



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 721.000 – *Standards For Prescription Format And Security In Massachusetts*.

The proposed amendments update the regulations which set forth standards governing prescription format and security in the Commonwealth. The proposed amendments implement sections of Acts of 2020, c. 267 authorizing independent practice for nurse practitioners with more than two years of approved supervised prescriptive practice, which also affect the format of prescriptions. The proposed amendments also update sections of the regulation which were designed to implement ePrescribing, which are outdated and no longer required, and add sections to bring the regulation into alignment with the other regulations of the Drug Control Program.

The public hearing will be held at **2:00 pm on March 11, 2024**. The hearing will be conducted on a **moderated conference call**. The information for the moderated conference call is:

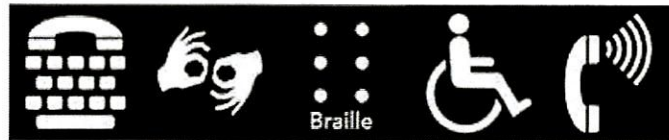
Dial-in Telephone Number: 800-369-3126
Participant Passcode: 1742503

A copy of the proposed amendments to 105 CMR 721.000 – *Standards For Prescription Format And Security In Massachusetts* 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 721.000

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, compliance with the regulation will not require small businesses to purchase a federally compliant electronic prescription system or software to comply with the 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 requirements for prescriptive practice</i>

		<i>to ensure consistency and protect the health and safety of residents. Its goals 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 regulation does not duplicate or conflict with other regulations.</i>
Yes	No X	Does the regulation require small businesses to cooperate with audits, inspections or other regulatory enforcement activities? <i>No, this regulation does not require small businesses to cooperate with inspections and other regulatory enforcement activities.</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>The regulation eases the filling of some prescriptions by making it clear that it is not the obligation of the pharmacist to verify that a nurse who fails to list a supervising practitioner is or is not authorized for independent practice, but does not contemplate small businesses specifically. In addition, the regulation provides alternative means of complying with prescription format and security requirements for regulated parties that qualify for a listed waiver or exception, which may include small businesses.</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 contemplate small businesses and therefore does not establish less stringent schedules or deadlines for such businesses.</i>
Yes	No X	Did the agency consolidate or simplify compliance or reporting requirements for small businesses? <i>No, the regulation does not contemplate small businesses and therefore does not consolidate or simplify compliance or reporting requirements for such businesses.</i>
Yes	No	Can performance standards for small businesses replace design or operational standards without hindering delivery of the regulatory objective?

	X	<i>No, performance standards cannot replace these regulations, which do not specifically contemplate small businesses.</i>
Yes	No	Are there alternative regulatory methods that would minimize the adverse impact on small businesses?
	X	<i>No, the current regulation provides alternative means of complying with prescription format and security requirements for regulated parties that qualify for a listed waiver or exception, which may include small businesses.</i>