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Center for Clinical Standards and Quality/Quality, Safety & Oversight Group

Ref: QSO-22-14-CLIA

DATE: **March 22, 2022**

TO: State Survey Agency Directors

FROM: Director
Quality, Safety & Oversight Group

SUBJECT: Clinical Laboratory Improvement Amendments of 1988 (CLIA) CMS Location and State Agency Updates to COVID-19 Survey Prioritization Guidance

Memorandum Summary

- ***CMS remains committed*** to taking critical steps to ensure America's clinical laboratories are in compliance with the CLIA regulations amid the public health emergency (PHE) caused by Coronavirus Disease 2019 (COVID-19).
- CMS is issuing this memorandum to CLIA State Agencies to provide updated guidance on actions to fully resume CLIA survey activities. These steps include:
  - Guidance for on-site surveys
  - Guidance for enforcement actions and PT review.

*This memorandum supersedes QSO-20-35-ALL, Enforcement Cases Held during the Prioritization Period and Revised Survey Prioritization, for CLIA only.

Background

Throughout the COVID-19 PHE, CMS has remained committed to ensuring that laboratory test results provided to healthcare consumers are accurate and reliable. Early on in the PHE, CMS took steps to allow states to focus their emergency response efforts on controlling the spread of COVID-19 by limiting survey activities. In August 2020, CMS prioritized the clinical laboratory survey activities in the memorandum, QSO-20-20-ALL Prioritization of Survey Activities. This guidance focused on immediate jeopardy (IJ) situations in which immediate corrective action was necessary because the laboratory's noncompliance with one or more condition-level requirements has already caused, was causing, or was likely to cause, at any time, serious injury or harm, or death, to individuals served by the laboratory or to the health or safety of the general public (including, but not limited to, injury or harm related to COVID-19). This memorandum clarified that pending enforcement actions were suspended, except for those related to unremoved IJ. Subsequently, QSO-20-35-ALL was issued, providing revised guidance on survey activities and resolving enforcement cases.

In November 2020, CMS issued QSO-21-04-CLIA, which gave State survey agencies the flexibility to perform on-site surveys and optional remote CLIA recertification surveys for laboratories that met specific criteria.

Discussion

CMS is providing updated guidance to State Agencies (SAs) on the prioritization given for CLIA laboratory survey activities that supersede the QSO-20-35-ALL memorandum, Enforcement Cases Held during the Prioritization Period and Revised Survey Prioritization. State Survey Agencies (SAs) may fully resume CLIA survey activity in accordance with the SOM Chapter 6 subject to the State's discretion and within their applicable COVID-19 restrictions and safety precautions. State Agencies should make every attempt to balance their workload to reduce the number of pending surveys.

1. On-Site Surveys

State Agencies can perform all regulatory required on-site surveys. Surveyors should continue to take into account individual laboratory location limitations and follow State restrictions. Surveyors can also continue to group their survey activities by geographical locations for the most effective use of travel.

- **Complaints**

  CMS continues to emphasize the importance of complaint investigations to identify serious concerns that threaten the accuracy and reliability of laboratory test results. Throughout the COVID-19 PHE, CMS has directed State Agencies to prioritize complaint investigations. The SA investigates complaints that involve possible immediate jeopardy within two working days of receiving the complaint and focus on the specific problem area. Otherwise, the SA follows procedures for prioritizing and investigating certification-related complaints as described in the State Operations Manual (SOM), Chapter 5. Laboratories with complaints pending are identified and given priority in scheduling regular certification surveys.

- **Initial Certification Surveys**

  An initial survey is generally performed within 3-12 months after a laboratory is issued a CLIA certificate of registration. Initial certification surveys remain a priority to ensure compliance in new laboratories that have not been surveyed. All initial surveys that were not completed before the PHE should be prioritized to ensure laboratories comply with CLIA regulations.

- **Recertification Surveys**

  State Agencies are required to conduct recertification surveys to determine whether or not a laboratory meets CLIA requirements. State agencies perform comprehensive surveys on a biennial basis with a quality assessment focus that evaluates the laboratories' systems

and processes to ensure quality test results and reviews information that effectively identifies problems that could cause actual or potential harm to patients. Recertification surveys are generally performed 6 to 12 months before a laboratory's current certificate expiration date and are announced 2-14 days before the survey date. In the QSO-20-35-ALL memorandum, State survey agencies were given the flexibility to perform specific routine surveys to provide CLIA certified laboratories an opportunity to respond to the PHE. CMS later issued guidance in the QSO-21-04-CLIA memorandum providing states the option to resume on-site surveys or perform CLIA recertification surveys remotely if a laboratory met specific criteria.

State Agencies are advised to fully resume recertification survey activities. State Agencies should prioritize laboratories that have not been surveyed in the past two years.

- **Validation Surveys**

  State Agencies should resume, to the extent possible, performing validation surveys to ensure consistency in the oversight of laboratories by Accreditation Organizations. Surveys are conducted within 90 days of the accreditation survey date and announced 2-14 days before the survey date. State Agencies are advised to perform validation surveys on-site; however, to achieve workload numbers, surveyors can utilize flexibility with a remote option if an on-site visit is not ideal due to a rise in local COVID-19 infections. If the Accreditation Organization survey was performed on-site, State Agency surveyors should plan to conduct an on-site survey. The State Agency can follow up with a remote validation survey for any accreditation survey performed remotely. State Agencies should prioritize initial, complaint, or recertification survey workload and incorporate validation surveys using the most efficient means possible.

- **Revisits**

  Revisits may be performed for all surveys that identified non-compliance and for which a revisit is needed to ensure compliance.

- **Special Surveys for Certificate of Waiver (CoW) and Provider Performed Microscopy (PPM) Laboratories**

  State Agencies should prioritize initial, complaint, or recertification survey workload and incorporate special surveys using the most efficient means possible. For the duration of the PHE, CMS-3401-IFC[1] (85 FR 54820, page 54862) requires the survey of 5% (approximately 1.6% performed each fiscal year from FY 2021 through FY2023) of a combination of CLIA CoW and PPM laboratories. Approximately 1.6% of the total CoW/PPM laboratories designated in the supplemental budgets in FY 2022 and FY 2023 should be surveyed as part of the special survey process.

[1] https://www.federalregister.gov/documents/2020/09/02/2020-19150/medicare-and-medicaid-programs-clinical-laboratory-improvement-amendments-clia-and-patient

2. Enforcement Actions and PT Desk Reviews

Pending and current enforcement actions and PT desk reviews will proceed as usual per the State Operations Manual (SOM), Chapter 6, Sections 6250 – 6298.

Contact: For questions related to CLIA, contact your CMS location.

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: State Agencies
CLIA Branch Managers
CLIA Location Staff