

Division of Medical Assistance
Commonwealth of Massachusetts
Office of Medicaid

NOTICE OF PUBLIC HEARING

Under the authority of M.G.L. c. 6A, section 16 and in accordance with M.G.L. c. 30A, the Division of Medical Assistance (the Division) will hold a remote public hearing on Friday, July 24, 2026, at 10 a.m. relative to the adoption of amendments to the following regulation.

130 CMR 401.000: Independent Clinical Laboratory Services

The proposed regulation is planned to go into effect no sooner than October 2, 2026. There is no fiscal impact on cities and towns.

The proposed amendments clarify the provider eligibility requirements for out-of-state providers and add an exception to the 180-day limitation on standing order requests for clinical laboratory services related to end stage renal dialysis (ESRD) treatment so that they may not exceed 365 days in length.

To [register to testify at the hearing and to get instructions on how to join the hearing online](#), go to www.mass.gov/info-details/masshealth-public-hearings. To join the hearing by phone, call (646) 558-8656 and enter meeting ID 935 397 8200# when prompted.

You may also [submit written testimony](#) instead of, or in addition to, live testimony. To submit written testimony, please email your testimony to masshealthpublicnotice@mass.gov as an attached Word or PDF document or as text within the body of the email with the name of the regulation in the subject line. All written testimony must include the sender's full name, mailing address, and organization or affiliation, if any. Individuals who are unable to submit testimony by email should mail written testimony to EOHHS, c/o D. Briggs, 100 Hancock Street, 6th Floor, Quincy, MA 02171. Written testimony will be accepted through 5 p.m. on July 24, 2026. The Division specifically invites comments as to how the amendments may affect beneficiary access to care.

To [review the current draft of the proposed regulation](#), go to www.mass.gov/info-details/masshealth-public-hearings or request a copy in writing from MassHealth Publications, 100 Hancock Street, 6th Floor, Quincy, MA 02171.

[Special accommodation requests](#) may be directed to the Disability Accommodations Ombudsman by email at ADAAccommodations@mass.gov or by phone at (617) 847-3468 (TTY: (617) 847-3788 for people who are deaf, hard of hearing, or speech disabled). Please allow two weeks to schedule sign language interpreters.

The Division may adopt a revised version of the proposed regulation taking into account relevant comments and any other practical alternatives that come to its attention.

In case of inclement weather or other emergency, [hearing cancellation announcements](https://www.mass.gov/info-details/masshealth-public-hearings) will be posted on the MassHealth website at www.mass.gov/info-details/masshealth-public-hearings.

Date of Newspaper Ad: July 3, 2024

Small Business Impact Statement

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

CMR No. and Title: 130 CMR 401.000: *Independent Clinical Laboratory Services*

Estimate of the Number of Small Businesses Impacted by the Regulation: There are currently 121 providers enrolled as independent clinical laboratories in the MassHealth network.

- Will small businesses have to create, file, or issue additional reports?
No. Small businesses will not have to create, file, or issue additional reports.
- Will small businesses have to implement additional recordkeeping procedures?
No. Small businesses will not have to implement additional recordkeeping procedures.
- Will small businesses have to provide additional administrative oversight?
No. Small businesses will not have to provide additional administrative oversight.
- Will small businesses have to hire additional employees in order to comply with the proposed regulation?
No. Small businesses will not have to hire additional employees to comply with the proposed regulation.
- Does compliance with the regulation require small businesses to hire other professionals (e.g. a lawyer, accountant, engineer, etc.)?
No. Small businesses are not required to hire other professionals to comply with the regulation.
- Does the regulation require small businesses to purchase a product or make any other capital investments in order to comply with the regulation?
No. Small businesses are not required to purchase a product or make any other capital investments to comply with the regulation.
- Are performance standards more appropriate than design/operational standards to accomplish the regulatory objective?
Yes. 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.
- Do any other regulations duplicate or conflict with the proposed regulation?
No. No other regulations duplicate or conflict with the proposed regulation.
- Does the regulation require small businesses to cooperate with audits, inspections or other regulatory enforcement activities?
No. The regulatory amendments do not require cooperation with additional audits, inspections, or other regulatory enforcement activities.
- Does the regulation require small businesses to provide educational services to keep up to date with regulatory requirements?
No. The regulatory amendments do not require small businesses to provide educational services to keep up with regulatory requirements.
- Is the regulation likely to *deter* the formation of small businesses in Massachusetts?

No. The regulation is unlikely to deter or encourage the formation of small businesses in Massachusetts.

- Is the regulation likely to encourage the formation of small businesses in Massachusetts?

Yes, increasing the maximum duration of standing orders requests to treat end stage renal dialysis (ESRD) to 365 days will reduce administrative burden on providers.

- Does the regulation provide for less stringent compliance or reporting requirements for small businesses?

Yes, it will increase the maximum duration of standing order requests for ESRD from 180 days to 365 days in length.

- Does the regulation establish less stringent schedules or deadlines for compliance or reporting requirements for small businesses?

No. This regulation does not establish any less stringent schedules or deadlines for compliance or reporting requirements for small businesses.

- Did the agency consolidate or simplify compliance or reporting requirements for small businesses?

No. The agency did not consolidate or simplify compliance or reporting requirements for small businesses.

- Can performance standards for small businesses replace design or operational standards without hindering delivery of the regulatory objective?

No. It cannot replace design or operational standards without hindering delivery of the regulatory objective.

- Are there alternative regulatory methods that would minimize the adverse impact on small businesses?

No. The regulation does not have an adverse impact on small businesses.