DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
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Center for Clinical Standards and Quality/Survey & Certification Group

Ref: Admin: 17-25-CLIA

DATE: **September 01, 2017**

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Clinical Laboratory Improvement Amendments of 1988 (CLIA) Enforcement Policies

Memorandum Summary

Enforcement Policies: The Centers for Medicare & Medicaid Services (CMS) is clarifying areas related to the following:

- Collecting Ownership and Operator Information;
- Office of the Inspector General (OIG) Exclusions;
- Electronic Transmission of Hard Copy for Plan of Corrections (POCs) or Allegations of Compliance (AOCs) and other Communication(s); and,
- Audio and Video Recording of Surveys and Exit Conferences.

Background

CMS is providing clarifications and guidance regarding collecting ownership and operatory information, electronic signatures, as well as audiotaping and videotaping of surveys and exit conferences. In addition, the memo seeks to clarify the regulatory enforcement actions associated with a laboratory's CLIA certificate when the OIG excludes a laboratory from Medicare.

Collecting Ownership and Operator Information

Both the CLIA statute and regulations outline adverse actions (i.e., sanctions) which can be taken based on an owner's and/or operator's actions. Furthermore, both the Statute and regulations require that an owner and operator of a laboratory may be banned from owning or operating a CLIA-certified laboratory for two years following the revocation of the laboratory's CLIA certificate. Therefore, it is very important for the SA and RO to collect ownership and operator information at the time of the initial, recertification or complaint survey and in cases when condition-level noncompliance is identified by the surveyor.

OIG Exclusion: Effect on a Laboratory's CLIA Certificate

If the OIG excludes a laboratory from participation in Medicare, CMS suspends the laboratory's CLIA certificate for the period during which the laboratory is excluded per 42 C.F.R. §493.1840(c). Generally, CMS does not suspend a CLIA certificate until after an Administrative Law Judge (ALJ) hearing decision that upholds the suspension (42 C.F.R. §§493.1840(d)(1); 42 C.F.R. §493.1844(d)(2)). The regulations at 42 C.F.R. §§493.1840(d)(2) and §493.1844(d)(2) provide exceptions where the laboratory's deficiencies pose immediate jeopardy, the laboratory has refused a reasonable request for information or work on materials or refused permission for CMS or a CMS agent to inspect the laboratory or its operation. Additional facts may support an argument that one of the exceptions applies, which would allow for the suspension to take effect prior to an ALJ hearing decision upholding the suspension, or alternatively, the passing of 60 days from the date that the laboratory received notice of the proposed sanction.

Unless one of the above exceptions applies, the suspension of an excluded laboratory would not be effective until:

1) 60 days have passed since the lab received notice of the imposed sanction, closing the timeframe for appeal and allowing the sanction to become final, or,
2) A timely appeal is filed and a decision is pending from s an ALJ to uphold the proposed suspension.

If the laboratory's CLIA certificate is suspended, the laboratory can further appeal the suspension of its CLIA certificate to the Departmental Appeals Board (DAB), and seek judicial review of the DAB hearing decision under 42 C.F.R. §493.1844(f), but they would do so while their CLIA certificate was suspended based on the ALJ findings.

Electronic Transmission of Hard Copy for Plan of Corrections (POCs) or Allegations of Compliance (AOCs) and other Communication(s)

The laboratory director (LD) or other authorized official must sign and date the CMS-2567, Statement of Deficiencies. Even if the CMS-2567 is signed by someone other than the LD, the LD remains responsible for the operation and administration of the laboratory. The completed, signed and dated CMS-2567 must be returned as part of the POC/AOC submission. The completed, signed and dated, CMS-2567 and supporting documentation can be sent to the SA/RO via hard copy, facsimile, or as an email attachment. Electronic copies are acceptable; however, an original set (i.e., hard copy) of documentation may also be sent to the SA or RO, as applicable, in addition to the electronic copy.

All CMS-2567s and other communications sent to laboratories (e.g., request for POC or AOC, enforcement) can be sent electronically or via fax; however, a hardcopy of the original letter may also be sent via mail or contract mail service (e.g., FedEx).

Form CMS-116, CLIA Application for Certification, documents require the signature of laboratory director or owner, whether hard copy or electronic. Per S&C-10-22-ALL, CMS would not require duplicative systems, i.e., both electronic and paper; however, CMS does expect the same retention requirements for both electronic and paper records.

Audio and Video Recording of Surveys and Exit Conferences

The State Operations Manual (SOM), Chapter 6, §6126 Exit Conference states the following:

> "*If the laboratory wishes to audio tape the conference, it must tape the entire meeting and provide surveyor(s) with a copy of the tape at the conclusion of the conference. Videotaping is also permitted if it does not intimidate the surveyor disrupt the conference, and a copy is provided at the conclusion of the conference. Use discretion in deciding whether to permit videotaping*." (See §2724.)

The SOM §2724 further states that it is at the sole discretion of the surveyor(s) to determine if videotaping is permitted.

While the CLIA Interpretive Guidelines and Chapter 6 of the SOM do not specifically cover taping of the survey, the surveyor may take the same approach with the survey as with guidance for the exit conference. If the laboratory cannot agree to provide an exact copy prior to the surveyor or survey team leaving the facility, the surveyor would be justified in refusing to conduct or continue the survey and/or exit conference.

Contact: For questions, please contact the LabExcellence mailbox at LabExcellence@cms.hhs.gov.

Effective Date: Immediately. This policy should be communicated with all survey and certification staff, their managers and the State/Regional Office training coordinators within 30 days of this memorandum.

/s/
David R. Wright

cc: Survey and Certification Regional Office Management