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

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TO: State Survey Agency Directors

FROM: Directors, Quality, Safety & Oversight Group (QSOG) and Survey & Operations Group (SOG)

SUBJECT: Revisions to the Review and Approval of Plans of Correction (POCs) and CLIA Allegations of Compliance (AOCs)

Memorandum Summary

- When noncompliance is cited at a level that requires a mandatory onsite revisit (per existing CMS policy and procedure), CMS and/or the State Survey Agency (the "State") will obtain a POC/AOC for the cited noncompliance.
- CMS and States should prioritize the revisit survey as the primary means of assessing compliance, rather than reviewing multiple submissions of a POC/AOC for approval.
- If CMS or the State are unable to approve a POC/AOC after two submissions by the facility or lab, they should reach out to the facility or lab to confirm their readiness and intention to request a revisit, which should then be scheduled accordingly.

Background:

When non-compliance is cited at a level requiring a mandatory onsite revisit to verify correction and compliance (per existing CMS policy and procedure[1]), CMS and/or the State Survey Agency (the "State") obtains a POC/AOC[2]. The findings identified during the subsequent onsite revisit survey will verify either compliance or continuing non-compliance with the regulatory requirements. Therefore, CMS and States should **prioritize the revisit survey as the primary means of assessing compliance following receipt, review, and approval of the POC/AOC (up to two submissions, as described below)**.

[1] State Operations Manual (SOM) chapters 5 and 6
[2] For laboratories, when Condition-level noncompliance is determined by the RO or State Agency surveyor, an AoC is requested (SOM, Ch.6: 6132.3 - Allegation of Compliance (AoC))

Discussion:

Complaint surveys, especially those alleging immediate jeopardy or actual harm to patient health and safety, are the primary oversight provided outside of statutory recertification surveys. These investigations of the most serious allegations lead to more severe findings, higher numbers of revisits, and additional enforcement workload. As a key part of the enforcement workload, the review and disapproval of multiple POCs/AOCs submitted by facilities and labs has resulted in increased resource burdens on those entities, as well as CMS and State Agencies.

While POCs and AOCs are an element of the compliance review and are a provider's or lab's allegation of compliance, they ultimately do not drive the compliance determination. Facilities should develop effective POCs/AOCs in good faith, including performing root cause analyses and implementing QAPI principles that will lead to sustained compliance. However, if CMS or the State are unable to approve a POC/AOC **after two submissions**, they should reach out to the facility or lab to confirm their readiness and intention to request a revisit and then perform a revisit survey, per existing policy and guidance. The date of compliance will be the POC completion dates indicated on the most recent POC submitted (as verified during the onsite revisit).

The POC/AOC submission is primarily to document the facility or lab's readiness and request for a revisit; it is their allegation of compliance. Since a mandatory revisit is required to determine compliance, CMS is not able to determine compliance solely through a review of the POC/AOC. Neither CMS nor the State have the resources to play the consultative role that multiple POC/AOC reviews convey.

Revisits are performed in accordance with guidelines provided in the State Operations Manual and at the discretion of CMS or the State. Survey and Operations Group (SOG) or Division of Clinical Laboratory Improvement and Quality (DCLIQ) Divisional Leadership should be notified anytime the CMS location or State believes a revisit should not be performed following two POC/AOC submissions or when they determine that the facility or lab should not receive any revisits at all.

This guidance does not apply to:

- The Plan of Removal process for Immediate Jeopardies identified in Appendix Q;
- Providers and suppliers who have been imposed a Directed Plan of Correction as an enforcement remedy;
- Surveys with deficiencies that only require a desk review to determine compliance through review of a POC (i.e., Offsite audits) as outlined in State Operations Manual (SOM), Chapter 7, Section 7317.2;
- Initial certification process;
- Other surveys with findings that do not require an onsite revisit;
- Life Safety Code Temporary Waiver requests; and
- Other circumstances that CMS or the State Agency believe, following CMS location review and recommendation, warrant additional POC/AOC submissions (as approved by CMS Divisional leadership).

Contact:
For questions or concerns relating to this memorandum, please contact your CMS Location.

Effective Date:
Immediately. Please communicate to all appropriate staff within 30 days.

/s/

Karen L. Tritz
Director, Survey & Operations Group

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.

Notification of Memo Releases:
Get guidance memos issued by the Quality, Safety and Oversight Group by going to CMS.gov page and entering your email to sign up. Check the box next to "CCSQ Policy, Administrative, and Safety Special Alert Memorandums" to be notified when we release a memo.