



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

MAURA T. HEALEY  
Governor

KIMBERLEY DRISCOLL  
Lieutenant Governor

KATHLEEN E. WALSH  
Secretary

ROBERT GOLDSTEIN, MD, PhD  
Commissioner

Tel: 617-624-6000  
[www.mass.gov/dph](http://www.mass.gov/dph)

### 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 the amendment of *105 CMR 222: Massachusetts immunization information system*. The public hearing will be held virtually on Friday, March 15, 2024, at 10:00 a.m. as a moderated conference call. The information for the conference call is below:

Dial in Telephone Number: 1-888-390-5183  
Participant Passcode: 1968518

Speakers 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](mailto:reg.testimony@mass.gov). Please submit electronic testimony as an attached Word document or as text within the body of an email and type "105 CMR 222 Regulation" in the subject line. All submissions 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 written or oral comments submitted to the Department may be posted on the Department's website and released in response to a request for public records. All testimony must be submitted by 5:00 p.m. on Friday, March 15, 2024.

A copy of the proposed amendments may be viewed on the Department's website or obtained from the Office of the General Counsel at 617-624-5220.

If you are deaf or hard of hearing, or are a person with a disability who requires accommodation, please contact Sofie Daley at least 5 days before the hearing at [sofie.daley@mass.gov](mailto:sofie.daley@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 222.000: Massachusetts Immunization Information System**

**Estimate of the Number of Small Businesses Impacted by the Regulation:** The number of Physician Offices potentially subject to the regulation is difficult to calculate because they are not licensed as such. According to the web site of the Board of Registration in Medicine, there are approximately 27,845 physicians with a full, active license and business address in MA, some of whom practice in independent offices that might qualify as small businesses but generally do not self-report as small businesses. The Board of Registration in Pharmacy, reports there are approximately 277 independent (non –chain) pharmacies most likely to qualify small businesses. These amendments should have little impact as these pharmacies have been subject to these regulations since 2015.

### Select Yes or No and Briefly Explain

Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	<p>Will small businesses have to create, file, or issue additional reports?</p> <p><i>Amending this regulation will not result in any additional or new reporting requirements.</i></p>
Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	<p>Will small businesses have to implement additional recordkeeping procedures?</p> <p><i>Amending this regulation will not result in any additional or new recordkeeping procedures.</i></p>
Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	<p>Will small businesses have to provide additional administrative oversight?</p> <p><i>Amending this regulation will not necessitate additional administrative oversight.</i></p>
Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	<p>Will small businesses have to hire additional employees in order to comply with the proposed regulation?</p> <p><i>Amending this regulation will not necessitate additional employees.</i></p>
Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	<p>Does compliance with the regulation require small businesses to hire other professionals (e.g. a lawyer, accountant, engineer, etc.)?</p> <p><i>Amending this regulation will not necessitate the hiring of other professionals.</i></p>
Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	<p>Does the regulation require small businesses to purchase a product or make any other capital investments in order to comply with the regulation?</p> <p><i>Amending this regulation will not require any purchase or investment by small businesses.</i></p>
Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	<p>Are performance standards more appropriate than design/operational standards to accomplish the regulatory objective?</p> <p>(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.)</p> <p><i>No, performance standards would not be appropriate to accomplish the regulatory objective.</i></p>

Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Do any other regulations duplicate or conflict with the proposed regulation?  <i>There are no other regulations in Massachusetts that oversee an immunization information system.</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>Amending this regulation will have no impact on small business in Massachusetts, and therefore will not require small businesses to cooperate with audits, inspections, or other enforcement activities.</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>There are no educational service requirements in this regulation pertaining to small businesses other than those implemented in 2015. Any necessary technical assistance is provided by the Immunization Division staff at the Bureau of Infectious Disease and Laboratory Sciences.</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>Amending this regulation will have no impact on small business in Massachusetts and is not likely to deter the formation of small businesses.</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>Amending this regulation will have no impact on small business in Massachusetts and is not likely to encourage the formation of small businesses.</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>Amending this regulation will have no impact on small business in Massachusetts, and these amendments therefore do 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>Amending this regulation will have no impact on small business in Massachusetts, and these amendments therefore do 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>Amending this regulation will have no impact on small business in Massachusetts.</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>Amending this regulation will have no impact on small business in Massachusetts, and therefore performance standards for small businesses would not be an appropriate replacement for these proposed amendments.</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>Amending this regulation will have no impact on small business in Massachusetts.</i>