105 CMR 700:

IMPLEMENTATION OF M.G.L. c. 94C

Post-Comment Period

Public Health Council | October 10, 2018

James G. Lavery, Director
Bureau of Health Professions Licensure

Lauren B. Nelson, Esq.
Director of Policy and Regulatory Affairs
Bureau of Health Professions Licensure

Background

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).
- Amendments were required to implement several new statutes, including provisions in the FY18 General Appropriations Act, and to ensure consistency and efficiency of terms and operations.

Overview of Pre-Comment Changes

The amendments proposed for public comment add:

- *Necessary definitions, including the titles of additional prescribing professions and terms relevant to research;*
- *Provisions required by new legislation, such as those addressing administration of immunizations by supervised medical assistants, administration of behavioral health and substance use disorder drugs by pharmacists; and registration of virtual manufacturers;*
- *Exemptions from registration for certain approved, low risk activities such as 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 to reduce regulatory burdens on research institutions, including hospitals, and streamline department staff operations.*
- *Transparency for the regulated industry regarding how to apply for waivers under this regulation.*

Final Amendments – Changes based on comments received

Research MCSR Application – 105 CMR 700.001; 700.009

SUMMARY OF PRE-COMMENT CHANGES

- Added a NEW definition of “Research Drug” - an investigational new drug as defined in 21 C.F.R. 312.3, or any scheduled drug, which is being used in a research study or program where it will be administered or dispensed to one or more human or animal subjects.

SUMMARY OF PROPOSED FINAL AMENDMENT

- Definition revised to clarify DCP's authority to ensure the safety and security of drugs used in research.
- “Research Drug” - an investigational new drug as defined in 21 C.F.R. 312.3, or the investigational use of any scheduled drug in a research study or project where it will be administered or dispensed.

Final Amendments – Changes based on comments received

Research MCSR Application – 105 CMR 700.001; 700.009

SUMMARY OF PRE-COMMENT CHANGES

- Added a requirement that a primary investigator must file a research MCSR application.

SUMMARY OF PROPOSED FINAL AMENDMENT

- Added eligible applicants:
  - Revised definition of “researcher” to include a supervisor, or department chair or chief academic officer; and
  - allowed a “researcher” to file a research MCSR application, unless it involves an Investigational New Drug, where federal law requires the applicant be the principal investigator.

Final Amendments – Changes based on comments received

Research MCSR Application – 105 CMR 700.009

SUMMARY OF PRE-COMMENT CHANGES

- Added language to clarify current practice that a primary investigator must receive commissioner's authorization of a research MCSR.

SUMMARY OF PROPOSED FINAL AMENDMENT

- Consistent with current practice, clarified that a "researcher" must receive authorization for an MCSR prior to procuring, possessing, and storing drugs to conduct research.

Final Amendments – Changes based on comments received

Research MCSR Application – 105 CMR 700.009

SUMMARY OF PRE-COMMENT CHANGES

- Amendments clarifying research application requirements retained the following language:
- “No person shall carry out any research project or study involving any research drug unless ….”

SUMMARY OF PROPOSED FINAL AMENDMENT

- Added a statement to the section involving information to be submitted with an application to clarify that a researcher may include multiple research projects or studies in a single application, as long as all required information is included for each such study or project.

Final Amendments – Changes based on comments received

Pharmacy Administration of Behavioral Health and Substance Use Disorder Medications 105 CMR 700.004

SUMMARY OF PRE-COMMENT CHANGES

- Amended, as mandated by Section 10 of chapter 238 of the Acts of 2016, to authorize pharmacists to administer mental health and substance use disorder medications, by single dose prescription, subject to prescriber's ongoing reassessment of the patient will be permitted.

SUMMARY OF PROPOSED FINAL AMENDMENT

- Removed the single dose limitation in favor of a prescriber's clinical discretion, pursuant to DPH guidance, to assure assessment intervals are satisfied by a prescription with refills.

Final Amendments – Changes based on comments received

Pharmacy Administration of Behavioral Health and Substance Use Disorder Medications 105 CMR 700.004

SUMMARY OF PRE-COMMENT CHANGES

- Amended the regulation to authorize pharmacists to administer mental health and substance use disorder medications by prescription, subject to the prescriber's ongoing assessment of the patient.

SUMMARY OF PROPOSED FINAL AMENDMENT

- Clarified that prescriber provides the assessment and determines the appropriate interval, based on clinical discretion and department guidance.

Final Amendments – Changes based on comments received

Pharmacy Administration of Behavioral Health and Substance Use Disorder Medications 105 CMR 700.004

SUMMARY OF PRE-COMMENT CHANGES

- Authorized pharmacist administration of mental health and substance use disorder medications subject to pre-administration education.

SUMMARY OF PROPOSED FINAL AMENDMENT

- Amended provision by replacing “pre-administration education” with “pre-administration patient counseling”, a term commonly understood by pharmacists who routinely provide such counseling.

Next Steps

- Based on a comprehensive review of 105 CMR 700: Implementation of M.G.L. c. 94c, and the incorporation of comments from stakeholders, DPH recommends Public Health Council approval of these amendments for promulgation.
- Specific medications and operational detail for implementation of pharmacy administration of mental health and substance use disorder medications 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.
- Revised MCSR applications with instructions reflecting amendments will be posted for use upon promulgation.
- This regulation is likely to undergo further amendment in short order to complete implementation of Chapter 208 of the Acts of 2018, an act for prevention and access to appropriate care and treatment of addiction.

Contact Information

- Thank you for the opportunity to present this information today.
- The DCP promotes access to safe and effective pharmaceutical care services in Massachusetts. We work to protect consumers against fraud, deception, and unsafe practices in the distribution, handling, and use of pharmaceuticals and medical devices.
- For more information regarding DCP or any of its programs, including the MCSR program, the Prescription Monitoring Program (PMP) and the Medication Administration Program (MAP), please find the relevant statutory language and the full current regulation here:

https://malegislature.gov/Laws/GeneralLaws/PartI/TitleXV/Chapter94C

https://www.mass.gov/regulations/105-CMR-70000-implementation-of-mgl-c94c

Please direct any questions to:
Lauren B. Nelson, Esq.
Director of Policy and Regulatory Affairs
Bureau of Health Professions Licensure