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Center for Clinical Standards and Quality/Survey & Certification Group

Ref: QSO-21-04-CLIA

DATE: **November 6, 2020**

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Clinical Laboratory Improvement Amendments of 1988 (CLIA) CMS Locations and State Agency Remote Survey Guidance - Optional Process

Memorandum Summary

- ***CMS is committed*** to taking critical steps to allow CMS Locations and State Agency surveyors flexibility to perform CLIA recertification surveys to ensure America's clinical laboratories are in compliance with the CLIA regulations amid the public health emergency (PHE) caused by the SARS-CoV-2 virus that causes Coronavirus Disease 2019 (COVID-19).
- CMS is issuing this memorandum to CMS Locations and CLIA State Agencies to provide important guidance to surveyors for ***optional*** implementation of this remote survey process during the PHE.
- All guidance in this memo is applicable only during the PHE.
- Laboratories must follow applicable Federal, State, and local laboratory requirements.
- This optional remote CLIA recertification survey process will only apply to laboratories with good compliance history. This does not apply to initial surveys.

Background

CMS is committed to taking critical steps to allow State Agency surveyors flexibility to perform surveys to ensure America's clinical laboratories are in compliance with the CLIA regulations amid the PHE. The intent of the CLIA program is to ensure that test results provided to individuals are accurate and reliable. During this public health emergency, our inspection efforts have been primarily focused on addressing immediate jeopardy situations and we have generally been exercising enforcement discretion for activities that do not rise to that level.

Discussion

CMS recognizes that many State Agencies (SAs) and CMS Locations have been unable to perform routine CLIA on-site surveys due to the current PHE and may be experiencing a backlog of laboratories needing to be surveyed. As a result, CMS has administratively extended laboratory certificates through December 31, 2020, so that no CLIA Certificate of Compliance or Certificate of Accreditation expires before a survey has occurred.

CMS recognizes each State has different variables that may impact the ability of the State Agencies to perform on-site CLIA surveys (e.g., COVID-19 hot spots, availability of surveyors, and travel limitations). Therefore, we are providing an option for State Agencies to perform remote CLIA surveys whenever possible for recertification surveys and some re-visits that may be necessary to resolve current enforcement on a case by case basis. CMS is providing this survey process as an option for the State Agencies; it is not mandatory. However, if a State Agency chooses to implement this remote survey process, we ask the State Agency notify the CMS location (formerly known as CMS Regional Office) and follow the process submitted as an attachment to this memo.

This optional remote CLIA recertification survey process will only be allowed for laboratories with good compliance history. Please refer to the attached Remote Survey Process document for eligibility criteria. Based upon previous survey data, a laboratory with good compliance history is more likely to sustain good compliance when there have been no substantive changes to the laboratory such as ownership, Laboratory Director, personnel, testing menu, etc. In addition, the likelihood that an onsite survey would uncover major quality issues would be significantly reduced in comparison to a laboratory with substantive changes. Therefore, these laboratories would be good candidates for a remote survey process. Conversely, for those laboratories without a good compliance history, a more traditional onsite survey must be performed in a safe manner. However CMS understands there may be extenuating circumstances that may not allow for an onsite survey. If this happens in your State, please contact your Operations Branch Manager for guidance. For surveys that warrant an onsite visit, the surveyor may review documents remotely using this remote CLIA survey process as guidance in order to reduce time onsite.

During this optional process, the surveyor will continue to follow the outcome-oriented survey process (OOSP) and the laboratory would still need to submit the required CLIA survey forms. The surveyor will conduct the process remotely which will include review of pertinent documents, interview of laboratory staff as well as other components of the survey process. During the remote survey process the surveyor may request that the laboratory scan documents for submission to CMS and/or request the laboratory use other available technology so that CMS can perform virtual observation. The remote survey process may take one to several days to complete. The surveyor should consider use of other tools available, i.e., State Operations Manual (SOM) Appendix C Interpretive Guidelines and SOM Chapter 6.

The remote survey process and findings will be evaluated periodically against onsite surveys to ensure consistency and efficacy, and will remain in effect until the public health emergency has ended or until State Agencies are notified by CMS that the process has been discontinued.

Contact: Questions about this document should be addressed to 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

Attachment: Remote CLIA Survey Process

cc: CLIA Branch Managers
CLIA Location Staff

CLIA Remote Survey Process
Surveyor Use Only

I. Pre-Survey Preparation:

- **Select Laboratory**
  - ✓ Laboratory with a CLIA certificate that will expire within 3-6 months, has expired or has previously been extended due to the Public Health Emergency (PHE).
  - ✓ Laboratory has paid survey fees.
  - ✓ No certificate of registrations are eligible—laboratory must have a certificate of compliance.
  - ✓ No condition level deficiencies during its most recent survey.
  - ✓ No substantiated complaints filed against the lab since the most recent recertification survey.
  - ✓ No unsuccessful Proficiency Test (PT) failures since the most recent certification survey.
  - ✓ No changes in specialties or subspecialties performed.
  - ✓ No changes in laboratory director (LD) or ownership since the last survey.
- **CMS-670 (Survey Team Composition and Workload Report) Record Keeping:**
  - ✓ If survey is performed remotely, with no on-site time, surveyor can record hours as "off-site" preparation hours. There won't be any "on-site" hours to record.
  - ✓ Due to the nature of the remote process, survey time may not be continuous, and is likely to be sporadic and slightly fragmented, taking place in blocks of time over several days.
  - ✓ Surveyor should keep detailed log/records of all survey activities that may include, but is not limited to:
    - Phone calls
    - Email review
    - Document review
    - Interviews
- **Schedule Survey**
  - ✓ The surveyor contacts the laboratory to inform them of the option for a remote survey. If the laboratory is amenable, the surveyor and the laboratory determine a time for the survey.
  - ✓ Surveyor will send Forms CMS-209 (OMB No. 0938-0151), CMS-116 (OMB No. 0938-0581), and any state required forms to be completed and returned prior to the survey.
  - ✓ Upon receipt of the completed forms, the surveyor determines time needed for survey and a list of documents to request at the survey.
  - ✓ Surveyor contacts the laboratory and arranges for survey dates.

II. Entrance interview

- ✓ Review/discuss submitted documents, Forms CMS-209 and CMS-116, test menu, volumes, and any other forms.
- ✓ **OPTIONAL.** Perform a virtual tour of the laboratory via electronic methods such as WebEx, Zoom, or other applications that have password protection

capability. Only those that have the invitation and the password would be allowed to participate.

III. Information Gathering:

- **Staff interviews**
  - ✓ Conduct interviews as needed with key staff members using the standard outcome oriented survey process (OOSP).
  - ✓ The surveyor may follow up with laboratory personnel for additional questions or requests.
  - ✓ **OPTIONAL.** Perform an interview of laboratory personnel via electronic methods such as WebEx, Zoom, or other applications that have password protection capability. Only those that have the invitation and the password would be allowed to participate.
- **Document Review**
  - ✓ Based on information gathered the surveyor may request additional documentation be submitted. Electronic submission (scanned documents over email, or via electronic methods such as WebEx, Zoom, or other applications), USPS mail, or other delivery services are options.
  - ✓ Surveyor may follow up any verbal requests in writing (email) with timeline for submission.
  - ✓ The surveyor confirms receipt of all requested documentation.
  - ✓ Surveyor reviews documentation, notes any findings, and contacts the laboratory to ask any follow up questions if needed.
- **Observation**
  - ✓ **OPTIONAL.** Perform observation of laboratory testing processes via electronic methods such as WebEx, Zoom, or other applications that have password protection capability. Only those that have the invitation and the password would be allowed to participate.

IV. Exit Conference

- ✓ Perform upon completion of survey as per routine OOSP.

V. Complete CMS 2567 and continue with certification process as per routine OOSP.