DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 493

[CMS-3326-N]

RIN 0938-AT47

Clinical Laboratory Improvement Amendments of 1988 (CLIA) Fees; Histocompatibility, Personnel, and Alternative Sanctions for Certificate of Waiver Laboratories; Extension of Comment Period

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS; Centers for Disease Control and Prevention (CDC), HHS.

ACTION: Proposed rule; extension of comment period.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) and the Centers for Disease Control and Prevention (CDC) within the Department of Health and Human Services (HHS) announce the extension of the comment period for the proposed rule entitled “Clinical Laboratory Improvement Amendments of 1988 (CLIA) Fees; Histocompatibility, Personnel, and Alternative Sanctions for Certificate of Waiver Laboratories.”

DATES: The comment period for the proposed rule published July 26, 2022 (87 FR 44896), is extended through September 26, 2022.

ADDRESSES: In commenting, please refer to file code CMS-3326-P.

Comments, including mass comment submissions, must be submitted in one of the following three ways (please choose only one of the ways listed):

1. **Electronically.** You may submit electronic comments on this regulation to [https://www.regulations.gov](https://www.regulations.gov). Follow the "Submit a comment" instructions.

2. **By regular mail.** You may mail written comments to the following address ONLY:
Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Attention: CMS-3326-P,
P.O. Box 8016,
Baltimore, MD 21244-8016.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. By express or overnight mail. You may send written comments to the following address ONLY:

Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Attention: CMS-3326-P,
Mail Stop C4-26-05,
7500 Security Boulevard,
Baltimore, MD 21244-1850.

FOR FURTHER INFORMATION CONTACT:
Sarah Bennett, CMS, (410) 786-3531, Serafina Brea, CMS, (410) 786-3531, or Heather Stang, CDC, 404-498-2769.

SUPPLEMENTARY INFORMATION:

In the “Clinical Laboratory Improvement Amendments of 1988 (CLIA) Fees; Histocompatibility, Personnel, and Alternative Sanctions for Certificate of Waiver Laboratories” proposed rule that appeared in the July 26, 2022 Federal Register (87 FR 44896), we solicited public comments on proposed changes to CLIA fees, histocompatibility and personnel requirements, and alternative sanctions for Certificate of Waiver laboratories.

In response to requests we received from several laboratory professional organizations, we are extending the comment period an additional 30 days. This extension will maximize the
opportunity for the public to provide meaningful input to CMS and CDC) for an additional 30
days.

**Dated:** August 24, 2022.

Xavier Becerra,

Secretary,

Department of Health and Human Services.

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