Commonwealth of Massachusetts
Department of Public Health
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Draft Proposed Amendments to 105 CMR 700.000 Implementation of M.G.L. c. 94C

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Department of Public Health

Summary of Regulation

- This regulation oversees who must register with the Drug Control Program for a Massachusetts Controlled Substances Registration, the security and storage of controlled substances, and also oversees the Prescription Monitoring Program.
- In accordance with Executive Order 562, the proposed changes remove provisions that are outdated or conflict with provisions in other health care regulations, and include several technical corrections.

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Summary of Amendments

The proposed amendments to this regulation will

- **increase readability and understanding** by removing outdated definitions and terms and incorporating plain language principles;
- **create consistency** with new and evolving areas of law,
- **reflect appropriate professional titles** for certain advanced practice nurses;
- **remove outdated registration requirements**;
- **bolster security requirements** regarding theft, loss, and tampering with controlled substances;
- **modernize the regulation** of hypodermic needles and investigational new drug research using human subjects; and
- **update provisions of the Prescription Monitoring Program**, as they have been amended by Chapter 52 of the Acts of 2016, *An Act relative to Substance Use, Treatment, Education and Prevention*.

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Regulation Changes: Prescription Definition

- In the current regulation, there is no definition for "Prescription" although this term is necessarily used throughout the regulation.
- The proposed regulation inserts the following definition for the term Prescription:

  "Prescription means an order for medication which is dispensed to or for an ultimate user. A prescription does not mean an order for medication which is dispensed for immediate administration to the ultimate user."

- This definition matches the definition used by the DEA

Regulation Changes: Advanced Practice Nurses and Physician Assistants Amendments

Amendments to 105 CMR 700.004, *Registration Requirements*, are proposed relative to the prescriptive practice of midlevel prescribers. The proposed changes:

- Update language to reflect the appropriate professional titles for certain advanced practice nurses: Certified Nurse Practitioners, Certified Registered Nurse Anesthetists, and Psychiatric Clinical Nurse Specialists;
- Clarify that nurses with prescriptive practices must provide specific information regarding their agreement with their supervising physician, including a copy of their prescription guidelines.
- Include notice requirements if prescriber is terminated, changes practice address, or changes supervising physician.

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Regulation Changes: Immunizations

- 105 CMR 700.004(B)(6) currently permits trained pharmacists to administer to customers the influenza vaccine and other immunizations pursuant to the order of a practitioner.
- The proposed amendments reflect a 2014 statutory change that permits appropriately licensed pharmacist interns to also administer vaccinations and immunizations under the supervision of a pharmacist.

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Regulation Changes: Immunizations (continued)

- The amendment also lowers the age limit to permit pharmacists and pharmacists interns to administer vaccinations and immunizations to those 9 years and older.
- This change will increase accessibility to vaccinations and immunizations.
- Finally, the proposed amendments require pharmacists to inform patients
  - whether the pharmacy receives the vaccine at no charge through the Massachusetts Immunization Program;
  - of primary care providers located near the pharmacy geographically; and
  - of the importance of establishing and maintaining a relationship with a pediatric or family practice for ongoing medical and well-child care, if the patient is a child.

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Regulation Changes: Security Requirements

- Proposed amendments to 105 CMR 700.005, *Security Requirements*, add a requirement that registrants report suspected tampering, in addition to the current reporting requirement for loss and theft.
- This change will clarify requirements , codify existing practice and fix confusing language.

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Regulation Changes: Hypodermic Instruments

- Proposed amendments delete 105 CMR 700.008, *Requirements Regarding Hypodermic Instruments*, to modernize the regulation of hypodermic needles and syringes:
- The current regulation allows these needles and syringes to be sold by pharmacists pursuant to a valid prescription, and permits pharmacists and prescribers to obtain a license to sell hypodermic needles and syringes without a prescription.
- This proposed deletion aligns with a change in state law:
  - In 2006 the law was changed to decriminalize the possession of hypodermic needles (§ 32I) and to allow the sale of hypodermic needles and syringes to anyone 18 or older, by a pharmacist; dealer in surgical supplies; or manufacturer of or dealer in embalming supplies (§ 27).

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Regulation Changes: Investigational Drug Research

- Proposed amendments to 105 CMR 700.009, *Research Involving Controlled Substances,* clarify that all research involving the investigational use of any drug on human beings requires the researcher to obtain a Massachusetts Controlled Substance Registration and provide evidence of compliance with federal laws regarding research, including the protection of human subjects, review by an institutional review committee, and obtaining informed consent.
- The amendments eliminate details that are unnecessarily duplicative of federal requirements.

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Regulation Changes: Prescription Monitoring Program

Amendments to 105 CMR 700.012, *Relative to the Prescription Monitoring Program*, achieve compliance with Chapter 52 of the Acts of 2016 by:

- Adding requirements that, effective October 15, 2016, a registered individual practitioner must utilize the prescription monitoring program each time the practitioner prescribes a narcotic drug that is contained in Schedule II or III; and
- Deleting no longer necessary placeholder language requiring additional utilization of the PMP.

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Regulation Changes: Prescription Monitoring Program (continued)

- Proposing additional language to 105 CMR 700.012(12)(C)(7) to outline the process by which the Department determines that a controlled substance in Schedule VI is an "additional drug" that carries a bona fide potential for abuse and must be reported to the PMP.
- Under this new process, the Department will review a drug's potential for:
  - Recreational use
  - Diversion for misuse
  - Contribution to overdose

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Regulation Changes: Prescription Monitoring Program (continued)

- Removing the specific identifiers that pharmacies are required to transmit to the Department.
  - These identifiers are fully identified in the PMP Dispensing Guide issued by the Department and used by all pharmacies that dispense controlled substances in Massachusetts.
- Inserting additional language regarding the requirement that a pharmacy review a customer identifier prior to dispensing controlled substances in Schedules II through V.
  - This language was formerly in 105 CMR 701.000, which is being proposed for rescission, but it belongs more appropriately in this regulation.

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Next Steps

- Following this initial presentation, a public hearing and comment period will be held.
- Approval of the proposed amendments, along with a review of public comments, will be requested at a subsequent meeting of the Public Health Council.

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Contact Information

- Thank you for the opportunity to present this information today.
- For more information regarding Drug Control, including the Prescription Monitoring Program, please find the relevant statutory language and the full current regulation here:
  https://malegislature.gov/Laws/GeneralLaws/PartI/TitleXV/Chapter94C

  http://www.mass.gov/courts/docs/lawlib/104-105cmr/105cmr700.pdf

Please direct any questions to:

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