Commonwealth of Massachusetts Executive Office of Health and Human Services

NOTICE OF PUBLIC HEARING

Under the authority of M.G.L. c. 118E and in accordance with M.G.L. c. 30A, the Executive Office of Health and Human Services (EOHHS) will hold a remote public hearing on Friday, April 19, 2024, at 10 a.m. relative to the adoption of amendments to the following regulation.

101 CMR 320.00: Rates for Clinical Laboratory Services

The proposed regulation contains rates effective for dates of service on or after September 1, 2024. There is no fiscal impact on cities and towns.

Pursuant to M.G.L. Chapter 118E, Sections 13C and 13D, the Executive Office of Health and Human Services (EOHHS) is required to establish and periodically review the rates to be paid by governmental units for noninstitutional health care services, including rates of payment for independent clinical laboratory services, provided under the MassHealth program.

The proposed amendments, effective September 1, 2024, are as follows:

- Most rates are proposed to be updated to 88.19% of the corresponding 2023 Medicare rates;
- Rates for codes that do not have corresponding 2023 Medicare rates will be increased by a two-year prospective cost adjustment factor (CAF) of 2.73%;
- Rates for Automated Test Panel (ATP) codes, which have bundled rates for sets of codes, will also be increased by a CAF of 2.73%;
- Rate for code 81528 (Cologuard) (multi-target stool DNA-based colorectal screening) is proposed at \$262.58, which is the same as the non-facility rate proposed, effective May 1, 2024, for colonoscopy code 45378 (diagnostic colonoscopy without intervention) in 101 CMR 316.00: *Rates for Surgery and Anesthesia Services*;
- Rates for COVID-19 testing codes are set to 100% of the corresponding 2023 Medicare rates. If no 2023 Medicare rate is available for a COVID-19 code, its rate is held constant to the existing rate in 101 CMR 320.00;
- Codes currently designated as individual consideration (I.C.) will continue to be priced using I.C.;
- All other rates are proposed to remain at their current levels; and
- The proposed amendments also give EOHHS the authority to issue administrative bulletins announcing selective contracts and/or rebate agreements with clinical laboratory vendors.

To register to testify at the hearing and to get instructions on how to join the hearing online, go to <u>www.mass.gov/service-details/executive-office-of-health-and-human-</u>

<u>services-public-hearings</u>. 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 <u>ehs-regulations@mass.gov</u> 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 5:00 p.m. on April 19, 2024. EOHHS specifically invites comments as to how the amendments may affect beneficiary access to care for MassHealth-covered services.

To review the current draft of the proposed regulation, go to <u>www.mass.gov/service-</u> <u>details/executive-office-of-health-and-human-services-public-hearings</u> 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 <u>ADAAccommodations@mass.gov</u> 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.

EOHHS 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 will be posted on the MassHealth website at <u>www.mass.gov/service-details/executive-office-of-health-and-human-services-public-hearings</u>.

March 29, 2024

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

CMR No: 101 CMR 320.00: Rates for Clinical Laboratory Services

Estimate of the Number of Small Businesses Impacted by the Regulation: There are currently 119 providers enrolled as independent clinical laboratories in the MassHealth network.

	Select Yes or No and Briefly Explain			
Yes	No ⊠	Will small businesses have to create, file, or issue additional reports? No. The proposed amendments will not require small businesses to create, file, or issue additional reports.		
Yes	No ⊠	Will small businesses have to implement additional recordkeeping procedures? No. The proposed amendments will not require additional recordkeeping procedures.		
Yes	No ⊠	Will small businesses have to provide additional administrative oversight? No. The proposed amendments will not require small businesses to provide additional administrative oversight.		
Yes	No X	Will small businesses have to hire additional employees in order to comply with the proposed regulation? No. The proposed amendments will not require small businesses to hire additional employees in order to comply with the proposed regulation.		
Yes	No ⊠	Does compliance with the regulation require small businesses to hire other professionals (e.g. a lawyer, accountant, engineer, etc.)? No. The proposed amendments will not require small businesses to hire other professionals to comply with the regulation.		
Yes	No ⊠	Does the regulation require small businesses to purchase a product or make any other capital investments in order to comply with the regulation? No. The proposed amendments will not require small businesses to purchase a product or make any other capital investments in order to comply with the regulation.		
Yes	No ⊠	Are performance standards more appropriate than design or 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. M.G.L. c. 118E §§ 13C and 13D require EOHHS to establish and periodically review rates to be paid by governmental units for noninstitutional health care services, including clinical laboratory services.		
Yes	No ⊠	Do any other regulations duplicate or conflict with the proposed regulation? No. No other regulations duplicate or conflict with the proposed regulation.		
Yes	No X	Does the regulation require small businesses to cooperate with audits, inspections or other regulatory enforcement activities? No. The proposed amendments will not require small businesses to cooperate with audits, inspections, or other regulatory enforcement activities.		
Yes	No X	Does the regulation require small businesses to provide educational services to keep up to date with regulatory requirements? No. The proposed amendments will not require small businesses to provide educational services to keep up to date with regulatory requirements.		
Yes	No ⊠	Is the regulation likely to <i>deter</i> the formation of small businesses in Massachusetts? No. The proposed amendments are unlikely to deter or encourage the formation of small businesses in Massachusetts as this regulation governs payments for clinical laboratory services provided to publicly aided individuals and is applied uniformly among providers.		

Yes	No ⊠	Is the regulation likely to <i>encourage</i> the formation of small businesses in Massachusetts? No. The proposed amendments to the regulation are unlikely to deter or encourage the formation of small businesses in Massachusetts as this regulation governs payments for clinical laboratory services provided to publicly aided individuals and is applied uniformly among providers.
Yes	No ⊠	Does the regulation provide for less stringent compliance or reporting requirements for small businesses? No. The proposed amendments do not distinguish between small and other businesses.
Yes	No ⊠	Does the regulation establish less stringent schedules or deadlines for compliance or reporting requirements for small businesses? No. The proposed amendments do not distinguish between small and other businesses.
Yes	No ⊠	Did the agency consolidate or simplify compliance or reporting requirements for small businesses? No. The proposed amendments do not distinguish between small and other businesses.
Yes	No ⊠	Can performance standards for small businesses replace design or operational standards without hindering delivery of the regulatory objective? No. Distinguishing small businesses from other businesses would not be practical to implement the proposed regulation.
Yes	No 🖂	Are there alternative regulatory methods that would minimize the adverse impact on small businesses? No. The regulation is required by statute and does not have an adverse impact on small businesses.