sup>92</sup>

The Board strongly urges physicians to see patients who are using Schedule II drugs for long-term treatment as often as possible and suggests that patients be clinically re-evaluated at least once every four months. Documentation should be placed in the record if this is impossible, impractical or inappropriate. As a best practice, the physician should speak with the patient or the patient’s primary physician by telephone before issuing a new Schedule II prescription.<sup>93</sup> 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.

Because of their extremely high potential for abuse, Schedule II controlled substances may not be prescribed to a member of a physician’s immediate family, except in an emergency.<sup>94</sup> The Board also has prohibited physicians from prescribing controlled substances in Schedules II through IV for their own use.<sup>95</sup>

Some examples of Schedule II narcotics include morphine, codeine, hydromorphone, hydrocodone, methadone,<sup>96</sup> meperidine, oxycodone, oxymorphone, Vicodin®, Lortab®, Lorcet®, and fentanyl. Schedule II stimulants include amphetamine (Dexedrine®, Adderall®),

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<sup>91</sup> 21 C.F.R. § 1306.11(d)(4); M.G.L. c. 94C; §20(c); and 247 CMR § 5.03(3).

<sup>92</sup> 21 C.F.R. § 1306.11(a).

<sup>93</sup> See Scott M. Fishman, M.D., “*Responsible Opioid Prescribing, A Physician’s Guide*,” Federation of State Medical Boards, (2d ed. 2014).

<sup>94</sup> 243 CMR 2.07(19).

<sup>95</sup> *Id.*

<sup>96</sup> Methadone may only be prescribed as an analgesic. Methadone may be prescribed for the treatment of chronic pain. However, when methadone is prescribed for treatment of opiate addiction, it must be through federally regulated opiate treatment programs.

methamphetamine and methylphenidate (Ritalin®).<sup>97</sup> Pursuant to the DEA Final Rule of October 6, 2014, hydrocodone combination products were moved from Schedule III to Schedule II.<sup>98</sup>

### **Prescribing Hydrocodone-only Extended-release Medication**

In 2014, the Board of Medicine promulgated a regulation on hydrocodone-only extended release medication.<sup>99</sup> Prior to prescribing a hydrocodone-only extended release medication that is not in an abuse deterrent form, a licensee must:

- (a) Thoroughly assess the patient, including an evaluation of the patient's risk factors, substance abuse history, presenting condition(s), current medication(s), a determination that other pain management treatments are inadequate, and a check of the patient's data through the online Prescription Monitoring Program;
- (b) Discuss the risks and benefits of the medication with the patient;
- (c) Enter into a Pain Management Treatment Agreement with the patient that appropriately addresses drug screening, pill counts, safe storage and disposal and other requirements based on the patient's diagnoses, treatment plan, and risk assessment unless a Pain Management Treatment Agreement is not clinically indicated due to the severity of the patient's medical condition;
- (d) Supply a Letter of Medical Necessity as required by the Board of Registration in Pharmacy pursuant to 247 CMR 9.04(8)(c); and
- (e) Document 243 CMR 2.07(25)(a) through (d) in the patient's medical record.

The purpose of 243 CMR 2.07(25) is to enhance the public health and welfare by promoting optimum therapeutic outcomes, avoiding patient injury and eliminating medication errors. Nothing in 243 CMR 2.07(25) alters the standard of care a licensee must use when prescribing any Schedule II, III or IV controlled substance.

### **Schedule III**

Schedule III controlled substances have a potential for abuse that is less than substances in Schedules I or II. Abuse of Schedule III substances may still lead to physical dependence or psychological dependence.<sup>100</sup>

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<sup>97</sup> 21 U.S.C. § 812(c).

<sup>98</sup> 79 Fed. Reg. 163 (Aug. 22, 2014).

<sup>99</sup> 243 CMR 2.07(25).

<sup>100</sup> 21 U.S.C. § 812(b)(3); M.G.L. c. 94C § 3(3).

Schedule III prescriptions may be issued for up to a 30-day supply with an exception for implantable infusion pumps with a Schedule III substance, which may be filled with a maximum of a 90-day supply.<sup>101</sup>

Schedule III prescriptions may be refilled up to five times within six months of the date of the prescription.<sup>102</sup> Controlled substances that are prescribed without an indication for refills cannot be refilled without authorization by the prescriber.

A Schedule III drug may be prescribed verbally in the absence of an emergency, but the prescription must be written and filed with the pharmacy within seven days.<sup>103</sup> Prescriptions for Schedule III substances may also be faxed. A follow-up hard copy does not need to be filed with the pharmacy.

The Board believes that good medical practice requires a physician to see a patient at least once every six months when prescribing a Schedule III - VI controlled substance over a long period of time. If this is impractical, inappropriate or impossible, an explanation should be recorded in the patient's chart. These exceptions should be extremely rare.

Board regulations prohibit physicians from prescribing controlled substances in Schedule III for their own use.<sup>104</sup>

Some examples of Schedule III controlled substances include: Subutex® and Suboxone®;<sup>105</sup> and combination products containing not more than 90 milligrams of codeine per dosage unit, such as Tylenol with Codeine®. Examples of Schedule III non-narcotics include:

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<sup>101</sup> M.G.L. c. 94C § 23(d).

<sup>102</sup> 21 U.S.C. § 829 (b).

<sup>103</sup> M.G.L. c. 94C § 17(c) and M.G.L. c. 94C § 20(c).

<sup>104</sup> 243 CMR 2.07(19).

<sup>105</sup> Subutex® and Suboxone® and approved generic equivalents require a DATA-waiver and a unique identification number for office-based opiate addiction treatment.

ketamine, benzphetamine (Didrex®) phendimetrazine, and anabolic steroids such as Depo-Testosterone®.<sup>106</sup>

#### **Schedule IV**

Schedule IV controlled substances have a low potential for abuse relative to the substances in Schedule III, but may still lead to physical or psychological dependence.<sup>107</sup> Schedule IV prescriptions may be refilled up to five times within six months of the date of the prescription.<sup>108</sup> A Schedule IV drug may be prescribed verbally in the absence of an emergency, but the prescription must be written and filed with the pharmacy within seven days.<sup>109</sup> Prescriptions for Schedule IV substances may also be faxed. A follow-up hard copy does not need to be filed with the pharmacy.

The Board has prohibited physicians from prescribing controlled substances in Schedule IV for their own use.<sup>110</sup>

Some examples of Schedule IV controlled substances include: long-acting barbiturates such as phenobarbital (Luminal®), and mephobarbital (Mebaral®); ultrashort-acting barbiturates such as methohexital (Brevital®); benzodiazepines such as estazolam (ProSom®), flurazepam (Dalmane®), temazepam (Restoril®), triazolam (Halcion®), midazolam (Versed®), alprazolam (Xanax®), diazepam (Valium®), lorazepam (Ativan®), clonazepam (Klonopin®); and dextropropoxyphene forms: Darvon®, Darvocet®, Dolene®, Propacet®, propoxyphene and tramadol (Ultram®).

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<sup>106</sup> 21 U.S.C. § 812(c).

<sup>107</sup> 21 U.S.C. § 812(b)(4); M.G.L. c. 94C, § 3.

<sup>108</sup> 21 U.S.C. § 829(b).

<sup>109</sup> M.G.L. c. 94C, §17(c); M.G.L. c. 94C, §20(c).

<sup>110</sup> 243 CMR 2.07(19).



## **Schedule V**

Schedule V controlled substances have a low potential for abuse compared to the substances in Schedule IV but may lead to some physical dependence or psychological dependence.<sup>111</sup> A Schedule V drug may be prescribed verbally in the absence of an emergency, but the prescription must be written and filed with the pharmacy within seven days.<sup>112</sup> Prescriptions for Schedule V substances may also be faxed. A follow-up hard copy does not need to be filed with the pharmacy.

Examples of Schedule V controlled substances include: cough preparations of not more than 100 milligrams of codeine per 100 milliliters or per 100 grams Robitussin AC® and Phenergan with Codeine®.

## **Schedule VI**

Prescription drugs that do not fall within Schedules II through V are considered to be Schedule VI controlled substances in Massachusetts.<sup>113</sup> This is a special Massachusetts schedule. Physicians may dispense up to a 30-day supply of Schedule VI sample medications. Larger supplies of sample medications, up to 90 days, may be dispensed as part of a manufacturer's indigent patient drug program.<sup>114</sup> Physicians must label all sample medications dispensed to patients, including those provided as part of an indigent patient drug program.<sup>115</sup> Physicians who provide samples of Schedule VI drugs to their patients are required to keep a record of such dispensing.<sup>116</sup>

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<sup>111</sup> 21 U.S.C. § 812(b)(5); M.G.L. c. 94C, §3(5)

<sup>112</sup> M.G.L. c. 94C, §17(c); M.G.L. c. 94C, §20(c).

<sup>113</sup> M.G.L. c. 94C, § 2(a); 105 CMR 700.002(F).

<sup>114</sup> 105 CMR 700.010

<sup>115</sup> 105 CMR 700.010

<sup>116</sup> 105 CMR 700.006(F)(5). *See infra* Part II, Section 4, "Dispensing."

As with all controlled substances, there are some Schedule VI drugs that can be misused or abused. Physicians are encouraged to visit the U.S. Department of Justice Diversion Control website at [www.deadiversion.usdoj.gov](http://www.deadiversion.usdoj.gov).

### **Prescribing Naloxone**

Opioid overdose is one of the leading causes of death in Massachusetts.<sup>117</sup> According to the Massachusetts Department of Public Health, “the rate of unintentional opioid-related overdose deaths, which includes deaths related to heroin, reached levels in 2013 previously unseen in Massachusetts.”<sup>118</sup>

In an overdose, opioids can slow breathing to the point of death. The drug naloxone (trade name Narcan®) is an opioid antagonist. Naloxone blocks the opioids and restores normal breathing when sprayed in the nose of someone who has overdosed. Naloxone is not an abusable drug.<sup>119</sup>

In 2012, the Massachusetts Legislature passed M.G.L. c. 94C, § 19(d):

Naloxone or other opioid antagonist may lawfully be prescribed and dispensed to a person at risk of experiencing an opiate-related overdose or a family member, friend or other person in a position to assist a person at risk of experiencing an opiate-related overdose. For purposes of this chapter and chapter 112, any such prescription shall be regarded as being issued for a legitimate medical purpose in the usual course of professional practice.

St. 2012, c. 192, § 11

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<sup>117</sup> “Fatalities in Massachusetts related to opioid overdose are projected to have increased by 46% from 2012 to 2013.” Center for Health Information and Analysis, *Access to Substance Use Disorder Treatment in Massachusetts*, (April 2015) page 1.

<sup>118</sup> “The rate of 14.5 deaths per 100,000 residents for 2013 was the highest ever for unintentional opioid overdoses and represents a 273% increase from the rate of 5.3 deaths per 100,000 residents in 2000.” Massachusetts Dept. of Public Health: *Data Brief: Fatal Opioid-related Overdoses among MA Residents*, (April 2015).

<sup>119</sup> Naloxone is a Schedule VI in Massachusetts, a schedule that consists of all prescription drugs that are not included in Schedules II – V.

In 2014, the Board issued a Statement supporting the Massachusetts Pharmacy Rescue Kit Access Program.<sup>120</sup> “The Board encourages its licensees to abide by the protocols of the program and the statute which allows for the prescribing of naloxone to individuals overdosing on opioids in the absence of a physician-patient relationship, and for a Standing Order for naloxone to be provided to pharmacists.” The Board notes that this is an exception to the Board’s long-held policy that prescribing must be done in the context of a physician-patient relationship.

### **3. PRESCRIPTIONS**

#### **The Prescription Slip**

The Massachusetts controlled substances law states:

A practitioner who dispenses a controlled substance by issuing a written prescription shall state on the prescription the name, address and registration number of the practitioner, the date of delivery of the prescription, the name, dosage and strength per dosage unit of the controlled substance, the name and address of the patient unless it is a veterinary prescription, the directions for use and any cautionary statements required, and a statement indicating the number of times to be refilled.<sup>121</sup>

Accordingly, every prescription written in the Commonwealth must be written on a form that contains the following:

- A signature line for the physician’s signature;
- Space in which the physician may write in his or her own handwriting the words “no substitution;”
- The name and address of the physician (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;
- The registration number of the physician;
- 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;

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<sup>120</sup> Board of Reg. in Medicine, Statement, (Adopted Sept. 10, 2014); accessible at <http://www.mass.gov/eohhs/docs/borim/board-statements/board-statement-naloxone-20140910.pdf>

<sup>121</sup> M.G.L. c. 94C, § 22(a).

- Directions for use, including any cautionary statements required; and
- A statement indicating the number of times the prescription may be refilled.<sup>122</sup>

### **Tamper Resistant Prescription Law**

Federal law requires that all written prescriptions for outpatient drugs that are paid for by Medicaid must be executed on a tamper-resistant prescription.<sup>123</sup> In addition, Massachusetts law requires that all prescriptions for drugs in Schedules II-VI be executed on a tamper-resistant form consistent with the Medicaid requirements even if not written for a Medicaid patient.<sup>124</sup> To be considered tamper-resistant, a prescription pad must contain the following three characteristics:

- 1) One or more industry-recognized features designed to prevent unauthorized copying of a completed or blank prescription form (for example: a high security watermark on the reverse side of blank, or the use of thermochromic ink);
- 2) One or more industry-recognized features designed to prevent the erasure or modification of information written on the prescription pad by the prescriber (for example: tamper-resistant background ink showing erasures or attempts to change written information); and
- 3) One or more industry-recognized features designed to prevent the use of counterfeit prescription forms (for example: sequentially numbered blanks or duplicate or triplicate blanks).<sup>125</sup>

### **Faxing Prescriptions**

For ambulatory patients, Schedule II substances may be faxed to pharmacies, but a hard copy prescription must accompany the patient before the medication can actually be dispensed.<sup>126</sup> 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

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<sup>122</sup> 105 CMR 721.020.

<sup>123</sup> U.S. Troop Readiness, Veterans' Care, Katrina Recovery and Iraq Accountability Appropriations Act of 2007, Pub. L. No. 110-28, § 7002 (2008).

<sup>124</sup> M.G.L. c. 94C, § 23(g); 105 CMR 721.020(F).

<sup>125</sup> Centers for Medicare and Medicaid Services, Bureau of Health Care Quality and Safety, *Memorandum to Prescribers and Pharmacists; "Medicaid Tamper Resistant Prescription Law"* (August 7, 2013).

<sup>126</sup> 21 C.F.R. § 1306.11(a)

programs.<sup>127</sup> 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.<sup>128</sup> 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.

### **Electronic Prescribing**

Federal law permits electronically transmitted prescriptions for Schedule II through V controlled substances. The Drug Enforcement Administration (DEA) issued an Interim Final Rule, overturning the federal prohibition on electronically prescribing controlled substances (EPCS), subject to certain restrictions.<sup>129</sup> The effective date of the Final Rule was June 1, 2010. The DEA Rule gives licensed prescribers the option of submitting electronic prescriptions and permits pharmacies to receive, dispense and archive electronic prescriptions with approved EPCS software. When electronically prescribing Schedule II-V controlled substances, there must be independent third party verification of the prescriber and there must be a two-factor authentication on each individual prescription.

Schedule III - VI prescriptions may be electronically transmitted from a physician to a pharmacy.<sup>130</sup> The prescription must be electronically transmitted in a manner that maintains patient confidentiality.<sup>131</sup> Such a prescription must either bear the physician's electronic signature or employ some other secure method of validation.<sup>132</sup>

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<sup>127</sup> 21 C.F.R. § 1306.11(g).

<sup>128</sup> 21 C.F.R. § 1306(11)(e).

<sup>129</sup> 75 Fed. Reg. No. 61 (Wednesday, March 31, 2010); Rules and Regulations, Drug Enforcement Administration, 21 C.F.R. Parts 1300, 1304, 1306 and 1311.

<sup>130</sup> M.G.L. c. 94C, §23(g); 247 CMR 5.02(1); 105 CMR 721.020(A)(3) and 105 CMR 721.030.

<sup>131</sup> 247 CMR 5.02(1).

<sup>132</sup> 105 CMR 721.030.

## **Verbal Authorization**

Schedule II controlled substances may not be prescribed without a written prescription except in emergency situations. A verbal prescription for a Schedule II drug must be written and filed with the pharmacy within seven days of being issued, and the prescription should have written on its face, “Authorization for Emergency Dispensing.”<sup>133</sup> Drugs in Schedules III - V may be prescribed by verbal prescription in the absence of an emergency but the prescription must be written and filed with the pharmacy within seven days. Verbal prescriptions may be communicated to a pharmacist by an expressly authorized employee or agent of the physician.<sup>134</sup>

## **4. DISPENSING**

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.<sup>135</sup> A physician must have a separate DEA certificate of registration and MCSR number for each location at which he or she dispenses controlled substances.<sup>136</sup>

### **General Requirements**

Federal law permits physicians to dispense Schedule II controlled substances without a prescription only in emergency situations.<sup>137</sup> Under both Federal and Massachusetts law, physicians may dispense controlled substances in Schedules III - V without a prescription, as long as the drug is being delivered or administered directly to the patient for legitimate medical

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<sup>133</sup> 21 C.F.R. § 1306.11(d)(4); M.G.L. c. 94C, §20(c); and 247 CMR 5.03(3).

<sup>134</sup> M.G.L. c. 94C, §20(c).

<sup>135</sup> The Federal and Massachusetts definitions of “dispense” are nearly identical. *See* 21 U.S.C. § 802(10) and M.G.L. c. 94C, § 1.

<sup>136</sup> 21 U.S.C. § 822(e); 105 CMR 700.004(F). *See* Part I, Section 1, “Registration Requirements.”

<sup>137</sup> 21 U.S.C. § 829(a).

purposes.<sup>138</sup> In Massachusetts, the physician must be dispensing the medication for immediate treatment, which 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.”<sup>139</sup> This includes sample medications in Schedules II - V that have been supplied to the physician by pharmaceutical company representatives.

Massachusetts physicians are permitted to dispense up to a 30-day supply of Schedule VI sample medications.<sup>140</sup> Physicians may dispense larger supplies of sample medications, up to 90 days, as part of a manufacturer's indigent drug program.<sup>141</sup> All sample medications dispensed to patients, including those provided as part of an indigent patient drug program, must be labeled.<sup>142</sup>

Under M.G.L. c. 94C, § 19, physicians may not issue prescriptions for controlled substances for the purpose of dispensing or selling those drugs to patients.<sup>143</sup>

### **Labeling**

When a physician does dispense a controlled substance 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 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.<sup>144</sup>

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<sup>138</sup> 21 U.S.C. § 829; M.G.L. c. 94C, § 9(b) and 105 CMR 700.010(A)(2).

<sup>139</sup> M.G.L. c. 94C, § 9(b).

<sup>140</sup> 105 CMR 700.010(A)(1).

<sup>141</sup> M.G.L. c. 94C, § 9 and 105 CMR 700.010(A)(1).

<sup>142</sup> M.G.L. c. 94C §22 and 105 CMR 700.010

<sup>143</sup> M.G.L. c. 94C, §19(b).

<sup>144</sup> M.G.L. c. 94C, §22(b) and 105 CMR 700.010

Physicians who provide samples of Schedule VI drugs to their patients must keep a record of the drug dispensed in the patient's medical record, noting:

- The name, dosage and strength of the substance dispensed;
- The volume of units dispensed;
- The date of the dispensing; and
- The name and address of the person to whom the medication was dispensed.<sup>145</sup>

*See also* Appendix D, DPH Labeling Guidelines for Sample Prescription Drugs.

### **Recordkeeping Requirements**

There are strict record-keeping requirements for physicians who stock controlled substances.<sup>146</sup> Physicians who stock controlled substances in Schedules II and III must maintain records of:

- Their receipt and/or administration, including the names and quantities of the controlled substances,
- The name and address of the patient to whom it is administered or dispensed;
- The name, dosage and strength per dosage unit of each controlled substance; and
- The date of the administration or dispensing.<sup>147</sup>

Inventories and records of Schedules II controlled substances that are dispensed to patients must be maintained in records separate from the inventories and records of other controlled substances dispensed.<sup>148</sup> Inventories and records of controlled substances in Schedules III, IV, and V must be maintained separately, as well.<sup>149</sup> All drug records and inventories must be readily retrievable from the physician's ordinary business records.<sup>150</sup>

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<sup>145</sup> 105 CMR 700.006(F)(5).

<sup>146</sup> 21 U.S.C. §§ 331(t), 333(b), and 353(c)-(d); 21 U.S.C. §§ 824, 827; 21 C.F.R. § 1304.21; M.G.L. c. 94C, § 9(d) and 105 CMR 700.006.

<sup>147</sup> 21 C.F.R. § 1304.03(b); 21 C.F.R. § 1304.22 and M.G.L. c. 94C, § 9(d).

<sup>148</sup> 21 U.S.C. § 827(b) and 21 C.F.R. § 1304.04(g).

<sup>149</sup> *Id.*

<sup>150</sup> *Id.*



Physicians must take a detailed, initial inventory of all controlled substances on hand for each location at which they dispense, with subsequent inventories done at least every two years.<sup>151</sup> All records related to controlled substances must be maintained at the registered location for at least two years and be available for inspection for a minimum of two years.<sup>152</sup>

Physicians who provide samples of Schedule VI drugs to their patients must keep a record of the drug dispensed (the record may be kept in the patient's medical record), noting:

- The name, dosage and strength of the substance dispensed;
- The volume of units dispensed;
- The date of the dispensing, and
- The name and address of the person to whom the medication was dispensed.<sup>153</sup>

### **Security Requirements**

All physicians who dispense controlled substances must have effective controls and procedures to guard against theft and diversion.<sup>154</sup>

Schedule II through V controlled substances must be in a securely locked, substantially constructed cabinet. Physicians are required to screen all employees or agents who will be working in areas where controlled substances are handled, and are prohibited from knowingly employing anyone who:

- Has been convicted of a felony offense related to controlled substances;
- Has been denied a DEA registration;
- Has had a DEA registration revoked; or
- Has surrendered a DEA registration for cause.<sup>155</sup>

Physicians should notify the DEA when they discover any thefts or significant losses of controlled substances from stock and complete the necessary DEA forms regarding the theft or

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<sup>151</sup> 21 C.F.R. § 1304.11(b); 21 C.F.R. § 1304.11(c) and 105 CMR 700.006.

<sup>152</sup> 21 U.S.C. § 827(c); 21 U.S.C. § 880; 21 C.F.R. § 1304.21 and 105 CMR 700.007.

<sup>153</sup> 105 CMR 700.006(F)(5).

<sup>154</sup> 21 C.F.R. §§ 1301.71(a), 1301.75 and 105 CMR 700.005(A).

<sup>155</sup> 21 C.F.R. § 1301.76(a) and 105 CMR 700.005(B).

loss.<sup>156</sup> Physicians must also report drug theft, loss or any drug discrepancy to the Massachusetts Drug Control Program (DCP) within 24 hours of discovery by:

- Telephoning DCP within 24 hours, then mailing a Drug Incident Report (DIR) to the DCP within 7 days; or
- By visiting the DCP website, downloading a DIR form and faxing that form to DCP with 24 hours.<sup>157</sup>

The submission of the DIR form will satisfy DCP's requirements for both a telephonic and written report. Physicians should submit all subsequent relevant information they discover to the DCP.

Physicians may dispose of out-of-date, damaged, or otherwise unusable or unwanted controlled substances, including samples, by transferring them to a registrant who is authorized to receive such materials. Schedule I and II controlled substances should be transferred via the DEA Form 222, while Schedule III–V compounds may be transferred via invoice. In Massachusetts, the DCP is responsible for drug destruction. Physicians should maintain copies of the records documenting the transfer and disposal of controlled substances for a period of two years.

## **5. PRESCRIPTION MONITORING PROGRAM**

The Commonwealth's Prescription Monitoring Program (PMP), which is administered by the Department of Public Health (DPH), is a repository for a patient's prescription history for Schedule II – V prescriptions.<sup>158</sup> All Massachusetts pharmacies and out-of-state pharmacies delivering to people in Massachusetts provide prescription data to the PMP.<sup>159</sup>

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<sup>156</sup> 21 C.F.R. § 1301.76(b).

<sup>157</sup> 105 CMR 700.005(D).

<sup>158</sup> M.G.L. c. 94C, § 24A.

<sup>159</sup> M.G.L. c. 94C, § 24A(2)(c); 105 CMR 700.012(A).

Physicians should note that DPH reviews the PMP information<sup>160</sup> and, if there is reasonable cause to believe a violation of law or breach of professional standards may have occurred, DPH will notify the Board or the appropriate law enforcement agency.<sup>161</sup> DPH will provide the Board with PMP information that the Board requires for an investigation.<sup>162</sup>

All questions about the specific operation of and access to the PMP should be addressed to DPH's Drug Control Program. *See* Appendix A (Contact information).

### **Required and Exempted Usage**

All physicians who have renewed their MCSR on or after January 1, 2013, were automatically granted authority to use the PMP,<sup>163</sup> which provides the physician with a patient's prescription history for the prior 12 months.<sup>164</sup>

All physicians, unless specifically exempted, are required to use the prescription monitoring program in the following circumstances:

- Prior to prescribing a narcotic drug in Schedule II or III to a patient for the first time;<sup>165</sup>
- Each time the prescriber issues a prescription to a patient for any drug in Schedule II or III that "has been determined by the Department of Public Health to be commonly misused or abused and which has been designated as a drug that needs additional safeguards in guidance to be issued by the Department of Public Health;"<sup>166</sup>
- Prior to prescribing a benzodiazepine to a patient for the first time;<sup>167</sup> and
- Prior to prescribing a Schedule IV or V controlled substance, "as designated in guidance to be issued by the Department," to a patient for the first time.<sup>168</sup>

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<sup>160</sup> M.G.L. c. 94C, § 24A(2)(e); 105 CMR 700.012(D)(5).

<sup>161</sup> *Id.*

<sup>162</sup> *Id.*

<sup>163</sup> M.G.L. c. 94C, § 7A; 105 CMR 700.012(G).

<sup>164</sup> Mass. Dept. of Public Health, Bureau of Health Care Safety and Quality, Prescription Monitoring and Drug Control Program "*PMP Frequently Asked Questions, November 2014.*"

<sup>165</sup> M.G.L. c. 94C, §24A(2)(c); 105 CMR 700.012(H)(1)(a).

<sup>166</sup> 105 CMR 700.012(H)(2).

<sup>167</sup> M.G.L. c. 94C, §24A(2)(c); 105 CMR 700.012(H)(1)(c).

Physicians are not required to use the PMP in the following circumstances, however:

- If they hold a MCSR that permits them to prescribe, administer, possess, order, or dispense samples of controlled substances only in Schedule VI;<sup>169</sup>
- If they have been granted a waiver by DPH;<sup>170</sup>
- When they are providing medical care to hospice patients;<sup>171</sup>
- When they are treating a patient in an Emergency Department and they *do not*:
  - anticipate writing a prescription for a controlled substance in Schedules II through V during that encounter with the patient;<sup>172</sup> or
  - prescribe more than a five-day supply of a controlled substance in Schedules II through V;<sup>173</sup>
- When emergency care is required and, in their professional opinion, utilization of the prescription monitoring program is likely to result in patient harm;<sup>174</sup>
- When they are providing medical care to hospital inpatients;<sup>175</sup>
- When delivering a controlled substance in a single dose or in a quantity that is essential for the immediate and proper treatment of the patient, until it is possible for the patient to have a prescription filled by a pharmacy;<sup>176</sup>
- When it is not reasonably possible to use the PMP, including when the system is not operational due to temporary technological or electrical failure;<sup>177</sup>
- When they are examining or treating a pediatric patient who is less than 8 years old; or
- Where DPH has articulated another exception.<sup>178</sup>

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<sup>168</sup> *Id.*

<sup>169</sup> 105 CMR 700.012(H)(3)(a).

<sup>170</sup> 105 CMR 700.012(H)(3)(i) and (I).

<sup>171</sup> 105 CMR 700.012(H)(3)(b).

<sup>172</sup> 105 CMR 700.012(H)(3)(c).

<sup>173</sup> *Id.*

<sup>174</sup> 105 CMR 700.012(H)(3)(d).

<sup>175</sup> 105 CMR 700.012(H)(3)(e).

<sup>176</sup> 105 CMR 700.012(H)(3)(f). *See also* M.G.L. c. 94C, § 9(b).

<sup>177</sup> 105 CMR 700.012(H)(3)(g).

<sup>178</sup> 105 CMR 700.012(H)(3)(j).

## **The Use of the PMP by the Physician’s Staff**

Physicians may authorize their support staff members to use the PMP on their behalf (“Delegates”).<sup>179</sup> Note, however, that individuals eligible to be primary PMP account holders (i.e., advanced practice nurses and physicians assistants with their own MCSR) cannot be delegates.<sup>180</sup>

DPH expects that medical offices that use delegates will have “written policies and procedures regarding the management and security of [PMP] data;” physicians are required to provide such written policies and procedures to DPH upon their request.<sup>181</sup>

Physicians are responsible for all delegate use of the PMP and must:

1. Take reasonable steps to ensure that delegates are sufficiently competent in the use of the PMP;<sup>182</sup>
2. Monitor delegates’ use of the PMP;<sup>183</sup>
3. Ensure that delegates comply with the PMP “Sub-account User Terms and Conditions;”<sup>184</sup>
4. Inform DPH when a delegate has violated the Sub-account User Terms and Conditions; and<sup>185</sup>
5. When a delegate is no longer authorized to be a delegate, inform DPH of this action within one business day.<sup>186</sup>

## **Consequences for Misuse of the PMP**

If DPH learns that a physician may have used the prescription monitoring program in a manner that is inconsistent with the terms and conditions for its use, DPH may immediately

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<sup>179</sup> M.G.L. c. 94C, §24A(2)(c); 105 CMR 700.012(J)(1). *See also* 105 CMR 700.012(D)(2)(a); 105 CMR 700.004(2)(n) through (q), (w).

<sup>180</sup> *Id.*

<sup>181</sup> 105 CMR 700.012(J)(2).

<sup>182</sup> 105 CMR 700.012(J)(3)(c).

<sup>183</sup> 105 CMR 700.012(J)(3)(b).

<sup>184</sup> 105 CMR 700.012(J)(3)(a).

<sup>185</sup> *Id.*

<sup>186</sup> *Id.*

restrict electronic access to the prescription monitoring program system;<sup>187</sup> and will contact the prescribing physician to investigate the potential violation.<sup>188</sup>

If the investigation does not reveal a violation, DPH will immediately reinstate electronic access.<sup>189</sup> If the investigation reveals a violation, DPH may, depending on the severity of the violation, take the following actions:

- Issue a warning letter to the physician;<sup>190</sup>
- Require training on the appropriate use of the PMP;<sup>191</sup>
- Temporarily suspend the access to the PMP;<sup>192</sup> and
- Take action pursuant to suspend, revoke, or refuse to renew the physician's MCSR.<sup>193</sup>

The primary account holder is responsible for all delegate use of the PMP and may be referred to the Board if delegate use is inconsistent with the Sub-Account User Terms and Conditions. If a delegate misuses the PMP, DPH may report the primary account holder to the Board.<sup>194</sup> Physicians may contest the DPH's findings, in writing, and request further review.<sup>195</sup>

## **6. MASSACHUSETTS MEDICAL MARIJUANA LAW**

On November 6, 2012, the citizens of Massachusetts voted through the initiative process to pass a medical marijuana law.<sup>196</sup> The law went into effect on January 1, 2013.<sup>197</sup>

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<sup>187</sup> 105 CMR 700.012(K)(1)(a).

<sup>188</sup> 105 CMR 700.012(K)(1)(b).

<sup>189</sup> 105 CMR 700.012(K)(2).

<sup>190</sup> 105 CMR 700.012(K)(3)(a).

<sup>191</sup> 105 CMR 700.012(K)(3)(b).

<sup>192</sup> 105 CMR 700.012(K)(3)(c).

<sup>193</sup> 105 CMR 700.012(K)(3)(d); 105 CMR 700.115.

<sup>194</sup> 105 CMR 700.012(J)(4).

<sup>195</sup> 105 CMR 700.012(K)(4).

<sup>196</sup> The Massachusetts law, St. 2012, c. 369, § 1, reads, "The citizens of Massachusetts intend that there should be no punishment under state law for qualifying patients, physicians and health care professionals, personal caregivers for patients, or medical marijuana treatment center agents for the medical use of marijuana, as defined herein." The federal law on marijuana is different from the Massachusetts law.

<sup>197</sup> St. 2012, c. 369, § 16.

Physicians are now permitted to do the following, without fear of punishment under state law:

- advise a qualifying patient about the risks and benefits of medical use of marijuana; and
- provide a qualifying patient with written certification, based upon a full assessment of the qualifying patient's medical history and condition, that the medical use of marijuana may benefit a particular qualifying patient.<sup>198</sup>

However, it is important to note that Massachusetts law does not grant immunity under federal law,<sup>199</sup> nor does it prevent the federal government from enforcing federal law.<sup>200</sup> Marijuana is a Schedule I controlled substance under federal law.

A physician may decline to prescribe medical marijuana. A physician is not required to authorize the use of medical marijuana for a patient.<sup>201</sup>

### **Physician Registration**

If a physician wants to certify qualifying patients to use medical marijuana, the physician must be registered with the Department of Public Health as a “certifying physician.”<sup>202</sup> In order to register, a physician must have at least one established place of practice in Massachusetts;<sup>203</sup> have an active full license to practice medicine in Massachusetts, without any prescribing restrictions;<sup>204</sup> and have a Massachusetts Controlled Substances Registration.<sup>205</sup> In addition, a certifying physician issuing a written certificate on or after July 1, 2014 must complete a minimum of 2.0 Category 1 continuing professional development (CPD) credits from a program that explains the proper use of marijuana, including side effects, dosage, and contraindications,

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<sup>198</sup> St. 2012, c. 369, § 3 “Protection from State Prosecution and Penalties for Health Care Professionals.”

<sup>199</sup> St. 2012, c. 369, § 7(F).

<sup>200</sup> St. 2012, c. 369, § 7(G).

<sup>201</sup> St. 2012, c. 369, § 7(C).

<sup>202</sup> 105 CMR 725.005.

<sup>203</sup> 105 CMR 725.005(A).

<sup>204</sup> 105 CMR 725.005(A)(1).

<sup>205</sup> 105 CMR 725.005(A)(2).

including with psychotropic drugs, as well as on substance misuse recognition, diagnosis, and treatment related to marijuana.<sup>206</sup>

Physicians need to register only once,<sup>207</sup> but must notify DPH after any changes to their information, within five business days of the change.<sup>208</sup>

### **Patients Who Qualify for the Medical Use of Marijuana**

Physicians may certify only patients who qualify for the medical use of marijuana and with whom they have a bona fide physician-patient relationship.<sup>209</sup> In order to qualify, a patient must be a Massachusetts resident<sup>210</sup> and have one of the following debilitating medical conditions,<sup>211</sup> which is active:<sup>212</sup>

- cancer;
- glaucoma;
- positive status for human immunodeficiency virus (HIV);
- acquired immune deficiency syndrome (AIDS);
- hepatitis C;
- amyotrophic lateral sclerosis (ALS);
- Crohn’s disease;
- Parkinson’s disease;
- multiple sclerosis (MS); or
- other debilitating condition as determined in writing by the physician.

“Debilitating” is defined as causing weakness, cachexia, wasting syndrome, intractable pain or nausea, or impairing strength or ability, and progressing to the extent that one or more of a patient’s major life activities is substantially limited.<sup>213</sup>

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<sup>206</sup> 105 CMR 725.010(A) and 725.005(C)(4).

<sup>207</sup> 105 CMR 725.005(C).

<sup>208</sup> 105 CMR 725.005(D).

<sup>209</sup> St. 2012, c. 369, §§ 2(K), 2(N), and 3; 105 CMR 725.004 (definition of “Bona Fide Physician-Patient Relationship”); 105 CMR 725.010(F) and (M).

<sup>210</sup> 105 CMR 725.004 (definition of “Qualifying Patient”).

<sup>211</sup> St. 2012, c. 369, § 2(C); 105 CMR 725.004 (definition of “Debilitating Medical Condition”).

<sup>212</sup> 105 CMR 725.010(F). NOTE: A patient’s debilitating medical condition is still active if it is the medical use of marijuana that has mitigated the patient’s symptoms.

<sup>213</sup> 105 CMR 725.004 (definition of “Debilitating”).



All patients under 18 years of age must also:

- have been diagnosed by two certifying physicians, at least one of whom is a board-certified pediatrician or board-certified pediatric subspecialist,<sup>214</sup> who have a role in the patient’s ongoing care and treatment;<sup>215</sup>
- have a debilitating medical condition that is life-limiting in that it:
  - does not respond to curative treatments; and
  - reasonable estimates of prognosis suggest death may occur within two years;<sup>216</sup>
- have a debilitating medical condition that is not life-limiting, but the two certifying physicians have:
  - determined that the benefits of the medical use of marijuana outweigh the risks;
  - discussed the potential negative impacts on neurological development with the parent or legal guardian of the qualifying patient;
  - obtained written consent of the parent or legal guardian; and
  - documented the rationale in the patient’s medical record and on the written certification.<sup>217</sup>

## **Certifying a Qualified Patient**

### **1. The Physician-Patient Encounter**

Before certifying a qualifying patient, the physician must:

- conduct a clinical visit with the patient, especially before the initial written certification;<sup>218</sup>
- conduct a clinical visit with the qualifying patient no less than once per year;<sup>219</sup>
- complete and document a full assessment of the patient’s medical history and current medical condition;<sup>220</sup>
- explain to the patient the potential benefits and risks of marijuana use;<sup>221</sup>
- have a role in the ongoing care and treatment of the patient;<sup>222</sup>
- review the qualifying patient’s prescription history, using the Massachusetts Prescription Monitoring Program (PMP);<sup>223</sup> and

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<sup>214</sup> 105 CMR 725.004 (definition of “Qualifying Patient”); 105 CMR 725.010(J).

<sup>215</sup> 105 CMR 725.004 (definition of “Bona Fide Physician-Patient Relationship”).

<sup>216</sup> 105 CMR 725.004 (definitions of “Life-Limiting Illness” and “Qualifying Patient”); 105 CMR 725.010(J).

<sup>217</sup> 105 CMR 725.010(J).

<sup>218</sup> 105 CMR 725.004 (definition of “Bona Fide Physician-Patient Relationship”) and 725.010(G). The physician may provide a renewal written certification after clinical visit or telephone consultation.

<sup>219</sup> 105 CMR 725.010(G).

<sup>220</sup> 105 CMR 725.004 (definition of “Bona Fide Physician-Patient Relationship”).

<sup>221</sup> *Id.*

<sup>222</sup> *Id.*

<sup>223</sup> 105 CMR 725.010(E). A physician should be aware of the dangers of combining opioids or benzodiazepines with medical marijuana.

- act in the usual course of their professional practice,<sup>224</sup> complying with the accepted standards of medical practice,<sup>225</sup> and with Board of Registration in Medicine regulations.<sup>226</sup>

If the physician determines that a qualifying patient requires more than 10 ounces as a 60-day supply, he or she must document the amount required and the rationale in the medical record.<sup>227</sup>

Physicians may charge an appropriate fee for a qualifying patient’s clinical visit.<sup>228</sup>

Health insurance providers are not required to reimburse any person for the expenses of the medical use of marijuana.<sup>229</sup>

## 2. **The Written Certification**

The written certification must be issued in a form and manner determined by DPH.<sup>230</sup> Qualifying patients must obtain a registration card from DPH.<sup>231</sup> To obtain a registration card, they must provide the written certification to DPH.<sup>232</sup>

When certifying a qualifying patient, the physician must:

- describe the patient’s pertinent symptoms;<sup>233</sup>
- specify the patient’s debilitating medical condition;<sup>234</sup>
- state that, in his or her professional opinion, the potential benefits of the medical use of marijuana would likely outweigh the health risks for the patient;<sup>235</sup>

<sup>224</sup> 105 CMR 725.004 (definition of “Bona Fide Physician-Patient Relationship”).

<sup>225</sup> 105 CMR 725.010(B).

<sup>226</sup> *Id.*

<sup>227</sup> 105 CMR 725.010(I). NOTE: Qualifying patients may lawfully possess 10 ounces of marijuana for medical use, unless the certifying physician states that 10 ounces is not a sufficient 60-day supply. St. 2012, c. 369, § 4(a); 105 CMR 725.004 (definition of “Sixty-Day Supply”).

<sup>228</sup> 105 CMR 725.010(K)(5).

<sup>229</sup> St. 2012, c. 369, § 7(B). This includes any government agency or authority that provides reimbursement for medical expenses.

<sup>230</sup> 105 CMR 725.010(N).

<sup>231</sup> St. 2012, c. 369, §§ 1(L) and 2(B); 105 CMR 725.015.

<sup>232</sup> 105 CMR 725.015(2) and (3).

<sup>233</sup> 105 CMR 725.004 (definition of “Written Certification”).

<sup>234</sup> *Id.*

<sup>235</sup> *Id.*

- indicate the period of time that the written certification is valid; the time period cannot be not less than 15 calendar days or longer than one year;<sup>236</sup>and
- document the amount of marijuana the patient requires if the patient requires more than 10 ounces as a 60-day supply; the physician must also document the rationale for more than 10 ounces.<sup>237</sup>

### **Prohibited Conduct**

Certifying physicians are prohibited from:

- issuing a written certification for himself or herself or for his or her immediate family members;<sup>238</sup>
- delegating to any other health care professional or any other person, authority to diagnose a patient as having a debilitating medical condition;<sup>239</sup>
- examining or counseling a patient at a Registered Marijuana Dispensary (RMD);<sup>240</sup>
- issuing a written certification at a RMD;<sup>241</sup>
- having a direct or indirect financial interest in a RMD;<sup>242</sup>
- offering anything of value, directly or indirectly, to RMD board members, executives, personnel, or any other person associated with an RMD, or from a patient’s personal caregiver;<sup>243</sup>
- offering a discount or any other thing of value to a qualifying patient based on the patient’s agreement or decision to use a particular personal caregiver or RMD;<sup>244</sup>
- directly or indirectly benefitting from a patient obtaining a written certification; and<sup>245</sup>

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<sup>236</sup> 105 CMR 725.010(H).

<sup>237</sup> 105 CMR 725.010(I).

<sup>238</sup> 105 CMR 725.010(L).

<sup>239</sup> 105 CMR 725.010(C). *But see* 105 CMR 725.650(C) (citing to M.G.L. c. 112, § 80I, which relates to advanced practice nurses’ authority to sign certificates that require the signature of a physician).

<sup>240</sup> 105 CMR 725.010(K)(3). NOTE: The physician’s co-workers, employees, and immediate family members are also prohibited from such interactions.

<sup>241</sup> *Id.*

<sup>242</sup> 105 CMR 725.010(K)(4). NOTE: The physician’s co-workers, employees, and immediate family members are also prohibited from such interactions.

<sup>243</sup> 105 CMR 725.010(K)(1). NOTE: The physician’s co-workers, employees, and immediate family members are also prohibited from such interactions.

<sup>244</sup> 105 CMR 725.010(K)(2). NOTE: The physician’s co-workers, employees, and immediate family members are also prohibited from such interactions.

<sup>245</sup> 105 CMR 725.010(K)(5) NOTE: The physician’s co-workers, employees, and immediate family members are also prohibited from such interactions.

- accepting or soliciting anything of value, directly or indirectly, from RMD board members, executives, personnel, or any other person associated with an RMD, or from a patient’s personal caregiver.<sup>246</sup>

A physician will not retain his or her DPH registration as a certifying physician if one of the following occurs:<sup>247</sup>

- The physician’s license to practice medicine in Massachusetts is suspended, revoked, or restricted with regard to prescribing, or the physician has voluntarily agreed not to practice medicine in Massachusetts;
- The physician’s Massachusetts Controlled Substances Registration is suspended or revoked;
- The physician has fraudulently issued a written certification of a debilitating medical condition;
- The physician has certified a qualifying patient for a debilitating medical condition on or after July 1, 2014, without appropriate completion of CPD credits; or
- The physician surrenders his or her registration.

## **7. SUPERVISION OF HEALTHCARE PRACTITIONERS WITH PRESCRIPTIVE AUTHORITY**

The term “healthcare practitioner with prescriptive authority” means an individual practitioner, other than a physician, dentist, veterinarian, or podiatrist, who is licensed, registered, or otherwise permitted by the United States or the jurisdiction in which he or she practices, to issue orders for a controlled substance in the course of professional practice. Healthcare practitioners with prescriptive authority include, but are not limited to, nurse practitioners, nurse midwives, nurse anesthetists, psychiatric clinical specialists, and physician assistants (PA) who are authorized to issue orders for controlled substances by the state in which

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<sup>246</sup> 105 CMR 725.010(K)(1). NOTE: The physician’s co-workers, employees, and immediate family members are also prohibited from such interactions.

<sup>247</sup> 105 CMR 725.005(B).

they practice.<sup>248</sup> In Massachusetts, physicians are required to supervise the prescriptive practices of nurse practitioners, certified registered nurse anesthetists, psychiatric clinical nurse specialists and physician assistants.<sup>249</sup> A supervising physician is not required for a certified nurse midwife (CNM); however the CNM must be part of a healthcare system and must be in a clinical relationship with an obstetrician-gynecologist.

### **Advanced Practice Registered Nurses (APRN)**

There are five categories of APRNs in Massachusetts. They include: Certified Registered Nurse Anesthetist (CRNA); Certified Nurse Midwife (CNM); Certified Nurse Practitioner (CNP); Psychiatric Clinical Nurse Specialist (PCNS); and Clinical Nurse Specialist (CNS).<sup>250</sup> Clinical Nurse Specialists, while recognized as APRNs, are not authorized by statute to have a prescriptive practice.

Under the supervision of a licensed physician, CNPs, PCNS, and CRNAs are permitted to issue prescriptions pursuant to guidelines mutually developed and agreed upon by the advanced practice registered nurse and the supervising physician.<sup>251</sup> The guidelines must be in accordance with the regulations of the Board of Registration in Medicine and the Board of Registration in Nursing.<sup>252</sup> The prescriptive practice of advanced practice registered nurses is defined and regulated by the Board of Registration in Nursing.<sup>253</sup>

The supervising physician must have an unrestricted full license in the Commonwealth; have completed training in, be board-certified in or have hospital admitting privileges in a specialty area appropriately related to the advanced practice registered nurse's area of practice;

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<sup>248</sup> 21 C.F.R. § 1200.01(28).

<sup>249</sup> M.G.L. c. 112, §§ 9E, 80B, 80C, 80E and 80G.

<sup>250</sup> 244 CMR 4.06.

<sup>251</sup> Clinical Nurse Midwives are not required to have guidelines for prescriptive practice. 244 CMR 4.07(2).

<sup>252</sup> M.G.L. c. 112, §§ 80E and 80G; 244 CMR 4.00 *et. seq.*, and 243 CMR 2.10.

<sup>253</sup> 244 CMR 4.00 *et. seq.*

and have a valid DEA certificate of registration and MCSR number.<sup>254</sup> In addition, if the physician is supervising a psychiatric clinical nurse specialist, the physician must have completed training in psychiatry approved by the Accreditation Council for Graduate Medical Education (ACGME) or the Royal College of Physicians and Surgeons of Canada (RCPSC), or be board-certified in psychiatry.<sup>255</sup> A physician who is not an anesthesiologist may supervise a CRNA's prescriptive practice as long as the physician complies with the requirements of a supervising physician.<sup>256</sup>

The supervising physician and advanced practice registered nurse must sign mutually developed and agreed-upon guidelines for prescriptive practice. The supervising physician must review the advanced practice registered nurse's prescriptive practice in accordance with the mutually agreed-upon guidelines, and must provide ongoing direction to the nurse regarding the prescriptive practice.<sup>257</sup>

The Board's regulations set out the minimum requirements for the mutually agreed-upon written guidelines. The Board may request to review the guidelines at any time.<sup>258</sup> The written guidelines must be very specific regarding the types of medications to be prescribed, any limitations on prescriptions, and when referral or physician consultation is required. When appropriate, the guidelines should address the treatment of common medical conditions and should include protocols for managing emergencies. The guidelines must include a mechanism and time frame for the supervising physician to review the APRN's prescriptive practice. In addition, there must be specific protocols for the initiation of intravenous therapies and Schedule

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<sup>254</sup> 244 CMR 4.02.

<sup>255</sup> *Id.*

<sup>256</sup> Mass. Board of Reg. in Medicine, "*Board Statement on 243 CMR 2.10*," (adopted December 21, 2011).

<sup>257</sup> *Id.*

<sup>258</sup> 243 CMR 2.10 and 244 CMR 4.02.

II drugs.<sup>259</sup> While the regulations permit the physician and the APRN to set the frequency of review of the APRN's prescriptive practice, the physician must review the initial prescription of Schedule II drugs within 96 hours of the prescription.<sup>260</sup>

APRNs who are authorized to prescribe Schedule II drugs may prescribe a hydrocodone-only extended release medication that is not in an abuse deterrent form.<sup>261</sup> Certain APRNs may be authorized to issue written certification for marijuana for medical use.<sup>262</sup> Such prescribing practices shall be completed in accordance with applicable regulations and written guidelines mutually developed and agreed-upon with the APRN and the supervising physician.

Physicians who supervise a CRNA's prescribing practice must be aware that such practice is limited to the immediate perioperative period, which is defined as the time period beginning on the day prior to surgery and ending upon the patient's discharge from post-anesthesia care.<sup>263</sup> The Board urges physicians to remember that they are responsible for the prescriptive activities of the APRNs whom they supervise. Physicians should provide supervision as necessary, taking into account the education, training and experience of the APRN, as well as the nature and scope of their practice. The Board expects that physicians will only enter into supervision agreements with advanced practice registered nurses for whom they are able to provide supervision, practice review, and ongoing direction for the advanced practice registered nurse's prescriptive practice.

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<sup>259</sup> 243 CMR 2.10 and 244 CMR 4.07.

<sup>260</sup> *Id.*

<sup>261</sup> 244 CMR 4.07(3); *See* Part II, Section 2, "Drug Schedules."

<sup>262</sup> 244 CMR 4.06(3)(d).

<sup>263</sup> M.G.L. c. 112, § 80H; 244 CMR 4.02.

## Physician Assistants

Physician assistants are permitted to engage in prescriptive practices under the supervision of a physician.<sup>264</sup> The supervising physician must have an unrestricted full license in the Commonwealth; have completed training in, be board-certified in, or have hospital admitting privileges in a specialty area related to the physician assistant's area of practice; and have a valid DEA certificate of registration and MCSR number.<sup>265</sup>

The physician and physician assistant must sign mutually developed and agreed-upon guidelines; and the physician must review the physician assistant's prescriptive practice at least every three months and provide ongoing direction to the physician assistant.<sup>266</sup>

The Board's regulations set out the minimum requirements for the mutually agreed-upon written guidelines.<sup>267</sup> The guidelines must specify the types of medications to be prescribed, include any limitations on prescriptions, and describe the circumstances in which physician consultation and referral is required. The guidelines must include a mechanism to monitor the prescribing practices, and include protocols for the initiation of intravenous therapies and Schedule II drugs. In addition, the guidelines must specify the frequency of review, and in the case of prescriptions for Schedule II controlled substances, the physician must review the prescription within 96 hours after its issuance.<sup>268</sup> The use of pre-signed prescription blanks or forms is prohibited.<sup>269</sup> Prior to prescribing a hydrocodone-only extended release medication that is not in an abuse-deterrent form, a PA must assess the patient, including an evaluation of the patient's risk factors, substance abuse history, presenting condition(s), current medication(s),

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<sup>264</sup> M.G.L. c. 112, §9E.

<sup>265</sup> 243 CMR 2.08(5)(a).

<sup>266</sup> *Id.*

<sup>267</sup> 243 CMR 2.08(5)(c).

<sup>268</sup> 243 CMR 2.08(5)(c)7.

<sup>269</sup> 243 CMR 2.08(5)(d).



must check the online Prescription Monitoring Program, and must discuss with the patient the risks and benefits of the medication.<sup>270</sup>

On November 4, 2012, the Legislature amended M.G.L. c. 112, § 9E, eliminating a physician assistant-to-supervising physician ratio. According to G.L. c. 112, § 9E and 263 CMR 5.05, there is no prescribed limit on the number of physician assistants that a supervising physician may supervise. The Board urges physicians to remember that they are responsible for the prescriptive activities of the PAs whom they supervise. The Board expects that physicians will only enter into supervision agreements with PAs for whom they are able to provide supervision, practice review, and ongoing direction for the physician assistant's prescriptive practice.

## **Pharmacists**

### **Collaborative Drug Therapy Management**

In January, 2009, the Commonwealth enacted the Collaborative Drug Therapy Management (CDTM) Act.<sup>271</sup> This law permits certain pharmacists and physicians to enter into a collaborative practice agreement, under which the pharmacist may then initiate, monitor, modify and discontinue a patient's drug therapy. Collaborative practice agreements must be in accord with the regulations of the Board of Registration in Medicine and the Board of Registration in Pharmacy.<sup>272</sup> The pharmacist must have advanced training and the scope of the collaborative practice must be within the scope of practice of the supervising physician.<sup>273</sup> Supervising physicians must have an unrestricted full license in the Commonwealth and must be

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<sup>270</sup> 263 CMR 5.07

<sup>271</sup> St. 2008, c. 528.

<sup>272</sup> 243 CMR 2.12 and 247 CMR 16.00.

<sup>273</sup> M.G.L. c. 112, §24B½.

engaged in the clinical practice of medicine in an area appropriately related to the scope of the collaborative practice.<sup>274</sup>

Collaborative practice agreements are allowed only in the following settings:

- Hospitals;
- Long Term Care facilities;
- Licensed inpatient or outpatient hospice settings;
- Ambulatory care clinics with onsite supervising by the attending physician and with a collaborating pharmacist who has no connection to any retail pharmacy; or
- Community retail drug businesses, with supervision by a physician according to the terms of the collaborative practice agreement and limited to the following: patients 18 years of age or older; an extension by 30 days of current drug therapy prescribed by the supervising physician; and administration of vaccines or the modification of dosages of medications prescribed by the supervising physician for asthma, chronic obstructive pulmonary disease, diabetes, hypertension, hyperlipidemia, congestive heart failure, HIV or AIDS and osteoporosis.

The collaborative practice agreement must specifically name each disease being co-managed by the pharmacist and physician. The agreement must detail the pharmacist's prescribing authority and practice protocols. A patient must be referred by a supervising physician to that physician's collaborating pharmacist, must be given notice of the collaboration and must, as appropriate to the setting of the agreement, consent to the collaboration.

Any collaborative practice agreement in the retail drug business setting may only permit the prescription of Schedule VI controlled substances. Any collaborative practice agreement in such a setting, which allows the pharmacist to initiate prescriptions for referred patients of the supervising physician, must state that the pharmacist may only issue prescriptions for Schedule VI controlled substances for a patient diagnosis specified in the supervising physician's individual referral of that patient. A copy of such a prescription shall be sent to the supervising physician within 24 hours.

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<sup>274</sup> 243 CMR 2.12(3).

A physician or physician group may hire pharmacists for the purpose of practicing collaborative drug therapy management under a collaborative practice agreement for the benefit of a patient of that physician or physician group. No retail pharmacy may employ a physician for the purpose of maintaining, establishing or entering into a collaborative practice agreement with a physician.<sup>275</sup> The Board urges physicians to remember that, when entering into a collaborative practice agreement with a pharmacist, the physician must provide reasonable and safe supervision and the physician retains responsibility for the care of the patient.

### **Epinephrine**

A prescriber may order and a physician may sell stock supply of non-patient specific epinephrine by auto-injector (EpiPen® and EpiPen Jr.® auto-injectors) for use at a Massachusetts public or private school for emergency treatment of severe allergic reactions (anaphylaxis).<sup>276</sup>

### **Vaccines**

The Massachusetts Department of Public Health has enacted regulations permitting qualified pharmacists who have completed an accredited training course to administer vaccines as designated by the MDPH.<sup>277</sup> The MDPH and the Board of Registration in Pharmacy adopted a policy on Pharmacist and Pharmacist Interns Administration of Vaccines, which authorizes qualified pharmacists to administer vaccines included in the CDC's Recommended Adult

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<sup>275</sup> M.G.L. c. 112, §24B ½, 243 CMR 2.12 and 247 CMR 16.00.

<sup>276</sup> 105 CMR 210.000. Additional information on epinephrine administration in Massachusetts schools can be obtained from the MDPH, Bureau of Community Health Access and Prevention - School Health Services.

<sup>277</sup> 105 CMR 700.004(B)(6).

Immunization Schedule to adults 18 years of age and older.<sup>278</sup> In order to administer a vaccine, a qualified pharmacist must have a prescription, a physician directive or a standing order.

## **8. GIFTS OR INDUCEMENTS FROM THE PHARMACEUTICAL INDUSTRY**

The Board takes seriously the potential for impropriety or the appearance of impropriety which may occur when pharmaceutical companies or medical device manufacturers give gifts to physicians.

The AMA has issued an ethical opinion regarding gifts to physicians from representatives of the pharmaceutical and medical device manufacturing industry.<sup>279</sup> The AMA opinion recommends that physicians avoid accepting inappropriate gifts by focusing on whether the gifts primarily entail a benefit to patients, and ensuring that the gifts do not come with a *quid pro quo*, such as providing gifts in relation to the physician's prescribing practices.

In Massachusetts, there are specific prohibitions related to the giving of gifts to physicians by pharmaceutical and medical device manufacturing companies.<sup>280</sup> Of particular relevance to physicians are the standards regarding financial inducements to physicians by pharmaceutical or medical device manufacturing companies. Similar to the AMA Opinion, these prohibitions are aimed at limiting the possibility of entangling the physician's practice of medicine with an expectation of *quid pro quo* from the pharmaceutical or medical device manufacturing company.

The rules prohibit or restrict many incentives previously provided by pharmaceutical or medical device manufacturing companies. Among the restrictions are the following:

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<sup>278</sup> MDPH, Drug Control Program, Immunization Program and Board of Registration in Pharmacy, *2015-01 Joint Policy Pharmacist and Pharmacy Intern Administration of Vaccines and FAQs*. The Joint Policy is at Appendix E.

<sup>279</sup> American Medical Assn., *Opinion 8.061 "Gifts to Physicians From Industry."* The entire opinion can be found online at <http://www.ama-assn.org/ama/pub/physician-resources/medical-ethics/code-medical-ethics/opinion8061.shtml>

<sup>280</sup> M.G.L. c. 111N and 105 CMR 970.000 *et. seq.*

- Pharmaceutical or medical device manufacturing companies may only provide or pay for meals for physicians that are modest and occasional in nature, and are directly related to an informational presentation;
- No pharmaceutical or medical device manufacturing companies may provide or pay for meals for a physician's spouse or other guest;
- No pharmaceutical or medical device manufacturing company may provide physicians with financial support related to the costs of attending CME events, conferences, or professional meetings;
- No pharmaceutical or medical device manufacturing companies may provide inducements or gifts or provide or pay for any entertainment or recreational items of any value, including but not limited to tickets, vacations or supporting equipment, to any physician who is not a salaried employee of the company.<sup>281</sup>

Benefit of \$50 Value or Greater

As of July 1, 2010, and annually thereafter, every pharmaceutical or medical device manufacturing company must disclose to the Department of Public Health the value, nature, purpose and particular recipient of any fee, payment, subsidy or other economic benefit with a value of at least \$50, which the company provides, directly or through its agents, to any covered recipient, including physicians, in connection with the company's sales and marketing activities.<sup>282</sup> A person who knowingly and willfully violates these rules can be punished by a fine of up to \$5,000 for each violation.<sup>283</sup>

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<sup>281</sup> M.G.L. c. 111N and 105 CMR 970.000 *et. seq.*

<sup>282</sup> M.G.L. c. 111N.

<sup>283</sup> *Id.*