



EXECUTIVE OFFICE OF ADMINISTRATION AND FINANCE

The Commonwealth of Massachusetts
Executive Office of Health and Human Services
Department of Public Health
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 Executive Office of Administration and Finance, along with Board of Registration in Pharmacy within the Department of Public Health, will hold a public hearing on amendments to the following regulations: 801 CMR 4.02 (247): Fees for Licenses, Permits, and Services to be Charged by State Agencies.

The proposed amendments will establish the fees for initial and renewal licensure of pharmacies licensed by the Board of Registration in Pharmacy.

The public hearing will be held at **1:00 p.m. on Wednesday, February 28, 2024**. The hearing will be conducted on a **moderated conference call**. The information for the moderated conference call is:

Dial-in Telephone Number: **1-888-455-9763**
Participant Passcode: **1180513**

A copy of the proposed amendments to 801 CMR 4.02 (247) may be viewed on the Department's website at <https://www.mass.gov/service-details/proposed-regulations-and-amendments-department-of-public-health> 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 "BORP 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 Wednesday, February 28, 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 Alex Gomez at least 5 days before the hearing at Tel # 617-624-5928, Fax # 617-624-5075, email Alex.Gomez@mass.gov, or TTY # 617-624-6001.



Small Business Impact Statement

(As required by M.G.L. c. 30A §§ 2, 3 & 5)

CMR No: 801 CMR 4.02 (247) Rates (Board of Registration in Pharmacy)

Estimate of the Number of Small Businesses Impacted by the Regulation: A search of the SBA website for businesses with the 446110 NAICS code showed two (2) pharmacies registered as small businesses in Massachusetts. According to the records of the Board of Registration in Pharmacy (“Board”), there are currently 1137 retail pharmacies in Massachusetts, of which 219 are independent (non-chain) and most likely to qualify as small businesses. Additionally, it is anticipated some of the non-resident pharmacies may be small businesses.

Select Yes or No and Briefly Explain

Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Will small businesses have to create, file, or issue additional reports? The proposed amendment establishes fees to apply and renew new pharmacy license types required pursuant to pharmacy reform legislation (St.2014, c.159), codified at M.G.L. c. 112, §§ 39 – 39J. The proposed amendment does not require small businesses to create, file or issue additional reports.
Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Will small businesses have to implement additional recordkeeping procedures? The proposed amendment establishes fees to apply and renew new pharmacy license types required pursuant to pharmacy reform legislation (St.2014, c.159), codified at M.G.L. c. 112, §§ 39 – 39J. The proposed amendment does not require small businesses to implement additional recordkeeping procedures.
Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Will small businesses have to provide additional administrative oversight? The proposed amendment establishes fees to apply and renew new pharmacy license types required pursuant to pharmacy reform legislation (St.2014, c.159), codified at M.G.L. c. 112, §§ 39 – 39J. The proposed amendment does not require small businesses to provide additional administrative oversight.
Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Will small businesses have to hire additional employees in order to comply with the proposed regulation? The proposed amendment establishes fees to apply and renew new pharmacy license types required pursuant to pharmacy reform legislation (St.2014, c.159), codified at M.G.L. c. 112, §§ 39 – 39J. The proposed amendment does not require small businesses to hire additional employees.
Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Does compliance with the regulation require small businesses to hire other professionals (e.g. a lawyer, accountant, engineer, etc.)? The proposed amendment establishes fees to apply and renew new pharmacy license types required pursuant to pharmacy reform legislation (St.2014, c.159), codified at M.G.L. c. 112, §§ 39 – 39J. The proposed amendment does not require small businesses to hire other professionals.
Yes <input type="checkbox"/>	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? The proposed amendment establishes fees to apply and renew new pharmacy license types required pursuant to pharmacy reform legislation (St.2014, c.159), codified at M.G.L. c. 112, §§ 39 – 39J. The proposed amendment does not require small businesses to purchase a product or make any other capital investments.
Yes <input type="checkbox"/>	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.)

		The proposed amendment establishes fees to apply and renew new pharmacy license types required pursuant to pharmacy reform legislation (St.2014, c.159), codified at M.G.L. c. 112, §§ 39 – 39J.
Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	<p>Do any other regulations duplicate or conflict with the proposed regulation?</p> <p>There is no other state agency that licenses the operation of a pharmacy or pharmacy compounding in the Commonwealth.</p> <p>The Department of Public Health (DPH), Bureau of Health Care Safety and Quality, oversees licensure of hospitals and clinics, which includes pharmacy operations within those licensed facilities. See 105 CMR 130.00 and 105 CMR 140.00. The Board's jurisdiction, pursuant to M.G.L. c. 112, § 39I, over institutional pharmacies is limited to sterile compounding and does not overlap or duplicate DPH regulations.</p> <p>The federal Food, Drug and Cosmetic Act, 21 USC 353a, also regulates the practice of pharmacy compounding. The proposed changes do not conflict with federal law.</p>
Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	<p>Does the regulation require small businesses to cooperate with audits, inspections or other regulatory enforcement activities?</p> <p>The proposed amendment establishes fees to apply and renew new pharmacy license types required pursuant to pharmacy reform legislation (St.2014, c.159), codified at M.G.L. c. 112, §§ 39 – 39J. The proposed amendment does not require small businesses to cooperate with audits, inspections or other regulatory enforcement activities.</p>
Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	<p>Does the regulation require small businesses to provide educational services to keep up to date with regulatory requirements?</p> <p>The proposed amendment establishes fees to apply and renew new pharmacy license types required pursuant to pharmacy reform legislation (St.2014, c.159), codified at M.G.L. c. 112, §§ 39 – 39J. The proposed amendment does not require small businesses to provide educational services.</p>
Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	<p>Is the regulation likely to <i>deter</i> the formation of small businesses in Massachusetts?</p> <p>Small businesses that operate pharmacies are already accustomed to having to apply for licensure and comply with state regulations and procedures. The new requirement that non-resident pharmacies also apply for licensure and conform to Massachusetts regulations will improve business conditions for in-state pharmacies by placing non-resident pharmacies on equal footing.</p>
Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	<p>Is the regulation likely to <i>encourage</i> the formation of small businesses in Massachusetts?</p> <p>Small businesses that operate pharmacies are already accustomed to having to apply for licensure and comply with state regulations and procedures. The new requirement that non-resident pharmacies also apply for licensure and conform to Massachusetts regulations will improve business conditions for in-state pharmacies by placing non-resident pharmacies on equal footing.</p>
Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	<p>Does the regulation provide for less stringent compliance or reporting requirements for small businesses?</p> <p>The proposed amendment establishes fees to apply and renew new pharmacy license types required pursuant to pharmacy reform legislation (St.2014, c.159), codified at M.G.L. c. 112, §§ 39 – 39J. The proposed amendment does not set reporting requirements.</p>
Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	<p>Does the regulation establish less stringent schedules or deadlines for compliance or reporting requirements for small businesses?</p> <p>The proposed amendment establishes fees to apply and renew new pharmacy license types required</p>

		pursuant to pharmacy reform legislation (St.2014, c.159), codified at M.G.L. c. 112, §§ 39 – 39J. The proposed amendment does not set compliance schedules requirements.
Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Did the agency consolidate or simplify compliance or reporting requirements for small businesses? The proposed amendment establishes fees to apply and renew new pharmacy license types required pursuant to pharmacy reform legislation (St.2014, c.159), codified at M.G.L. c. 112, §§ 39 – 39J. The proposed amendment does not set compliance schedules or requirements.
Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Can performance standards for small businesses replace design or operational standards without hindering delivery of the regulatory objective? The proposed amendment establishes fees to apply and renew new pharmacy license types required pursuant to pharmacy reform legislation (St.2014, c.159), codified at M.G.L. c. 112, §§ 39 – 39J. The proposed amendment does not set compliance schedules or requirements.
Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Are there alternative regulatory methods that would minimize the adverse impact on small businesses? The proposed amendment establishes fees to apply and renew new pharmacy license types required pursuant to pharmacy reform legislation (St.2014, c.159), codified at M.G.L. c. 112, §§ 39 – 39J. The proposed amendment does not set compliance schedules or requirements.