

105 CMR 722.000
Dispensing Procedures for Pharmacists
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 722.000, *Dispensing Procedures for Pharmacists*.
- These amendments are proposed as part of the regulatory review process, mandated by Executive Order 562.
- 105 CMR 722.000 sets forth procedures which clinic and hospital pharmacies must follow when dispensing drug products in accordance with M.G.L. c. 94C and the regulations promulgated thereunder.

As a reminder, on June 8, 2016, the Department presented to the Public Health Council proposed revisions to 105 CMR 722.000, *Dispensing Procedures for Pharmacists*. Specific preliminary revisions included:

- Renaming the regulation to *Dispensing Procedures for Clinic and Hospital Pharmacies* reflect that it applies to clinic and hospitals pharmacies;
- Rescinding those sections that relate to the professional practice of pharmacists in all settings and moving the sections to a more appropriate Code of Massachusetts Regulations, 247 CMR 9.00, *Code of Professional Conduct: Professional Standards for Registered Pharmacists, Pharmacies and Pharmacy Departments*; and
- Updating the definition of “hospital employee” to reflect that many hospitals are part of larger health systems and their employees are not always direct employees of the specific hospital that contains the hospital pharmacy.

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 722.000. The further revisions will achieve the following:

- Clarify definitions; and
- Align the waiver requirements with clinic regulations.

Post-Comment Review: Definitions

<p>Changed the definition of "Clinic Employee" to reflect that clinics may be part of larger health systems.</p>	
Current Regulation	<p>Definition not included in the current regulation.</p>
Proposed Change	<p><u>Clinic Employee</u> means persons currently on payroll or medical staff members of the clinic and their spouses and dependents living in the same household; clinic volunteers; students working at the clinic, or individuals contracted for employment by the clinic.</p>
Further Change	<p><u>Clinic Employee</u> means persons currently on payroll or medical staff members of the clinic, system, or accountable care organization, and their spouses and dependents living in the same household; clinic volunteers; students working at the clinic, or individuals contracted for employment by the clinic, system, or accountable care organization.</p>

Post-Comment Review: Definitions

<p>Changed the definition of "Clinic Patient" to align more closely with the regulation definition of "Hospital Outpatient".</p>	
Current Regulation	Definition not included in the current regulation.
Proposed Change	<u>Clinic Patient</u> means a person currently under treatment at the clinic
Further Change	<u>Clinic Patient</u> means a person formally registered as a patient who is currently receiving services or under treatment at the clinic.

Post-Comment Review: Waivers

- The current regulation requires an “emergency” to justify granting a waiver of any requirement imposed by this regulation.
- The preliminary review amended the regulation for language consistency and efficiency.
- Commenters suggested that DPH amend the provision in the regulation which requires an “emergency” to justify a waiver on the grounds that the standard is unreasonably high and is in conflict with the waiver standard that is currently applied to clinics and clinic pharmacies.
- In response, the Department amended the waiver provision to align the waiver requirements with those of other health care facility licensure regulations.

- 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 dispensing procedures for clinic and hospital pharmacists please find the full current regulation here:

<http://www.mass.gov/eohhs/docs/dph/regs/105cmr722.pdf>