Issue Brief

FEDERAL ISSUE BRIEF

Analysis provided for MHA by Larry Goldberg, Goldberg Consulting

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CMS Finalizing CLIA Fees; Histocompatibility, Personnel, and Alternative Sanctions for Certificate of Waiver Laboratories

The Centers for Medicare & Medicaid Services (CMS) are finalizing a rule to: (1) adjust laboratory fees to provide sustainable funding for the user-fee-funded Clinical Laboratory Improvement Amendments of
1988 (CLIA) fees and clarifies the CLIA fee regulations; (2) revise certain requirements for both the histocompatibility test specialty as well as personnel qualifications and responsibilities for CLIA laboratories; and (3) provide additional discretion to CMS by allowing it to impose alternative sanctions against noncompliant Certificate of Waiver laboratories, rather than being limited only to imposing principal sanctions of revocation, suspension or limitation of a laboratory's CLIA certificate.

The rule is scheduled for publication in the **Federal Register** on December 28. A display copy of the 203-page document is currently available at: https://public-inspection.federalregister.gov/2023-28170.pdf. Most will be effective January 27, 2024.

Fees

The fee increase includes an across-the-board increase of 18% and an inflation factor (CPI-U) of 1.049598. To calculate the 4.9598% compound factor for the 2-year increase, CMS multiplied together factors for each of the 2 years as follows:

- Factor Year 1 (Budgeted Rate for Fiscal Year (FY) 2024) = 1.026
- Factor Year 2 (Budgeted Rate for FY 2025) = 1.023

The compounded factor = 1.026 x 1.023 = 1.049598

CMS says it calculated that the one-time 18% across-the-board increase would generate approximately 12.1 million dollars annually while the inflation factor would generate approximately 4.6 million dollars. Based on the more recent data available for this final rule, other proposed fees would generate approximately 7.7 million dollars for a total of approximately 24.4 million dollars per year.

CMS provides the following costs and benefits table.

Questions? Contact Andrew Wheeler, MHA's Vice President of Federal Finance, at 573-893-3700 | ext. 1336 or awheeler@mhanet.com.

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Summary of Costs and Benefits

Provision Description	Total Impact/Costs
CLIA Fee Regulations for CLIA laboratories	CMS estimates that the overall impact of updating the CLIA fees would be an increase of $24,371,183. The final rule impacts approximately 298,791 CLIA certified laboratories: Certificate of Waiver (CoW) = 235,175; Certificate for Provider-performed Microscopy (PPM) Procedures = 29,717; Certificate of Registration (CoR) = 2,891; Certificate of Compliance (CoC) = 17,694; Certificate of Accreditation (CoA) = 15,935. *[Comment – the individual numbers above add to 301,412.]* Although the effect of the changes will increase laboratory costs, implementation of these changes would be negligible in terms of workload for laboratories as these fee increases are operational and technical in nature and do not require additional time to be spent by laboratory employees.
Histocompatibility and Personnel Regulations for CLIA laboratories	CMS estimates that the overall impact of adding requirements for the changes in personnel, histocompatibility, and travel for laboratory director (LD) on-site visits would range from $20,894,051 to $30,520,189 in the first year. The estimated costs included: (1) Laboratories updating policies and procedures related to personnel and histocompatibility, (2) Accrediting organizations and exempt States updating policies and procedures related to personnel, histocompatibility, and laboratory director site visit, (3) Travel for site visits-Driving, and 4) Travel for site visits-Flying. Although the requirements will increase laboratory costs, the implementation of the final rule will streamline and simplify regulations, add flexibility in laboratory hiring practices, ensure that the LD is on-site at least twice per year, and align histocompatibility testing with current methods and practices.
Alternative Sanction	CMS believes this final rule will increase flexibility, decrease potential burden while moving those laboratories toward compliance, and have no added economic impact on CoW laboratories. As previously described, this regulatory change could decrease the burden for sanctions imposed for improper proficiency testing referral. Although CMS has no data indicating that principal sanctions have been imposed on CoW laboratories for this reason in the past, if it occurred in the future, the ability to impose alternative sanctions, if appropriate, would be less punitive and potentially decrease any quantifiable economic impact. At this time, CMS cannot quantify what that impact would be.

Clinical Laboratory Improvement Amendments of 1988 (CLIA) Fees

The rule authorizes a fee increase for the CoW. A CoW laboratory is limited to performing tests categorized by FDA as waived, which are simple laboratory examinations and procedures that have an

insignificant risk of an erroneous result, including those that employ methodologies that are so simple and accurate as to render the likelihood of erroneous results by the user negligible, or that the Secretary has determined pose no unreasonable risk of harm to the patient even if performed incorrectly. Some examples of waived tests include fingerstick tests for blood glucose or cholesterol.

CMS says the CoW fee will increase by an additional $25.00. The current $180.00 biennial CoW fee will become $205.00. (Page 25)

However, the regulatory analysis section of the rule says this fee will increase from $180.00 to $248.00 as noted in the below. (Page 146)

Certificate of Waiver (CoW) Waived Test Categorization Fee*

Type of CLIA certificate	**Current Fee (c)**	**New Fee (n) based on $25 CoW increase with the ATB and Biennial Increase of 18% *4.96%**
Certificate of Waiver (CoW)	$180	$248

*Total CoW lab estimate going into FY 2024 is 235,175/2 = 117,588. The fees are biennial; therefore, approximately half the CoW laboratories are affected annually.

CLIA Requirements for Histocompatibility, Personnel, and Alternative Sanctions for CoW Laboratories

This rule could impact all of the 319,487 CLIA-certified laboratories (accessed from the CMS Quality Improvement Evaluation System (QIES) database September 2022) to some extent. The changes to the personnel requirements will impact 33,747 certificate of compliance (CoC) and certificate of accreditation (CoA) laboratories, as well as 27,257 certificate for provider performed microscopy procedures (PPM) Certificate laboratories. (Page 149)

Comment

This reader has found this rule to be confusing inasmuch as the math and numbers do not appear to follow within the preamble. In the above paragraph, CMS says that 319,474 facilities are CLIA certified. Yet, CMS' cost benefit table says the number is 298,791 facilities.

While the amounts of payments for the CLIA funding appear small, nonetheless laboratories need to review this rule for possible impacts.

Note, we have not addressed changes removing specific requirements for "obsolete methods and practices and eliminating redundant requirements that CMS says will decrease the burden on laboratories performing histocompatibility testing."