DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
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Center for Clinical Standards and Quality/ Quality, Safety & Oversight Group

Admin Info: 24-09-CLIA

DATE: December 18, 2023

TO: State Survey Agency Directors

FROM: Director, Quality, Safety & Oversight Group (QSOG)

SUBJECT: Onsite/Offsite Follow-up/Revisit Survey Guidance

Memorandum Summary

- **Offsite follow-up/revisit surveys are authorized for the following:**
  - When no condition-level non-compliance is cited within 12 months of the original survey and for mandatory condition-level deficiencies related to proficiency testing (PT) enrollment, 42 CFR § 493.801, unsuccessful participation in PT, 42 CFR § 493.803, and **personnel qualifications** in subpart M – Personnel for Nonwaived Testing, 42 CFR §493.1351 through 42 CFR §493.1495.

- **Onsite follow-up/revisit surveys are authorized for the following:**
  - To verify compliance or confirm continuing serious non-compliance.
  - Prior to the imposition of principal sanctions when the laboratory does not provide an acceptable credible allegation of compliance (AoC) and for condition-level non-compliance related to **personnel responsibilities** in subpart M – Personnel for Nonwaived Testing, 42 CFR §493.1351 through 42 CFR §493.1495.

Background:

CMS is providing guidance to State Survey Agencies (SAs) to appropriately determine whether to perform an onsite or offsite follow-up/revisit survey.

Onsite follow-up/revisit surveys are performed to verify compliance with condition-level deficiencies. If the laboratory has submitted a credible AoC, the SA will determine whether compliance must be verified by an onsite follow-up/revisit survey or offsite, based on evidence submitted by the laboratory. An onsite follow-up/revisit survey is **not** required for mandatory condition-level deficiencies related to proficiency testing (PT) enrollment, unsuccessful participation in PT, and personnel qualifications in subpart M.

Discussion:

Offsite

Within 12 months of the original survey, the SA conducts an offsite follow-up/revisit survey when no condition-level deficiencies are cited. This offsite follow-up/revisit survey is normally conducted by transmission mail, mail, or telephone. An onsite follow-up/revisit survey of

standard-level deficiencies is warranted in rare circumstances such as when the laboratory-provided evidence of correction does not verify correction of the deficiency and/or the documentation provided indicates potential risk to the quality of patient test results.

An offsite follow-up/revisit survey is performed following citation of mandatory condition-level deficiencies related to PT enrollment 42 CFR § 493.801, unsuccessful participation in PT 42 CFR § 493.803, and **personnel qualifications** in subpart M – Personnel for Nonwaived Testing, 42 CFR §493.1351 through 42 CFR §493.1495.

Onsite

When a laboratory has failed to comply with one or more CLIA conditions, the SA performs an onsite follow-up/revisit survey after the laboratory makes a credible AoC. When conducting an onsite follow-up/revisit survey, the SA verifies that the evidence of correction is acceptable and that the AoC is credible.

In some cases, the condition-level deficiencies may allow for e-mail, mail, or telephone contact in place of an onsite visit, (e.g., the laboratory agreed to amend its written policies). An onsite follow-up/revisit survey is **not** required for mandatory condition-level deficiencies related to PT enrollment 42 CFR § 493.801, unsuccessful participation in PT 42 CFR § 493.803, and **personnel qualifications** in subpart M – Personnel for Nonwaived Testing, 42 CFR §493.1351 through 42 CFR §493.1495. An onsite follow-up/revisit survey **is** performed for condition-level deficiencies related to **personnel responsibilities** in subpart M – Personnel for Nonwaived Testing, 42 CFR §493.1351 through 42 CFR §493.1495.

If the condition-level deficiencies indicate a potential risk to the quality of patient test results, an onsite follow-up/revisit survey must be performed. If the laboratory does not give the SA a credible AoC for outstanding condition-level deficiencies, an onsite follow-up/revisit is required prior to the imposition of principal sanctions.

The SA may consult with CMS for a determination regarding the appropriate type of follow-up/revisit. Any additional onsite follow-up/revisit surveys must be approved by CMS.

Contact:

For questions or concerns about this memorandum, please contact the LabExcellence mailbox at LabExcellence@cms.hhs.gov.

Effective Date:

Immediately. Please communicate to all appropriate staff within 30 days.

/s/
David R. Wright
Director, Quality, Safety & Oversight Group

Resources to Improve Quality of Care

Check out CMS's new Quality in Focus interactive video series. The series of 10–15 minute videos are tailored to provider types and aim to reduce the deficiencies most commonly cited during the CMS survey process, like infection control and accident prevention. Reducing these common deficiencies increases the quality of care for people with Medicare and Medicaid.

Learn to:

- *Understand surveyor evaluation criteria*
- *Recognize deficiencies*
- *Incorporate solutions into your facility's standards of care*

See the Quality, Safety, & Education Portal Training Catalog, and select Quality in Focus.