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TO: Interim Commissioner Lauren A. Smith and Members of the Public Health Council

FROM: Madeleine Biondolillo, MD, Director, Bureau of Health Care Safety and Quality

DATE: February 13, 2013

RE: Proposed Amendments to 105 CMR 700.000 (Controlled Substances Act) related to use of the Prescription Monitoring Program

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Introduction

The Drug Control Program (DCP) is proposing amendments to regulations at 105 CMR 700.000 to enhance utilization of the Massachusetts Prescription Monitoring Program (PMP). The PMP is a critical tool for addressing the problems of illicit use and abuse of prescription drugs, which affect both public health and public safety in the Commonwealth. The goals of the enhancements are to (1) increase utilization of the PMP in order to provide prescribers and dispensers with additional information that can inform clinical decision making, and (2) better address the morbidity and mortality resulting from prescription drug misuse and abuse by identifying individuals in need of intervention or treatment. DCP consulted with the boards of registration in medicine, dentistry, podiatry, and nursing as part of this process. The proposed amendments, included herein as Attachment A, are required by Chapter 244 of the Acts of 2012.

Background

The Department established the PMP in 1992, pursuant to joint regulations with the Board of Registration in Pharmacy. Chapter 283 of the Acts of 2010 codified the PMP in M.G.L. c. 94C, §24A. The PMP is a tool that supports safe prescribing and dispensing and assists in addressing prescription drug misuse and abuse. The PMP collects prescribing and dispensing information on Massachusetts Schedule II through V controlled substances dispensed pursuant to a prescription. Schedules II through V consist of those prescription pharmaceuticals with recognized potential for abuse or dependence (e.g., narcotics, stimulants, sedatives), and consequently, they are among those most sought for illicit and inappropriate (non-medical) use. DCP utilizes PMP data to determine prescribing and dispensing trends; provide patient prescription history information to prescribers and dispensers; provide educational information

to healthcare providers and the public; and provide case information to regulatory and law enforcement agencies concerning drug distribution and diversion.[1]

In December 2010, DCP launched the Massachusetts Online Prescription Monitoring Program (MA Online PMP) to provide patient prescription history reports to authorized prescribers and dispensers online and on request. Currently, over 2,000 providers are enrolled and in CY 2011 providers conducted more than 50,000 lookups of their patients' prescription histories. DCP began making the MA Online PMP available to investigative agencies in September 2011. By the end of the last quarter of 2011, 50 investigators had been enrolled and had obtained 166 case reports.

Chapter 244 requires DPH to automatically enroll practitioners[2] in the MA Online PMP when they apply to obtain or have had a recall to renew a Massachusetts Controlled Substance Registration (MCSR). This automatic enrollment will increase the number of individuals authorized to utilize the MA Online PMP. New MCSR practitioner forms that incorporate fields for additional information needed for program operations of automatic enrollment (e.g. an individual and personal email) and the terms and conditions of use of the MA Online PMP are posted on the DCP website.

Proposed Amendments

The amendments proposed here will fulfill the statutory mandates of Chapter 244 and improve public health and safety by:

- requiring PMP participants to utilize the PMP prior to seeing a new patient;
- defining those situations in which a participant would not be required to utilize the PMP prior to seeing a new patient; and
- creating delegates, a class of PMP end users who, as authorized support staff, use the system on behalf of a registered participant.

Two other requirements of Chapter 244 are for a continuing education training on PMP use for pharmacists and for a pamphlet for pharmacists to distribute to patients receiving a prescription for a narcotic or controlled substance in Schedule II or III. The Department is coordinating with academic experts, experts in prescription monitoring programs and DPH staff to develop these. DCP will be working with the Board of Registration in Pharmacy on specifics of operations for distributing the pamphlets.

Summary

Enhancement of the Massachusetts PMP is a prominent goal of the Commonwealth's *Substance Abuse Strategic Plan* and a priority of the Department of Public Health. DPH has been awarded competitive grants from the U.S. Department of Justice to design and implement technological and other enhancements to the PMP. Chapter 244 of the Acts of 2012 has charged the Department with enhancing utilization of the PMP and these proposed

[1] Diversion is the channeling of licit pharmaceuticals for illicit purposes. Methods of diversion include but are not limited to forgeries, seeking controlled substances from multiple providers, and altering prescriptions.
[2] Practitioners who prescribe controlled substance drug products in Schedule II–V are physicians, dentists and podiatrists. The Department will soon analyze the policies and operations for automatically enrolling mid-level prescribers and pharmacists.

amendments will contribute to the ultimate goal of reducing mortality and morbidity from prescription drug misuse and abuse in the Commonwealth. DCP plans to hold a public hearing on the proposed amendments in March 2013.

Attachment A

700.001: Definitions

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Delegate means an authorized support staff member who may utilize the prescription monitoring program on behalf of a participant.

New patient means an individual person who has not received any professional services from the participant within the previous 12 months.

Participant means a registered individual practitioner or other person who is duly authorized to prescribe or dispense a controlled substance by a Massachusetts Board of Registration and is authorized by the Department to utilize the prescription monitoring program.

Primary account holder means a participant who remains responsible for ensuring that utilization of the prescription monitoring program by a delegate is limited to authorized purposes.

Utilize means to access (directly or through a delegate) and review a patient's prescription history within the prescription monitoring program.

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700.012: Prescription Monitoring Program

(A) Pharmacy Reporting Requirements.
(1) The reporting requirement of 105 CMR 700.012 shall apply to every pharmacy in a health facility registered with the Commissioner that dispenses a controlled substance pursuant to a prescription in Schedules II through V, or a controlled substance classified by the Department as an additional drug, and to any pharmacy in another state, commonwealth, district or territory that delivers such a controlled substance to a person in Massachusetts. Such a pharmacy shall, in accordance with standards established by the Commissioner or designee, transmit to the Department or its agent the following information for each such prescription:
(a) pharmacy identifier;
(b) prescription number;
(c) customer identifier, as defined in 105 CMR 700.001;
(d) relationship of customer to patient;
(e) patient name;
(f) patient address;
(g) patient date of birth;
(h) patient gender;
(i) source of payment for prescription;
(j) date prescription written by prescriber;
(k) date the controlled substance is dispensed;
(l) identifier of controlled substance dispensed;
(m) metric quantity of controlled substance dispensed;
(n) estimated days supply of controlled substance dispensed;
(o) refill information; and
(p) prescriber identifier.

(2) 105 CMR 700.012 shall not apply to the dispensing pursuant to a medication order of a controlled substance to an inpatient in a hospital.
(3) A pharmacy that dispenses a controlled substance subject to the requirements in 105 CMR 700.012 must report the customer identifier required by 105 CMR 701.004. A pharmacy may dispense a controlled substance without a customer identifier, provided it meets the requirements of 105 CMR 701.004(B) and provides to the Department those informational fields required by the Department.
(4) The Commissioner or designee may waive or modify the requirement in 105 CMR 700.012(A)(1)(c) and/or (d), for a pharmacy to report a customer identifier and/or the relationship of the customer to the patient, for prescription refills, prescription deliveries and/or other activities/situations specified by the Commissioner or designee.
(5) The information required by 105 CMR 700.012 shall be transmitted to the Department or its agent in accordance with any procedures established by the Commissioner or designee at least once every seven days and no later than ten days after dispensing, or as otherwise specified in guidelines of the Department, by use of encrypted electronic device or electronic transmission method in a format approved by the Commissioner or designee.
(6) If a pharmacy is not able to submit dispensing information by electronic means, the Commissioner or designee may issue a waiver to authorize another means of transmission, provided that all information required in accordance with 105 CMR 700.012(A) is submitted in this alternate format.

(B) Prescription Monitoring Program Advisory Council.
(1) The Commissioner of the Department of Public Health may establish a Prescription Monitoring Program Advisory Council to advise the Department on the implementation of 105 CMR 700.012. The membership of the Advisory Council may include, but need not be limited to, representatives of the Department of Public Health; Executive Office of Health and Human Services; Executive Office of Public Safety; of Registration responsible for licensing professionals authorized to prescribe or dispense controlled substances, including the Boards of Registration in Medicine, Pharmacy, Dentistry, Podiatry, Veterinary Medicine, Optometry, Nursing and Physician Assistants; representatives of associations or societies representing professions authorized to prescribe or dispense controlled substances, patient interests, privacy interests; and a person with expertise in the design or operation of a secure automated data system.
(2) The Prescription Monitoring Program Advisory Council may assist the Department and Boards of Registration, as appropriate, in designing education programs for the appropriate use of prescription monitoring program information.

(C) Prescription Monitoring Program Medical Review Group.
(1) The Commissioner may establish the Prescription Monitoring Program Medical Review Group to advise the Department on accepted medical practice standards related to the disclosure of information pursuant to subsection 105 CMR 700.012(D)(5)(b). The Medical Review Group shall advise the Department in the evaluation of prescription information and clinical aspects of the implementation of 105 CMR 700.012.
(2) Members of the Medical Review Group shall be licensed health care practitioners and pharmacists and, to the extent feasible, at least one member shall be licensed in the same discipline as the practitioner whose records are under review. Practitioners serving on the Medical Review Group must have a valid Controlled Substances Registration for Schedules II through VI pursuant to M.G.L. c. 94C, § 7.

(D) Privacy, Confidentiality and Disclosure.

(1) Except where otherwise provided by judicial order, statute or regulation, including but not limited to 105 CMR 700.012(D)(2), the information collected pursuant to 105 CMR 700.012 shall be kept confidential by the Department.

(2) The Department shall, upon request and to the extent made feasible by 105 CMR 700.012(F), provide data collected pursuant to 105 CMR 700.012 to:

(a) an individual authorized and registered to prescribe or dispense controlled substances, for the purpose of providing medical or pharmaceutical care to a patient;

(b) a person authorized to act on behalf of an entity designated by M.G.L. c. 94C, § 24A, provided the request is in connection with a bona fide specific controlled substance or additional drug-related investigation, and further provided that such entity is:

1. a state board or regulatory agency that supervises or regulates a profession that may prescribe or dispense controlled substances;

2. a local, state or federal law enforcement agency or prosecutorial office working with the Executive Office of Public Safety engaged in the administration, investigation or enforcement of criminal law governing controlled substances;

3. the Executive Office of Health and Human Services, acting with regard to a MassHealth program recipient;

4. the United States Attorney;

5. the Office of the Attorney General; or

6. the office of a District Attorney.

(c) a duly authorized representative of a health department or other agency in another state, commonwealth, district, territory or country that maintains prescription information in a data system with privacy, security and other disclosure requirements consistent with those established in the Commonwealth, in accordance with a valid, written reciprocal data sharing agreement establishing the terms and conditions for exchange of data; and

(d) an individual or the individual's parent or legal guardian, who requests the individual’s own prescription monitoring information in accordance with procedures established under M.G.L. c. 66A and other applicable statute or regulation of the Commonwealth.

(3) A request for information collected pursuant to 105 CMR 700.012 shall be in writing or, if applicable, transmitted electronically pursuant to 105 CMR 700.012(F) and shall be made in accordance with procedures established by the Commissioner or designee to ensure compliance with the requirements of 105 CMR 700.012(D) and (E).

(4) The Commissioner or designee may initiate disclosure of data on a patient or research subject collected pursuant to 105 CMR 700.012 to an individual authorized and registered to prescribe or dispense controlled substances in any or all of the Schedules II through V, and Schedule VI if applicable, pursuant to 105 CMR 700.000, provided that:

(a) The authorized individual has prescribed or dispensed such a controlled substance to the patient or research subject;

(b) The Commissioner or designee has determined that the patient or research subject is receiving a controlled substance or additional drug from more than one source and in quantities that he determines to be harmful to the health of the patient or research subject or that disclosure is otherwise necessary to prevent the unlawful diversion of a controlled substance; and

(c) Such disclosure shall not require or direct the authorized individual to take action that he or she believes to be contrary to the patient's or research subject's best interests.

(5) (a) The Department shall review the prescription monitoring information collected pursuant to 105 CMR 700.012. If there is reasonable cause to believe a violation of law or breach of professional standards may have occurred, the Department shall notify the

appropriate law enforcement or professional licensing, certification or regulatory agency or entity and provide prescription monitoring information required for an investigation.
(b) Disclosure at the initiation of the Commissioner or designee pursuant to 105 CMR 700.012(D)(4) and (5) shall be in conformance with any protocols established by the Commissioner or designee, who may consult with the Medical Review GroupWhen such consultation is provided on Commissioner initiated disclosure, the Medical Review Group shall review the content and application of the protocols, make recommendations to the Commissioner for effective use of such protocols and as needed review specific instances of Commissioner initiated disclosure. If undertaking such review, the Medical Review Group may be provided upon request with such pertinent information as needed.
(6) The Commissioner or designee may provide de-identified, aggregate data to a public or private entity for statistical research or educational purposes.
(7) Data collected pursuant to 105 CMR 700.012(A) shall not be a public record and shall not be disclosed to anyone other than those persons specifically authorized under 105 CMR 700.012(D).

(E) Security Protections.
(1) Any disclosure or transmission of personally identifying information collected pursuant to 105 CMR 700.012 shall be in accordance with Department security requirements for such disclosure and transmission, including requirements for technical non-repudiation, confidentiality, and authentication, as those terms are defined in 105 CMR 721.000. Such protections shall include the establishment of a record of each request and transmission.
(2) A person authorized to receive information pursuant to 105 CMR 700.012(D) shall promptly notify the Department of any potential violation of confidentiality or use of the data in a manner contrary to 105 CMR 700.012 or applicable professional standards.
(3) A person's Controlled Substances Registration may be suspended or terminated in accordance with 105 CMR 700.004(L)(1) for the following:
(a) a request for data pursuant to 105 CMR 700.012(D), or use or disclosure of data, that involves a willful failure to comply with the standards in 105 CMR 700.012 for request, transmission or disclosure of data;
(b) a failure to reasonably protect data in accordance with the requirements of 105 CMR 700.012 or other applicable state or federal law; or
(c) an attempt to obtain data through fraud or deceit.

(F) Electronic Transmission of Prescription Monitoring Program Information
(1) The Department may establish means for secure electronic transmission of prescription monitoring program information to facilitate disclosure of such information authorized pursuant to 105 CMR 700.012.
(2) The Department may allow an authorized individual listed in 105 CMR 700.012(D)(2)(a)-(c), or a designee of such individual as approved by the Commissioner or designee, to use the secure electronic transmission system established pursuant to 105 CMR 700.012(F)(1) in accordance with security protocols established by the Commissioner or designee.
(3) Use of the secure electronic transmission system shall be limited to the uses authorized by 105 CMR 700.012.
(4) An authorized end user of the secure electronic transmission system must agree and attest to terms and conditions of use established by the Commissioner or designee.
(5) Failure of an end user to comply with 105 CMR 700.012 may result in revocation of the end user's authorization to use the secure electronic transmission system and may subject the end user to further sanction pursuant to 105 CMR 700.012(E)(3) or other state law.

(G) Automatic Authorization to Utilize the Prescription Monitoring Program

(1) Effective January 1, 2013, every practitioner except a veterinarian who holds a valid Massachusetts Controlled Substance Registration will automatically, in a manner and schedule determined by the Department, be granted authority to utilize the prescription monitoring program, as established pursuant to 105 CMR 700.012(F).
(2) To complete a Massachusetts Controlled Substance Registration, a practitioner must accept the Terms and Conditions of use for the prescription monitoring program.

(H) Requirement to Utilize the Prescription Monitoring Program Prior to Seeing a New Patient

(1) A participant, including an attending physician in a hospital or other inpatient facility, must utilize the prescription monitoring program prior to seeing a new patient. Compliance with this provision shall be met by a review of the most recent 12-month prescription history of the new patient.
(2) 105 CMR 700.012(H)(1) shall not apply to:
(a) Optometrists licensed according to M.G.L. c. 112, § 68;
(b) Participants and other authorized prescribers who are restricted by federal or state authority to prescribing, administering, possessing, ordering, or sampling controlled substances in Schedule VI;
(c) Participants granted a waiver pursuant to 105 CMR 700.012(I);
(d) An instance in which it is not reasonably possible to utilize the prescription monitoring program, including when the system is not operational due to temporary technological or electrical failure;
(e) An instance in which acute care is required and utilization of the prescription monitoring program would result in patient harm;
(f) Participants providing care to a new patient in a hospital or other inpatient facility, except for the attending physician; and
(g) Other exceptions as defined in guidance issued by the Department.

(I) Waiver of Requirement to Utilize the Prescription Monitoring Program

(1) The Department may waive the requirements established in 105 CMR 700.012(H)(1) for a participant who submits a request in a manner and form determined by the Department, if the Department determines that a waiver is appropriate based on the criteria listed in 105 CMR 700.012(I)(2).
(2) A request for a waiver of the requirements in 105 CMR 700.012(H)(1) shall include a description of the following:
(a) The participant's history of compliance with laws and regulations related to controlled substances;
(b) A substantial hardship created by a natural disaster or other emergency beyond the control of the participant;
(c) Technological limitations not reasonably within control of the participant; and
(d) Temporary technological limitations within the control of the participant that will be rectified within six months.

(J) Delegate Sub-Accounts

(1) A primary account holder may submit a written request to create sub-accounts, in a manner and form determined by the Department, for up to two delegates to utilize the prescription monitoring program on behalf of the primary account holder. An individual eligible to be a primary account holder may not be a delegate.

(2) A primary account holder who seeks to authorize more than two delegates may, in a manner and form determined by the Department, request a waiver of 105 CMR 700.012(J)(1).

(3) A request for delegate sub-accounts must include an attestation that the primary account holder will:

(a) Ensure that delegates comply with the prescription monitoring program Sub-Account User Terms and Conditions;

(b) Monitor delegate use of the prescription monitoring program and inform the Department when a delegate has violated the Sub-Account User Terms and Conditions or is no longer authorized by the participant to be a delegate; and

(c) Take reasonable steps to ensure that the delegate is sufficiently competent in the use of the prescription monitoring program.

(4) The primary account holder is responsible for all delegate use of the prescription monitoring program and may be referred to the appropriate licensing authority if delegate use is inconsistent with the Sub-Account User Terms and Conditions.