

**Commonwealth of Massachusetts  
Division of Medical Assistance**

**NOTICE OF PUBLIC HEARING**

Pursuant to 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, August 25, at 1:00 p.m. relative to the adoption of amendments to:

**130 CMR 406.000: Pharmacy Services**

The proposed amendments to 130 CMR 406.000 update coverage for the MassHealth pharmacy program. Specifically, the proposed amendments include provisions to:

- allow MassHealth to pay for drugs used for the treatment of obesity;
- add language about step therapy protocol exceptions when necessary to comply with M.G.L. c.118E, § 51A;
- remove the language “male or female” from the language about fertility drugs and drugs for sexual dysfunction to make the language more gender inclusive;
- clarify that drugs for cosmetic purposes will be covered if medically necessary (e.g., for treatment relating to alopecia or gender identity);
- clarify coverage of compounded drugs;
- add language about a state requirement that pharmacies must offer prospective drug review and counseling and document a patient’s refusal for counseling if applicable, consistent with requirements in M.G.L. c.94C, § 21A; and
- add in language referencing the use of rates in 101 CMR 317.00: *Rates for Medicine Services* to pay for some items listed on the MassHealth Non-Drug Product List, to conform with current practice.

The proposed regulation is planned to go into effect no sooner than January 1, 2024.

To register to testify at the hearing and to get instructions on how to join the hearing online, go to [www.mass.gov/service-details/masshealth-public-hearings](http://www.mass.gov/service-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 it to [masshealthpublicnotice@mass.gov](mailto: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 D. Briggs, 100 Hancock Street, 6th Floor, Quincy, MA 02171. Written testimony will be accepted through 5:00 p.m. on August 25, 2023. The Division specifically invites comments as to how the amendments may affect beneficiary access to care.

To review the current draft of the proposed actions, go to [www.mass.gov/service-details/masshealth-public-hearings](http://www.mass.gov/service-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](mailto: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 actions 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 will be posted on the MassHealth website at [www.mass.gov/service-details/masshealth-public-hearings](http://www.mass.gov/service-details/masshealth-public-hearings).

August 4, 2023

## Small Business Impact Statement

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

**CMR No: 130 CMR 406.000: Pharmacy Services**

**Estimate of the Number of Small Businesses Impacted by the Regulation: 250**

**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? No. Small businesses will not have 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? No. Small businesses will not have to implement additional recordkeeping procedures.
Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Will small businesses have to provide additional administrative oversight? No. Small businesses will not have 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? No. Small businesses will not have to hire additional employees to comply with the proposed regulation.
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.)? No. Small businesses are not required to hire other professionals to comply with the regulation.
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? No. Small businesses are not required to purchase a product or make any other capital investments in order to comply with the regulation.
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.) No. Performance standards are not more appropriate than design/operational standards to accomplish the regulatory objective.
Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Do any other regulations duplicate or conflict with the proposed regulation? No. No other regulations duplicate or conflict with the proposed regulation.
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? Yes. The amendments require providers to provide certain records to regulators upon request to prevent abuse and enhance program integrity.
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? No. The regulatory amendments do not require small businesses to provide educational services to keep up with regulatory requirements.

Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Is the regulation likely to <i>deter</i> the formation of small businesses in Massachusetts? No. The regulation is unlikely to deter or encourage the formation of small businesses in Massachusetts.
Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Is the regulation likely to <i>encourage</i> the formation of small businesses in Massachusetts? The regulation is unlikely to deter or encourage the formation of small businesses in Massachusetts.
Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Does the regulation provide for less stringent compliance or reporting requirements for small businesses? No. The regulation does not distinguish between small and other businesses, but instead seeks to apply uniform standards.
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? No. The regulation does not distinguish between small and other businesses, but instead seeks to apply uniform standards.
Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	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.
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? Performance standards cannot be used without hindering delivery of the regulatory objective.
Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Are there alternative regulatory methods that would minimize the adverse impact on small businesses? The goals of the regulation could not be achieved through alternative methods that would minimize the adverse impact on small businesses.