

105 CMR 721.000
***Standards for Prescription Format and
Security in Massachusetts***

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 721.000, *Standards for Prescription Format and Security in Massachusetts*.
- These amendments are proposed as part of the regulatory review process, mandated by Executive Order 562.
- 105 CMR 721.000 sets forth the standards for format and security in the Commonwealth that all prescriptions issued by practitioners or reduced to writing by pharmacists must meet in order to comply with M.G.L. c. 112, § 12D and M.G.L. c. 94C.

As a reminder, on June 8, 2016, the Department presented to the Public Health Council proposed revisions to 105 CMR 721.000, *Standards for Prescription Format and Security in Massachusetts*. Specific preliminary revisions included:

- Complying with a provision in Chapter 52 of the Acts of 2016 that prescriptions for opioids in Schedule II must include a notation that patients may request that the prescription be filled for less than the full quantity prescribed; and
- Moving the provisions relative to emergency situations in which controlled substances in Schedule II may be dispensed upon oral prescription from 105 CMR 701.000 to this regulation.

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 721.000. The further revisions will achieve the following:

- Provide further clarification for the notation of the prescriber's DEA number on prescriptions; and
- Align emergency prescribing provisions to mirror a similar regulation, 247 CMR 5.03, regarding emergency situations.

Post-Comment Review: DEA Number on Prescriptions

- The current regulation requires a valid prescription to show the prescriber's registration number, without defining the term "registration number".
- Upon preliminary review, the Department retained this requirement.
- In response to comments, the Department clarified the requirement by inserting a definition for Registration Number, specifying that it is the DEA number.
 - The definition includes a limited exception for practitioners who do not have a DEA number, because they prescribe only from Schedule VI. These practitioners must use their Massachusetts Controlled Substance Registration (MCSR) number.

- The current regulation does not include emergency prescribing provisions because such provisions were included in 105 CMR 701.000.
- Upon preliminary review, a new subsection was included, moved from 105 CMR 701.000, that defines an “emergency situation” in which oral prescriptions can be issued, and describes the procedure by which a pharmacist may dispense Schedule II medications upon receiving an oral prescription.
- In response to comments and to simplify the regulatory scheme, the Department aligned the emergency prescribing provisions with 247 CMR 5.03, by including the following:
 - Reference to oral and electronic transmission; and
 - A process for reducing such a prescription to writing and confirming the identity of the authorized prescriber.

- 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 *Prescription Format and Security*, please find the full current regulation here:
<http://www.mass.gov/eohhs/docs/dph/regs/105cmr721.pdf>