Draft Proposed Amendments to 105 CMR 700.000 Implementation of M.G.L. c. 94C

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Commonwealth of Massachusetts
Department of Public Health

Summary of Regulation

This regulation, 105 CMR 700.000, *Implementation of M.G.L. c. 94C*, which was most recently published as amended on May 5, 2017, having been reviewed under Executive Order 562:

- Sets forth consistent standards for the safety, security and storage of controlled substances;
- Outlines Drug Control Program (DCP) requirements for practitioners and facilities to receive a Massachusetts Controlled Substances Registration (MCSR); and
- Manages oversight of the Massachusetts Prescription Awareness Tool (MassPAT) through the Prescription Monitoring Program (PMP).

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Summary of Amendments

The proposed amendments to this regulation add:

- *Necessary definitions, including adding the titles of additional prescribing professions;*
- *Provisions required by new legislation, such as those addressing administration of immunizations by supervised medical assistants, administration of psychotropic drugs by pharmacists; and registration of virtual manufacturers;*
- *Exemptions from registration for certain approved, low risk activities such the purchase, storage or administration of naloxone; the purchase of Schedule VI drugs for use in pharmacy schools; and volunteer activities by a prescriber;*
- *Clarification of existing regulations regarding research studies and the prescription monitoring program; and*
- *Transparency for the regulated industry regarding how to apply for waivers under this regulation.*

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Regulation Changes: Pharmacist Administration of Mental Health and Substance Use Medications

Amendments to 105 CMR 700.001, *Definitions*, and 700.004, *Registration Requirements*, were required to implement section 10 of chapter 283 of the acts of 2016 (FY17 GAA), which amended the definition of "administer" in M.G.L. c. 94C to allow pharmacists to administer medications to treat mental health or substance use disorders.

Proposed changes include:

- Amending the definition of "Administer" to align with statutory definition;
- Adding a new subsection in 105 CMR 700.004, outlining the circumstances under which a pharmacist or pharmacy intern may administer specified mental health and substance use disorder drugs, in single dose packaging, pursuant to a prescription, and upon routine assessment;

Specific medications and frequency of assessment will be included in provider guidance, drafted in consultation with the Department of Mental Health and distributed to pharmacies, prescribers and mental health and substance use treatment facilities.

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Regulation Changes: Medical Devices

Amendments to 105 CMR 700.001, *Definitions*, and 700.003, *Registration of Persons for a Specific Activity or Activities in Accordance with M.G.L. c. 94C, § 7(g)* , are proposed to allow medical device manufacturers to obtain an MCSR for the limited purpose of purchasing and storing Schedule VI controlled substances which are to be used solely to test the device as part of the quality control processes.

Proposed changes include:

- Adding a new definition of "Device" that aligns with the FDA definition;
- Adding a new subsection in 105 CMR 700.003, to allow manufacturers and their third-party testing facilities to register for this limited purpose;

This proposal will resolve a barrier that prevented FDA regulated manufacturers that require controlled substances (like sterile saline) to test their devices.

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Regulation Changes: Health Facilities

Amendments to 105 CMR 700.001, *Definitions*, are proposed to eliminate duplicative terms for "long term care facilities" and clarify the requirement that all clinics, regardless of facility licensure, must have a Massachusetts Controlled Substance Registration (MCSR).

Proposed changes include:

- Amending the definition of "Health Facility" by deleting the outdated terms "infirmary maintained in a town," "convalescent home," "nursing home," and "charitable home for the aged," as they are already covered by the term "long term care facility";
- Further amending the definition of "Health Facility" to clarify that a clinic established, as authorized by M.G.L. c. 111, § 52, solely to provide service to employees or students of a corporation or institution, is required to register under 105 CMR 700.004 if the clinic possesses and dispenses controlled substances;
  - a medical office building, or a solo or group practice, wholly owned and controlled by one or more of the practitioners, is not required to obtain a clinic MCSR.

This amendment clarifies that a controlled substance registration is necessary regardless how a clinic is authorized to operate, if the clinic possesses or dispenses controlled substances .

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Regulation Changes: Medical Assistant

Amendments to 105 CMR 700.001, *Definitions*, and 700.004, *Registration Requirements*, were required to align with M.G.L. c. 112, § 265, which authorizes certain medical assistants to administer immunizations under the supervision of a practitioner.

Proposed changes include:

- Adding a new definition of "Medical Assistant" that aligns with statute;
- Adding a new subsection in 105 CMR 700.004, to exempt a medical assistant from the MCSR requirement when administering immunizations under the supervision of a practitioner, as in accordance with Departmental guidance;

This exemption reflects specific authority given to medical assistants under M.G.L. c. 112, § 265 and aligns with current DPH guidance.

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Regulation Changes: Research Study

Amendments to 105 CMR 700.001, *Definitions*, and 700.009, *Research Involving Controlled Substances*, are proposed to clarify requirements and streamline the approval of research studies involving any research drug.

Proposed changes include:

- Adding a new definition of "Research Drug" to align with federal law relative to research studies and to clarify that research includes administering or dispensing research drugs to humans or animals;
- Amending 105 CMR 700.009, to
  - clarify that the primary investigator is the applicant and registrant, instead of each individual researcher or individual study,
  - provide flexibility by leaving application requirements to Departmental guidance, and
  - eliminate collection of specific informed consent documents that duplicate many records required by Institutional Review Board (IRB) process;

This clarification will reduce regulatory burdens on research institutions, including hospitals, and streamline department staff operations.

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Regulation Changes: Virtual Manufacturers

Amendments to 105 CMR 700.001, *Definitions*, and 700.004, *Registration Requirements*, are proposed pursuant to M.G.L. c. 94C, § 7, as amended by section 43 of chapter 47 of the acts of 2017 (FY18 GAA), to require registration by a manufacturer or distributer of a controlled substance, who has a principal place of business in the Commonwealth, but at no time takes physical possession of any controlled substance in the Commonwealth.

Proposed changes include:

- Adding a definition of "Virtual Manufacturer" to align with M.G.L. c. 94C, § 7;
- Adding a new subsection to 105 CMR 700.004, to require virtual manufacturers and distributors to register with the Department

This new requirement will resolve a barrier that prevented virtual manufacturers from doing business in other states because they could not demonstrate registration in their home state.

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Regulation Changes: Naloxone Access

Amendments to 105 CMR 700.003, *Registration of Persons for Administration in Community Programs, and* 700.004, *Registration Requirements*, are proposed to eliminate as many barriers to naloxone access as possible at a state level.

Proposed changes include:

- Adding an exemption from the MCSR requirement for anyone purchasing, storing, possessing, or administering naloxone, or other DPH-approved opioid antagonist.
- Unlike the existing special registration program for first responder agencies and municipal and state-associated organizations, no distribution is permitted.

These amendments streamline access to naloxone, by adding a broad, general registration exemption for naloxone for anyone, includingnon-municipal, non-state-associated organizations, without interfering with an individual's ability to obtain naloxone from a pharmacy as an "ultimate user" for future administration to a person experiencing an opioid overdose.

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Regulation Changes: Medication Administration Program (MAP)

Amendments to 105 CMR 700.003, *Registration of Persons for Administration in Community Programs*, are proposed to codify key elements of existing Medication Administration Program (MAP) guidance, namely the MAP Policy Manual and associated advisories.

Proposed changes include:

- Codifying existing MAP policy by clarifying the appropriate MAP population as stable and non-self-administering, as those terms are defined and discussed in the MAP Policy Manual; and
- Codifying existing MAP policy by clarifying that medication administration activities must be performed without interference from other duties or obligations of community program employment.

Identifying the appropriate population to be served by unlicensed MAP certified staff and requiring those staff to undertake medication administration duties, without distraction from housekeeping and other caretaking functions, is an imperative of safe medication administration for individuals in a MAP.

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Regulation Changes: Exemptions from Registration

Amendments to exemption provisions of 105 CMR 700.004, *Registration Requirements*, are proposed to establish individual and circumstantial exemptions to controlled substance registration requirements.

In addition to exemptions already discussed, proposed changes include:

- Adding respiratory therapists, dental hygienists, and perfusionsts to the list of health care providers exempt from registration when acting under the direction of an authorized practitioner, or in connection with activities associated with an educational training program;
- Exempting pharmacy school instructors purchasing Schedule VI medications for instructional use; and
- Exempting recreational camps licensed by the Department and their staff when administering epinephrine via auto-injectors, to align with recently approved recreational camp regulations.

Pharmacy schools are less likely than other health profession schools to have registered prescribers on faculty to order Schedule VI supplies, like saline.

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Regulation Changes: Registration Requirements

Amendments to 105 CMR 700.004, *Registration Requirements*, are proposed to add flexibility, efficiency, and consistency, and eliminate burdens to regulated parties when registering for controlled substance activities.

Proposed changes include:

- Allowing registrants to perform up to 10 hours per month of volunteer work that includes possession, dispensing and administration of controlled substances, without obtaining a separate MCSR for the volunteer work, in addition to the MCSR for their normal place of business or practice;
- Eliminating a list of specific application requirements; and
- Creating consistent procedures and timelines throughout the regulation, including professional licensing termination and controlled substance disposition procedures.

These amendments will eliminate a barrier to volunteerism by registrants, and provide flexibility and consistency by leaving details to evolving Departmental guidance.

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Regulation Changes: Prescription Monitoring Program (MassPAT)

Amendments to 105 CMR 700.012, *Prescription Monitoring Program*, are proposed in response to conscientious prescriber requests for MassPAT to permit self-assessment, and to align PMP processes with DCP and licensing board processes.

Proposed changes include:

- Allowing prescribers to utilize MassPAT to review their own prescribing history;
- Aligning PMP user termination events and timelines with MCSR and professional licensing regulations.

These changes align PMP and MassPAT with prescriber and program best practices.

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Regulation Changes: Waiver

A new section, 105 CMR 700.140, *Waiver of Requirements Imposed on Registrants*, is proposed to be added to the regulation to provide registrants with the ability to request waivers from any requirement in the regulation.

- The addition of a general waiver provision aligns with other licensing regulations like Hospitals, 105 CMR 130, and Long Term Care Facilities, 105 CMR 150;
- Waiver applications must include:
  - A statement of undue hardship;
  - Assurance that a waiver will not jeopardize health and safety;
  - A statement of compensating features; and
  - Submission of supporting documentation.

This change allows the Drug Control Program to receive and respond to unique waiver requests.

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
  https://www.mass.gov/files/documents/2017/09/11/105cmr700.pdf

Please direct any questions to:

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