



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 Department of Public Health will hold a public hearing and comment period on the proposed amendments to 105 CMR 140.000 *Licensure of Clinics* regarding birth centers and 105 CMR 130.000: *Hospital Licensure* regarding birth centers and tiering of stroke services and on the proposed rescission of 105 CMR 142.000 *Operation and maintenance of birth centers*. These proposed amendments and proposed rescission were filed on September 20, 2024.

In August 2024, *An Act promoting access to midwifery care and out-of-hospital birth options* was passed and include a number of requirements for “freestanding birth centers” for the Department to include in the clinic licensure regulations. The proposed amendments to both the hospital and clinic licensure regulations, consistent with the statutory changes, update the requirements for hospitals and clinics providing birth center services.

Additionally, the Department is proposing to rescind the now obsolete regulations 105 CMR 142.000, *Operation and maintenance of birth centers*, as all content of 105 CMR 142.000 was lifted and integrated into 105 CMR 130.000 in 2017 and into 105 CMR 140.000 in 2021.

The Department is further proposing changes to 105 CMR 130.000: *Hospital Licensure*, in accordance with Section 90 of the Massachusetts FY24 budget, approved August 2023, which requires the Department to promulgate regulations that create statewide criteria for designating hospitals in a tiered system.

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

Dial-in Telephone Number: **800-619-7796**  
Participant Passcode: **1474860**  
To Testify Press: **\*1**

A copy of the proposed amendments to 105 CMR 130.000 and 105 CMR 140.000, as well as the proposed rescission of 105 CMR 142.000, may be viewed on the Department’s website at

<http://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 written testimony electronically to [Reg.Testimony@mass.gov](mailto: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. Please submit electronic testimony as an attached Word document and type “Healthcare Facility Licensure 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. **All comments must be submitted by 5:00 p.m. on October 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 Stacy Hart at least 5 days before the hearing at Tel #857-274-1120, or email [Stacy.Hart@mass.gov](mailto:Stacy.Hart@mass.gov).



**Small Business Impact Statement***(As required by M.G.L. c. 30A §§ 2, 3 & 5)***Agency:** Department of Public Health**CMR No:** 105 CMR 130.000: Hospital licensure**Estimate of the Number of Small Businesses Impacted by the Regulation:** Presently, there are approximately 96 hospitals in Massachusetts. It is unlikely that any of these businesses qualify as a small business.**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?  <i>No, small businesses will not have to create, file, or issue additional reports.</i>
Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	Will small businesses have to implement additional recordkeeping procedures?  <i>Yes, if these updates were to apply to a small business, they would have to maintain new minimum records for each pregnant and birthing person served at a birth center.</i>
Yes <input type="checkbox"/>	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.</i>
Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	Will small businesses have to hire additional employees in order to comply with the proposed regulation?  <i>Yes, if these updates were to apply to a small business, they may have to hire additional employees in order to comply with new minimum standards for stroke services.</i>
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.)?  <i>No, compliance with the regulation does not require small businesses to hire other professionals.</i>
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?  <i>No, the regulation does not require small businesses to purchase a product or make any other capital investments in order to comply with the regulation.</i>
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.)  <i>No, performance standards are not more appropriate to accomplish these regulatory objectives.</i>
Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Do any other regulations duplicate or conflict with the proposed regulation?  <i>No, no other regulations duplicate or conflict with the proposed regulation.</i>
Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	Does the regulation require small businesses to cooperate with audits, inspections, or other regulatory enforcement activities?  <i>Yes, if these updates were to apply to a small business, they would require small businesses to cooperate with inspections and other regulatory enforcement activities in order for DPH to ensure the health and safety of residents.</i>

Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	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 <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Is the regulation likely to <i>deter</i> the formation of small businesses in Massachusetts?  <i>No, the regulation is not likely to deter the formation of small businesses in Massachusetts</i>
Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Is the regulation likely to <i>encourage</i> the formation of small businesses in Massachusetts?  <i>No, the regulation is not likely to encourage the formation of small business in Massachusetts.</i>
Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Does the regulation provide for less stringent compliance or reporting requirements for small businesses?  <i>No, the regulation does not provide for less stringent compliance or reporting requirements for small businesses.</i>
Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Does the regulation establish less stringent schedules or deadlines for compliance or reporting requirements for small businesses?  <i>No, the regulation does not establish less stringent schedules or deadlines for compliance or reporting requirements for small businesses.</i>
Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Did the agency consolidate or simplify compliance or reporting requirements for small businesses?  <i>No, the Department did not consolidate or simplify compliance or reporting requirements for small businesses.</i>
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?  <i>No, performance standards cannot replace these proposed amendments to regulation.</i>
Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Are there alternative regulatory methods that would minimize the adverse impact on small businesses?  <i>No, there are no alternative regulatory methods that would minimize the impact on small businesses.</i>

**Small Business Impact Statement***(As required by M.G.L. c. 30A §§ 2, 3 & 5)***Agency:** Department of Public Health**CMR No:** 105 CMR 140.000: Licensure of Clinics**Estimate of the Number of Small Businesses Impacted by the Regulation:** Presently, there are approximately 952 clinics and clinic satellites in Massachusetts. It is likely that some identify as a small business, but the exact number is not known.**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?  <i>No, small businesses will not have to create, file, or issue additional reports.</i>
Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	Will small businesses have to implement additional recordkeeping procedures?  <i>Yes, if these updates were to apply to a small business, they would have to maintain new minimum records for each pregnant and birthing person served at a birth center.</i>
Yes <input type="checkbox"/>	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.</i>
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?  <i>No, small businesses will not have to hire additional employees in order to comply with the proposed regulation.</i>
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.)?  <i>No, compliance with the regulation does not require small businesses to hire other professionals.</i>
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?  <i>No, the regulation does not require small businesses to purchase a product or make any other capital investments in order to comply with the regulation.</i>
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.)  <i>No, performance standards are not more appropriate to accomplish these regulatory objectives.</i>
Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Do any other regulations duplicate or conflict with the proposed regulation?  <i>No, no other regulations duplicate or conflict with the proposed regulation.</i>
Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	Does the regulation require small businesses to cooperate with audits, inspections, or other regulatory enforcement activities?  <i>Yes, this regulation does require small businesses to cooperate with inspections and other regulatory enforcement activities in order for DPH to ensure the health and safety of residents.</i>

Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	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 <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Is the regulation likely to <i>deter</i> the formation of small businesses in Massachusetts?  <i>No, the regulation is not likely to deter the formation of small businesses in Massachusetts</i>
Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	Is the regulation likely to <i>encourage</i> the formation of small businesses in Massachusetts?  <i>Yes, the regulation may encourage the formation of small businesses in Massachusetts, specifically, the formation of licensed clinics offering birth center services.</i>
Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Does the regulation provide for less stringent compliance or reporting requirements for small businesses?  <i>No, the regulation does not provide for less stringent compliance or reporting requirements for small businesses.</i>
Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Does the regulation establish less stringent schedules or deadlines for compliance or reporting requirements for small businesses?  <i>No, the regulation does not establish less stringent schedules or deadlines for compliance or reporting requirements for small businesses.</i>
Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Did the agency consolidate or simplify compliance or reporting requirements for small businesses?  <i>No, the Department did not consolidate or simplify compliance or reporting requirements for small businesses.</i>
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?  <i>No, performance standards cannot replace these proposed amendments to regulation.</i>
Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Are there alternative regulatory methods that would minimize the adverse impact on small businesses?  <i>No, there are no alternative regulatory methods that would minimize the impact on small businesses.</i>

**Small Business Impact Statement***(As required by M.G.L. c. 30A §§ 2, 3 & 5)***Agency:** Department of Public Health**CMR No:** 105 CMR 142.000: Operation and maintenance of birth centers**Estimate of the Number of Small Businesses Impacted by the Regulation:** As of August 2024, there is one (1) birth center operating in the Commonwealth of Massachusetts. The Department is aware of one additional birth center that is currently in the process of opening.**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?  <i>This proposal is for the wholesale rescission of an obsolete regulation. It does not contemplate small businesses separately.</i>
Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Will small businesses have to implement additional recordkeeping procedures?  <i>This proposal is for the wholesale rescission of an obsolete regulation. It does not contemplate small businesses separately.</i>
Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Will small businesses have to provide additional administrative oversight?  <i>This proposal is for the wholesale rescission of an obsolete regulation. It does not contemplate small businesses separately.</i>
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?  <i>This proposal is for the wholesale rescission of an obsolete regulation. It does not contemplate small businesses separately.</i>
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.)?  <i>This proposal is for the wholesale rescission of an obsolete regulation. It does not contemplate small businesses separately.</i>
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?  <i>This proposal is for the wholesale rescission of an obsolete regulation. It does not contemplate small businesses separately.</i>
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.)  <i>This proposal is for the wholesale rescission of an obsolete regulation. It does not contemplate small businesses separately.</i>
Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Do any other regulations duplicate or conflict with the proposed regulation?  <i>This proposal is for the wholesale rescission of an obsolete regulation. It does not contemplate small businesses separately.</i>

Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Does the regulation require small businesses to cooperate with audits, inspections, or other regulatory enforcement activities?  <i>This proposal is for the wholesale rescission of an obsolete regulation. It does not contemplate small businesses separately.</i>
Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Does the regulation require small businesses to provide educational services to keep up to date with regulatory requirements?  <i>This proposal is for the wholesale rescission of an obsolete regulation. It does not contemplate small businesses separately.</i>
Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Is the regulation likely to <i>deter</i> the formation of small businesses in Massachusetts?  <i>This proposal is for the wholesale rescission of an obsolete regulation. It does not contemplate small businesses separately.</i>
Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Is the regulation likely to <i>encourage</i> the formation of small businesses in Massachusetts?  <i>This proposal is for the wholesale rescission of an obsolete regulation. It does not contemplate small businesses separately.</i>
Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Does the regulation provide for less stringent compliance or reporting requirements for small businesses?  <i>This proposal is for the wholesale rescission of an obsolete regulation. It does not contemplate small businesses separately.</i>
Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Does the regulation establish less stringent schedules or deadlines for compliance or reporting requirements for small businesses?  <i>This proposal is for the wholesale rescission of an obsolete regulation. It does not contemplate small businesses separately.</i>
Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Did the agency consolidate or simplify compliance or reporting requirements for small businesses?  <i>This proposal is for the wholesale rescission of an obsolete regulation. It does not contemplate small businesses separately.</i>
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?  <i>This proposal is for the wholesale rescission of an obsolete regulation. It does not contemplate small businesses separately.</i>
Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Are there alternative regulatory methods that would minimize the adverse impact on small businesses?  <i>This proposal is for the wholesale rescission of an obsolete regulation. It does not contemplate small businesses separately.</i>