



Center for Clinical Standards and Quality/QUALITY & SAFETY SPECIAL ALERT MEMO

Ref: QSSAM-27-01-[CLIA]

SPECIAL ALERT-CLIA LABORATORIES

DATE: October 7, 2026
TO: State Survey Agency Directors
FROM: Director, Quality, Safety & Oversight Group (QSOG)
SUBJECT: Third-Party Solicitations Resembling Official CLIA Communications

Memorandum Summary

- CMS is aware that Clinical Laboratory Improvement Amendments (CLIA) -certified laboratories in several states have received solicitation documents from a third-party entity that are styled as bills or invoices and may be mistaken for official CLIA communications.
- CLIA-certified laboratories are encouraged to carefully review any solicitation, invoice, or other correspondence that appears to be an official CMS or government communication, including the sender, purpose of the communication, and any requested fees or payment instructions.
- Laboratories that are unsure whether a communication is associated with the CLIA program should contact their [State Agency CLIA office](#) or the CMS CLIA Program, at LabExcellence@cms.hhs.gov, for assistance.

This memorandum does not create new regulatory requirements and does not update the State Operations Manual. It reinforces existing CLIA program obligations and protections for certified laboratories.

CMS is aware that CLIA-certified laboratories in several states have received solicitation documents from a third-party entity that are styled as bills or invoices and may be mistaken for official CLIA communications. This document is not issued by CMS and does not represent an official CLIA fee or government notice. Official CLIA communications come only from CMS or your State Survey Agency.

CLIA-certified laboratories are encouraged to carefully review any solicitation, invoice, or other correspondence that appears to be an official CMS or government communication, including the sender, purpose of the communication, and any requested fees or payment instructions. Laboratories that are unsure whether a communication is associated with the CLIA program should contact their State Survey Agency or the CMS CLIA program for assistance.

Background

The CLIA program is administered by CMS under the Department of Health and Human Services (HHS). CLIA establishes minimum quality standards for all laboratory testing performed on human

specimens in the United States to ensure the accuracy, reliability, and timeliness of patient test results. Any laboratory that performs testing on human specimens for health assessment or for the diagnosis, prevention, or treatment of disease must hold a valid CLIA certificate issued by CMS.

CMS oversees the CLIA program through the Quality, Safety & Oversight Group (QSOG) within the Center for Clinical Standards and Quality (CCSQ). State Survey Agencies conduct onsite inspections of laboratories on behalf of CMS to assess compliance with CLIA requirements. The results of these surveys and inspections are recorded in the CMS systems and made publicly available through the Quality, Certification and Oversight Reports (QCOR) system, a free, web-enabled reporting application accessible at CMS [Quality, Certification and Oversight Reports \(QCOR\)](#).

Discussion

CMS has recently received inquiries from various State Agencies regarding a solicitation from a third-party entity to CLIA-certified laboratories. The document may be mistaken for an official CMS notice regarding CLIA fees or another government communication and has been reported by laboratories in several states, including Iowa, Texas, and Minnesota.

This third-party entity is not affiliated with CMS and does not act on CMS's behalf. Official CLIA communications come only from CMS or the State Survey Agency. The laboratory's certification and survey information is publicly available at no cost through the [CMS QCOR](#) website.

What Laboratories Should Do?

1. Contact your [State Agency CLIA office](#) or the CMS CLIA Program at LabExcellence@cms.hhs.gov if you have questions related to this special alert.
2. Share this alert with your laboratory's billing, compliance, and administrative staff.
3. Verify your laboratory's email address is current with CMS to ensure receipt of official electronic CLIA communications.

/s/

Melissa C. Daly
Acting Director, Quality, Safety & Oversight
Group