BUREAU OF HEALTHCARE
SAFETY & QUALITY

DRAFT REGULATIONS
RELATED TO THE USE OF THE PRESCRIPTION MONITORING PROGRAM

PUBLIC HEALTH COUNCIL

June 18, 2014

The proposed amendments will fulfill the statutory mandates in Chapter 244 of the General Laws. They will also strengthen the public health response to the opioid epidemic as outlined in the public health emergency by the Governor. The proposed amendments:

- Require utilization of the PMP prior to issuing to a patient, for the first time, a prescription for a narcotic drug in schedule II or III;
- Enable the Department to issue guidance on PMP utilization prior to prescribing commonly abused and addictive drugs in schedules II and III;
- Create delegates to use the PMP on behalf of a registered participant;
- Create a process by which access to the PMP may be suspended or revoked if a user violates the terms and conditions of the system; and
- Permit a prescription of naloxone to be written and dispensed to a bystander, as well as to the ultimate user.

- The proposed PMP amendments are authorized by M.G.L. c. 94C, s. 24A(c), as amended by Chapter 244 of the Acts of 2012 and Chapter 38 of the Acts of 2013
- The proposed amendments permitting naloxone prescriptions for bystanders are authorized by c. 192 of the acts of 2012, and amended c. 94C, section 19
- The proposed Physician Assistants amendments are authorized by M.G.L. c. 112, §9E, as amended by Chapter 244 of the Acts of 2012

PRESCRIPTION MONITORING PROGRAM

700.012 Prescription Monitoring Program, add a new section:

(G) Automatic Authorization to Utilize the Prescription Monitoring Program

(1) Effective January 1, 2013, every registered individual practitioner except a veterinarian who holds a valid Massachusetts Controlled Substance Registration will automatically, in a manner and form determined by the Department, be granted authority to utilize the prescription monitoring program, as established pursuant to 105 CMR 700.012(F).

What this will do: This is already required by statute this will make our regulations consistent with statute; it will also automatically enroll all prescribers (except veterinarians), in addition to physicians (MD/DO).

700.012 Prescription Monitoring Program, add a new section:

(H) Requirement to Utilize the Prescription Monitoring Program

(1) A registered individual practitioner must utilize the prescription monitoring program prior to prescribing, to a patient for the first time:

(a) a narcotic drug in Schedule II or III; or

(b) a benzodiazepine; or

(c) a Schedule IV or V controlled substance, as designated in guidance to be issued by the Department.

What this will do: This is already required by statute so this will make our regulations consistent with statute. It will require checking the PMP prior to prescribing, for the first time, narcotic drugs in Schedule II and III and prescribing a benzodiazepine. It will also permit the Department to issue guidance that requires checking when prescribing certain Schedule IV or V.

(H) Requirement to Utilize the Prescription Monitoring Program (*continued*), add a new section:

(2) A registered individual practitioner must utilize the prescription monitoring program each time the prescriber issues a prescription to a patient for any drug in Schedule II or III which has been determined by the Department 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.

(a) The Department shall convene an advisory group to develop this guidance.

(b) The advisory group shall consist of nine members, chaired by the Commissioner or the Commissioner's designee, and must include experts in the fields of medicine, nursing, pharmacy, pain management treatment, addiction treatment, academia, and law enforcement.

(c) The advisory group will hold a public hearing before each revision to the guidance and shall invite comment prior to adding any drug to the guidance.

(d) The advisory group shall meet no less than one time a year and as many times as needed. Each member shall serve a three year term.

What this will do: Create an advisory group to provide the Department information relating to when a prescriber should be required by the Department to utilize the PMP for specifically determined Schedule II or III drugs

(H) Requirement to Utilize the Prescription Monitoring Program (*continued*), add a new section:

(3) 105 CMR 700.012(H)(1) and (2) shall not apply to:

(a) A registered individual practitioner authorized to prescribe, administer, possess, order, or dispense **samples of controlled substances only in Schedule VI**;

(b) A registered individual practitioner providing medical, dental, podiatric, pharmaceutical, or nursing care **to hospice patients;**

(c) A registered individual practitioner treating a patient in an **Emergency Department** who does not anticipate writing a prescription for a controlled substance in Schedules II-V during that encounter with the patient or does not prescribe more than a five-day supply of a controlled substance in Schedules II-V;

(d) An instance in which **emergency care** is required and utilization of the prescription monitoring program would result in patient harm;

(e) A registered individual practitioner providing medical, dental, podiatric, pharmaceutical or nursing care to **hospital inpatients**;

f) A registered individual practitioner providing medications **for immediate treatment** in accordance with M.G.L. c. 94C, § 9(b);

(g) 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;

(h) A registered individual practitioner examining or treating a **patient under 48 months** of age;

(i) A registered individual practitioner granted **a waiver** pursuant to 105 CMR 700.012(I); and

(j) **Other exception**s as defined in guidance issued by the Department**.**

What this will do: Outline the situations where 700.012(H) does not apply to a prescriber and when they do not have to use the PMP prior to prescribing.

(I) Waiver of Requirement to Utilize the Prescription Monitoring Program, add a new section

(1) The Department may waive the requirements established in 105 CMR 700.012(H)(1) and (2) 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) and (2) 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; or

(d) Temporary technological limitations within the control of the participant that will be rectified within six months.

What this will do: Outline when a waiver can be granted to a prescriber (as compared to a situation or waiver).

(J) Delegate Sub-Accounts, add a new section:

(1) A primary account holder may authorize **support staff as delegates** to use the prescription monitoring program on behalf of the participant when the participant submits a written request to create delegate sub-accounts in a manner and form determined by the Department. An individual eligible to be a primary account holder may not be a delegate.

(2) A primary account holder submitting a request to establish delegate sub-accounts must provide, upon request by the Department, the hospital's, clinic's, medical office's or pharmacy's written policies and procedures regarding the management and security of prescription monitoring data and reports.

(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 within one business day; 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.

What this will do: Define the authorization of delegates so that prescribers can have help utilizing the PMP.

(K) 700.012 Suspension of Authorization to Utilize the Prescription Monitoring Program; add a new section

1 If the Department learns, by means of system audit, complaint, or other mechanism, that a participant has, or may have, utilized the prescription monitoring program in a manner that is inconsistent with the terms and conditions for its use, the Department:

a) May immediately restrict the participant's electronic access to the prescription monitoring program system; and

b) Shall contact the participant to investigate the potential violation.

2 If the Department determines after investigation that the participant did not utilize the prescription monitoring program in a manner that is inconsistent with the terms and conditions for its use, the Department shall immediately reinstate the participant's electronic access to the prescription monitoring program system, if such access has been restricted.

3 If the Department determines after investigation that the participant did utilize the prescription monitoring program in a manner that is inconsistent with the terms and conditions for its use, the Department may, depending on the severity of the violation, take the following action:

a) Issue a warning letter to the participant;

b) Require the participant to undergo training on the appropriate use of the prescription monitoring program;

c) Temporarily suspend the participant's access to the prescription monitoring program; and

d) Take action pursuant to 105 CMR 700.115.

4 If the Department takes action under 105 CMR 700.012(K)(3), the participant may contest the Department's findings, in writing, and request further review.

What this will do: Put parameters on the coarse of action if someone is found in misuse and/or abuse of the PMP.

Add a new title: 700.100 Complaints

The Department shall investigate every complaint about drug diversion or tampering received related to a registrant's registration pursuant to M.G.L. c. 94C and 105 CMR 700.000.

- If the Department finds that an investigation is not required because the alleged act or practice is not in violation of M.G.L. c. 94C or 105 CMR 700.000, or any policies of the Department pursuant thereto, the Department shall make a note in the complaint file of this finding and the reasons on which it is based.
- If the Department finds that an investigation is required, because the alleged act or practice may be in violation of M.G.L. c. 94C or 105 CMR 700.000, or any policies of the Department pursuant thereto, the Department shall investigate. If a finding is made that the act or practice does constitute such a violation, the Department shall apply whichever enforcement procedure(s), as provided in 105 CMR 700.000, is appropriate to remedy the situation and the Department shall notify other interested parties, including law enforcement or a licensing board, as appropriate, of its action in this matter.
- Investigation of complaints may lead to enforcement actions, including a warning letter or a letter of reprimand; or a revocation, suspension, or refusal to renew a registration by the Department. The Department may specify in any such enforcement action taken against a registrant a requirement to undergo and successfully complete remedial training, in accordance with terms set out in the enforcement action.

What this will do: This will outline how the Drug Control Program will investigate complaints about drug diversion or tampering related to the registrant's MCSR.

Add a new title: 700.105: <u>Grounds for Revocation, Suspension, or Refusal to Renew a Registration,</u>

- Grounds for revocation, suspension, or refusal to renew a registration include, but are not limited to, whether the registrant:
  - has furnished false or fraudulent material information in any application filed under the provisions of this chapter;
  - has been convicted under any state or federal law of any criminal violation relating to his fitness to be registered under this chapter;
  - has had his federal registration suspended or revoked to manufacture, distribute, dispense, administer or possess controlled substances;
  - is, upon good cause, found to be unfit or unqualified to manufacture, distribute, dispense, or possess any controlled substance;
  - has violated any provision of M.G.L. c. 94C; or
  - has used the online prescription monitoring program system, or prescription data derived therefrom, in a manner inconsistent with the terms and conditions for such use.
- Revocation, suspension, or refusal to renew a registration may be appealed in accordance with 105 CMR 700.115.

What this will do: Provide prescribers guidance as to the grounds for revocation, suspension, or refusal to renew a registration of their MCSR.

Add a new title: 700.110: Summary Suspension of Registration

- Pursuant to M.G.L. c. 94C, § 14, the Commissioner may, without a hearing, if the Commissioner finds that public health or safety is endangered, immediately suspend a registration. Written notice of the reasons for the suspension shall promptly be issued by the Department. The affected person shall also be notified in writing of the right to an adjudicatory hearing and shall be promptly afforded an opportunity for a hearing provided that written request for a hearing is submitted within 14 days after notification of suspension.
- After hearing or waiver thereof, the Department may modify a registration or suspend, revoke, or refuse to renew a registration pursuant to 105 CMR 700.115.
- Upon receipt of notice of the Department's final decision, the affected person must immediately return to the Department a registration previously issued.

What this will do: Give prescribers guidance on the suspension of an MCSR registration.

Add a new title: 700.115: Suspension, Revocation, or Refusal to Renew a Registration

- If the Department initiates action to suspend, revoke, or refuse to renew a registration, the affected person shall be notified in writing of the reasons for the Department's action and of his/her right to an adjudicatory proceeding.
- Written request for a hearing must be submitted within 14 days of receipt of notification of Department action.
- After hearing or waiver thereof, the Department may modify, suspend, revoke, or refuse to renew a registration.
- If the Department requires a suspension of a registration, the Department shall indicate the term of the suspension.
- If the Department requires a revocation or refusal to renew a registration, the Department shall indicate whether or not the registrant may, at a future date, reapply for a registration.
- Upon receipt of notice of the Department's final decision, the affected person must immediately return to the Department a registration previously issued.

What this will do: Provide guidance to prescribers on the coarse of action in the event of a suspension, revocation or refusal to renew a registrant's MCSR.

Add a new title: 700.120: Void Registrations

- A registration is void if the registrant's underlying professional licensure on which the registration is based is suspended or revoked.

Add a new title: 700.125: Adjudicatory Proceedings

- All adjudicatory proceedings will be conducted in accordance with M.G.L. c. 30A and the Standard Rules of Practice and Procedure, 801 CMR 1.01 et seq.
- The Commissioner shall designate a Presiding Officer to conduct a hearing and render a tentative decision containing findings of fact and rulings of law. If the Presiding Officer finds any single ground for revocation, suspension, or refusal to renew any registration, the Presiding Officer shall render a decision affirming the action initiated by the Department.

Add a new title: 700.130: Nonexclusivity of Enforcement Procedures

- The enforcement procedures contained in 105 CMR 700.000 are not mutually exclusive. Any enforcement procedures may be invoked simultaneously if the situation so requires.

What these will do: Provide guidance to prescribers on voided registrations, adjudicatory proceedings and nonexclusivity of enforcement procedures.

NALOXONE FOR BYSTANDERS

Adds a new sentence 721.020

(4) name and address of the patient, except in a veterinary prescription or a prescription for expedited partner therapy issued in accordance with 105 CMR 700.003(J), in which case the words “Expedited Partner Therapy”, “E.P.T.” or “EPT” may be used in place of the name of the patient, and the address may be left blank; or in the case of a prescription for naloxone the person taking delivery of the naloxone may be used in place of the name of the patient, and the address may be left blank.

What this will do: Permit a prescription of naloxone to be written and dispensed to a bystander instead of to the ultimate user.

PHYSICIAN ASSISTANT'S PRESCRIBING

Strike 2 words:721.020

(G) a prescription issued by a nurse practitioner, psychiatric nurse, ~~physician assistant~~, nurse anesthetist or pharmacist shall also contain the name of the supervising physician.

What this will do: Make the language in the regulations consistent with the statute.

QUESTIONS?