



The Commonwealth of Massachusetts
Executive Office of Health and Human Services
Department of Public Health
Bureau of Health Professions Licensure
250 Washington Street, Boston, MA 02108-4619

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NOTICE OF PUBLIC HEARING

Notice is hereby given pursuant to M.G.L. c. 30A, §2, that the Department of Public Health will hold a public hearing on amendments to the following regulations: 105 CMR 722.000 - *Dispensing Procedures for Clinic and Hospital Pharmacies*.

The proposed amendments update the regulations which set forth standards governing prescription format and security in the Commonwealth. The proposed amendments update the regulation to bring it into alignment with other regulations of the Department.

The public hearing will be held at **3:00 pm on March 11, 2024**. The hearing will be conducted on a **moderated conference call**. The information for the moderated conference call is:

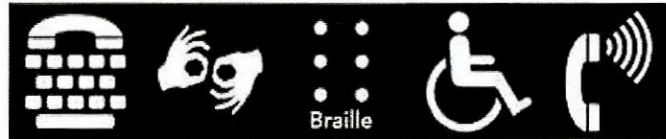
Dial-in Telephone Number: 888-324-6864
Participant Passcode: 6598688

A copy of the proposed amendments to 105 CMR 722.000 – *Dispensing Procedures for Clinic and Hospital Pharmacies* may be viewed on the Department's website at www.mass.gov/dph/proposed-regulations or requested from the Office of the General Counsel by calling 617-624-5220.

Speakers who testify at the public hearing are requested to provide a copy of their oral testimony. The Department encourages all interested parties to submit testimony electronically to the following address: Reg.Testimony@mass.gov, or by mail to William Anderson, Office of the General Counsel, Department of Public Health, 250 Washington Street, Boston, MA 02108. All submissions must include the sender's full name and address. When electronically submitting comments, type "DCP Regulations" in the subject line and attach a Word document with your comments or type your comments in the body of your email. All submissions must include the sender's full name and address.

The Department will post all testimony that complies with these instructions on its website. **All comments must be submitted by 5:00 p.m. on March 11, 2024**. All comments received by the Department may be released in response to a request for public records.

If you are deaf or hard of hearing, or are a person with a disability who requires accommodation, please contact Shauntay King at least 5 days before the hearing at Tel # 617-894-4352, or email shauntay.m.king@mass.gov.



Small Business Impact Statement
Standards for Prescription Format and Security in Massachusetts
(As required by M.G.L. c. 30A §§ 2, 3 & 5)

CMR No: 105 CMR 722.000

Estimate of the Number of Small Businesses Impacted by the Regulation: 259

A search of the SBA website showed zero (0) pharmacies registered as small businesses in Massachusetts. According to Board of Registration in Pharmacy records, there are currently 1160 retail pharmacies in Massachusetts, of which 259 are independent (non-chain) and most likely to qualify as small businesses.

These regulations also apply to individual, licensed practitioners who prescribe medication (~56,000). The number that would qualify as small businesses is not clear.

Select Yes or No and Briefly Explain

Yes	No <input checked="" type="checkbox"/>	Will small businesses have to create, file, or issue additional reports? <i>No, small businesses will not have to create, file, or issue additional reports as a result of proposed amendments to this regulation.</i>
Yes	No <input checked="" type="checkbox"/>	Will small businesses have to implement additional recordkeeping procedures? <i>No, small businesses will not have to implement additional recordkeeping procedures as a result of proposed amendments to this regulation.</i>
Yes	No <input checked="" type="checkbox"/>	Will small businesses have to provide additional administrative oversight? <i>No, small businesses will not have to provide additional administrative oversight as a result of proposed amendments to this regulation.</i>
Yes	No <input checked="" type="checkbox"/>	Will small businesses have to hire additional employees in order to comply with the proposed regulation? <i>No, small businesses will not have to hire additional employees in order to comply with proposed amendments to this regulation.</i>
Yes	No <input checked="" type="checkbox"/>	Does compliance with the regulation require small businesses to hire other professionals (e.g. a lawyer, accountant, engineer, etc.)? <i>No, compliance with the regulation will not require small businesses to procure vendor services.</i>
Yes	No <input checked="" type="checkbox"/>	Does the regulation require small businesses to purchase a product or make any other capital investments in order to comply with the regulation? <i>No, small businesses will not have to purchase products or make other capital investments to comply with proposed amendments to this regulation.</i>
Yes	No <input checked="" type="checkbox"/>	Are performance standards more appropriate than design/operational standards to accomplish the regulatory objective?(Performance standards express requirements in terms of outcomes, giving the regulated party flexibility to achieve regulatory objectives and design/operational standards specify exactly what actions regulated parties must take.) <i>No -this regulation, which is required by statute, sets forth clear minimum standards to ensure</i>

		<i>consistency among programs and protect the health and safety of residents. Its objectives could not be implemented with performance standards.</i>
Yes	No X	Do any other regulations duplicate or conflict with the proposed regulation? <i>No, the proposed amendments do not duplicate or conflict with other regulations.</i>
Yes X	No	Does the regulation require small businesses to cooperate with audits, inspections or other regulatory enforcement activities? <i>Yes, the regulation requires small businesses to cooperate with inspections and other regulatory enforcement activities in order for DPH to ensure appropriate dispensing procedures for clinic and hospital pharmacies are being adhered to. However, the proposed amendments to this regulation do not increase this burden.</i>
Yes	No X	Does the regulation require small businesses to provide educational services to keep up to date with regulatory requirements? <i>No, this regulation does not require small businesses to provide educational services to keep up to date with regulatory requirements.</i>
Yes	No X	Is the regulation likely to <i>deter</i> the formation of small businesses in Massachusetts? <i>No, this regulation is not likely to encourage or deter the formation of small businesses in Massachusetts.</i>
Yes	No X	Is the regulation likely to <i>encourage</i> the formation of small businesses in Massachusetts? <i>No, this regulation is not likely to encourage or deter the formation of small businesses in Massachusetts.</i>
Yes	No X	Does the regulation provide for less stringent compliance or reporting requirements for small businesses? <i>For family planning clinics and substance use disorder treatment clinics that may be considered small business, the regulation provides for less stringent compliance or reporting requirements by not requiring them to maintain a pharmacy on-site. However, the proposed regulation does not contemplate small businesses, specifically.</i>
Yes	No X	Does the regulation establish less stringent schedules or deadlines for compliance or reporting requirements for small businesses? <i>No, the regulation does not provide for less stringent schedules or deadlines for compliance or reporting.</i>
Yes	No X	Did the agency consolidate or simplify compliance or reporting requirements for small businesses? <i>No, the compliance standards and reporting requirements are the same for all regulated parties, and do not change relative to volume of service delivered or number of staff employed.</i>
Yes	No	Can performance standards for small businesses replace design or operational standards without

	X	<p>hindering delivery of the regulatory objective?</p> <p><i>The regulation provides alternative means of complying with dispensing procedures for regulated parties that qualify for a listed waiver or exception, which may include small businesses.</i></p>
Yes	No X	<p>Are there alternative regulatory methods that would minimize the adverse impact on small businesses?</p> <p><i>No - the current regulation provides alternative means of complying with dispensing procedures for regulated parties that qualify for a listed waiver or exception, which may include small businesses.</i></p>