

**105 CMR 700.000**  
***Implementation of M.G.L. c. 94C***  
**Final Regulatory Amendment Presentation**

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- The purpose of this presentation is to request final promulgation by the Public Health Council of the proposed revisions to 105 CMR 700.000, *Implementation of M.G.L. c. 94C*.
- These amendments are proposed as part of the regulatory review process, mandated by Executive Order 562.
- This regulation sets forth standards for the implementation of M.G.L. c. 94C, and ensures a high quality of care, industry standardization, and strong consumer protection for individuals receiving controlled substances.

As a reminder, on June 8, 2016, the Department presented to the Public Health Council proposed revisions to 105 CMR 700.000, *Implementation of M.G.L. c. 94C*. Specific preliminary revisions included:

- Increasing readability and understanding by removing outdated definitions and terms and incorporating plain language principles;
- Creating consistency with new and evolving areas of law;
- Reflecting appropriate professional titles for certain advanced practice nurses;
- Removing outdated registration requirements;
- Bolstering security requirements regarding theft, loss, and tampering with controlled substances;
- Modernizing the regulation of hypodermic needles and investigational new drug research using human subjects; and
- Updating 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*.

As a result of the comments received during the public comment period, including the public hearing on August 3, 2016, DPH recommends further revisions to 105 CMR 700.000. The further revisions will achieve the following:

- Further refine definitions and terminology;
- Clarify prescriptive authority of non-physicians;
- Amend requirements of pharmacists offering immunizations;
- Align supervision and guideline requirements of advanced practice nurses with expanded scope of practice; and
- Provide an option for signing prescriptions electronically.

## *Compounding*

- The current definition for the term “compounding” related only to manufacturing.
- The preliminary review broadened the definition of the term “compounding”.
- In response to comments, the Department retained the term, but deleted the definition, deferring to the subject matter expertise of the Board of Pharmacy regulations. 247 CMR 2.00 et seq.

## *Provider ID*

- The current regulation and preliminary revision referenced and defined the seven-digit National Association of Boards of Pharmacy (NABP) Number.
- In response to comments, the Department amended the regulation to accurately reference the NCPDP Provider ID, meaning the unique six-digit number issued by the National Counsel for Prescription Drug Programs.

## Post-Comment Review: Prescribing Authority

- The current regulation allows a certified nurse practitioner, psychiatric clinical nurse specialist, certified registered nurse anesthetist, certified nurse midwives, physician assistants and optometrists to issue written prescriptions and medication orders for Schedule II through VI controlled substances.
- The preliminary review amended the regulation for language consistency and efficiency.
- In response to comments, the Department has replaced references to “written prescription” with “prescription”, because the word “written” may be read to prevent certified nurse practitioners, psychiatric clinical nurse specialists, certified registered nurse anesthetists, certified nurse midwives, physician assistants, and optometrists from issuing oral prescriptions.
  - By removing references to a particular form of prescription, the regulation requires only that prescribers comply with the prescribing requirements of M.G.L. 94C § 20 and M.G.L. 112 § 80G, which apply to all prescribers, nurses and pharmacists alike.

## Post-Comment Review: Pharmacist Immunization

- The current regulation permits a registered pharmacist to dispense immunizations designated by the Department to persons 18 years of age or older.
- The preliminary review permitted a registered pharmacist and pharmacist intern to dispense immunizations designated by the Department to persons 9 years of age or older.
- In response to comments, the Department has further clarified the provision for pharmacists to provide a list of primary care providers to those 9-18 years of age receiving an immunization in the pharmacy, to encourage primary care and development of a relationship with a pediatrician.

## Post-Comment Review: Prescribing Guidelines

- The current regulation requires advanced practice nurses to have guidelines mutually agreed upon with supervising physicians.
- The preliminary review amended the regulation to require submission of copies to the Drug Control Program (DCP).
- In response to comments, the Department removed the requirement that advanced practice nurses submit copies of guidelines to DCP, as advanced practice nursing guidelines are available to the Board of Registration in Nursing upon request.



## Further Revision Highlights: Electronic Signature

- The current regulation allows a pharmacy to dispense a controlled substance without a customer identifier, provided it meets the requirements of 105 CMR 701.004(B).
- The preliminary review inserted additional language from 105 CMR 701.000 allowing a pharmacy to dispense a controlled substance without a customer identifier if the customer signs his or her name on the prescription.
- In response to comments requesting modernization of the signature requirements, the Department amended the regulation to provide an additional option of electronic signature when dispensing a controlled substance in Schedule II through V without a customer identifier.

- Staff requests the Public Health Council approve the proposed regulations for promulgation.
- Following Public Health Council approval, the Department will file the amended regulation with the Secretary of the Commonwealth for final enactment.

- Thank you for the opportunity to present this information today.
- For more information on 105 CMR 700.000, *Implementation of M.G.L. c. 94C*, please find the relevant statutory language (M.G.L. c. 94C) 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>