



The Commonwealth of Massachusetts
Executive Office of Health and Human Services
Department of Public Health
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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 emergency amendments to the following regulation: 105 CMR 700.000 – *Implementation of M.G.L. c. 94C*.

The emergency amendments update the regulation which implements M.G.L. c. 94C, the Controlled Substances Act. The emergency amendments implement the statutory authorization for pharmacists to prescribe hormonal contraceptives. They were duly filed with the Secretary of the Commonwealth on October 13, 2023 and are currently in effect.

The public hearing will be held on **Monday, November 6, 2023, at 1:30 pm**. This hearing will be conducted on a **moderated conference call**. The information for the moderated conference call is:

Dial-in Telephone Number: 888-603-6976

Participant Passcode: 6938553

A copy of the proposed amendments to 105 CMR 700.000 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, or requested from the Office of the General Counsel by calling 617-624-5220.

The Department encourages all interested parties, including those who testify at the public hearing, to submit written testimony electronically to Reg.Testimony@mass.gov. Please submit electronic testimony as an attached Word document and type "105 CMR 700.000 Emergency Regulations" in the subject line of the email. All submitted testimony must include the sender's full name and address. The Department will post all electronic testimony that complies with these instructions on its website. Parties who are unable to submit electronic testimony should mail submissions to William Anderson, Office of the General Counsel, Department of Public Health, 250 Washington Street, Boston, MA 02108.

All comments must be submitted by 5:00 p.m. Monday, November 6, 2023. 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
105 CMR 700.000, Implementation of M.G.L. c. 94C
(As required by M.G.L. c. 30A §§ 2, 3 & 5)

CMR No: 105 CMR 700.000

Estimate of the Number of Small Businesses Impacted by the Regulation: The proposed regulatory amendments are not expected to impact small businesses.

Select Yes or No and Briefly Explain

Yes	No X	Will small businesses have to create, file, or issue additional reports? <i>The proposed regulatory amendments implement a statutory authorization and are not expected to impact small businesses.</i>
Yes	No X	Will small businesses have to implement additional recordkeeping procedures? <i>The proposed regulatory amendments implement a statutory authorization and are not expected to impact small businesses.</i>
Yes	No X	Will small businesses have to provide additional administrative oversight? <i>The proposed regulatory amendments implement a statutory authorization and are not expected to impact small businesses.</i>
Yes	No X	Will small businesses have to hire additional employees in order to comply with the proposed regulation? <i>The proposed regulatory amendments implement a statutory authorization and are not expected to impact small businesses.</i>
Yes	No X	Does compliance with the regulation require small businesses to hire other professionals (e.g. a lawyer, accountant, engineer, etc.)? <i>The proposed regulatory amendments implement a statutory authorization and are not expected to impact small businesses.</i>
Yes	No X	Does the regulation require small businesses to purchase a product or make any other capital investments in order to comply with the regulation? <i>The proposed regulatory amendments implement a statutory authorization and are not expected to impact small businesses.</i>
Yes	No X	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. The proposed changes must be made through regulation to implement statutory changes to practitioner scope of practice.</i>
Yes	No X	Do any other regulations duplicate or conflict with the proposed regulation? <i>There are no other regulations that duplicate or conflict with the proposed amendments to this regulation, although complimentary changes may also be made in pharmacists' scope of practice regulations.</i>

Yes	No X	Does the regulation require small businesses to cooperate with audits, inspections or other regulatory enforcement activities? <i>The proposed regulatory amendments will be accompanied by detailed guidance that includes provisions clarifying statutory requirements for pharmacists who prescribe and dispense contraceptives.</i>
Yes	No X	Does the regulation require small businesses to provide educational services to keep up to date with regulatory requirements? <i>The proposed regulatory amendments implement a statutory authorization and are not expected to impact small businesses</i>
Yes	No X	Is the regulation likely to <i>deter</i> the formation of small businesses in Massachusetts? <i>The proposed regulatory amendments implement a statutory authorization and are not expected to impact small businesses</i>
Yes	No X	Is the regulation likely to <i>encourage</i> the formation of small businesses in Massachusetts? <i>The proposed regulatory amendments implement a statutory authorization and are not expected to impact small businesses</i>
Yes	No X	Does the regulation provide for less stringent compliance or reporting requirements for small businesses? <i>The proposed regulatory amendments implement a statutory authorization and are not expected to impact small businesses.</i>
Yes	No X	Does the regulation establish less stringent schedules or deadlines for compliance or reporting requirements for small businesses? <i>The proposed regulatory amendments implement a statutory authorization and are not expected to impact small businesses</i>
Yes	No X	Did the agency consolidate or simplify compliance or reporting requirements for small businesses? <i>The proposed regulatory amendments implement a statutory authorization and are not expected to impact small businesses</i>
Yes	No X	Can performance standards for small businesses replace design or operational standards without hindering delivery of the regulatory objective? <i>No. The proposed changes must be made through regulation to implement statutory changes to pharmacists' scope of practice.</i>
Yes	No X	Are there alternative regulatory methods that would minimize the adverse impact on small businesses? <i>The proposed regulatory amendments implement a statutory authorization and are not expected to impact small businesses</i>