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: 23-14-NLTC

DATE: September 6, 2023

TO: State Survey Agency Directors

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

SUBJECT: Resuming Validation of Accrediting Organization Surveys

Memorandum Summary

- **Validation of Accrediting Organization (AO) Surveys -** Validation survey activity will resume in Fiscal Year (FY) 2024.
- **Validation Survey Approach and Methodology:** Validation surveys will be performed by national survey contractor(s) and utilize the direct observation methodology piloted in 2018-2019.
- CMS has created a Standard Operating Procedure (SOP) for use by the national contractor(s) and will update the State Operations Manual (SOM) to reflect the direct observation validation survey (DOVS) process and guidance at a future date.

Background:

On March 4, 2020, CMS released memorandum QSO-20-12-ALL, which suspended all non-emergency surveys, including any validation surveys, performed by the State Survey Agencies (SAs), of facilities participating in Medicare via the deeming authority of CMS-approved AO programs. This suspension of validation surveys allowed SAs to focus on potentially emergent concerns related to the COVID-19 Public Health Emergency (PHE). Now that the PHE has ended, CMS will resume AO validation survey activities, using national contract surveyors, beginning in FY 2024.

Discussion:

With the end of the PHE on May 11, 2023, CMS is resuming routine oversight activities that promote ongoing quality of care and patient safety. Historically, SAs performed AO validation surveys to ensure the AOs were consistently and accurately surveying deemed providers and suppliers for compliance with Medicare health and safety requirements. However, the COVID-19 PHE created numerous resource challenges and a survey backlog for SAs. To meet these challenges, CMS has engaged national contract surveyors to complete this work, utilizing a

similar approach to the previously piloted 2018-2019 DOVS that was suspended temporarily during the PHE. Instead of the traditional 60-day "look-back" validation surveys, where a full survey is performed within 60 days of an AO's full accreditation survey and AO-identified deficiencies are compared to SA-identified deficiencies of the same provider or supplier, CMS-contracted DOVS surveyors will be present during an AO accreditation survey to directly observe and evaluate the ability of the AO surveyors to assess compliance with the Medicare conditions.

SAs are still responsible for all other survey functions stipulated in Section 1864 of the Act and the annual CMS Mission and Priority Document (MPD). The FY 24 MPD will be revised to reflect this change.

CMS has created a Standard Operating Procedure (SOP) for use by the national contractor. The State Operations Manual (SOM) will be updated to reflect the DOVS process and guidance at a future date and communicated via QSO memorandum.

Contact:
Contact QSOGAccreditationCO@cms.hhs.gov with any questions.

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

/s/

Karen L. Tritz	David R. Wright
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Attachment- CMS Standard Operating Procedures for Direct Observation Validation Surveys

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.

CMS Standard Operating Procedure for
Direct Observation Validation Surveys

PURPOSE: The intent behind this Standard Operating Procedure (SOP) is to provide direction to the national CMS contractor(s).

APPLICABILITY: This SOP applies to nine (9) Medicare-participating deemed provider/supplier types - Ambulatory Surgical Centers (ASCs); Critical Access Hospitals (CAHs); End-Stage Renal Disease (ESRD) Facilities; Home Health Agencies (HHAs); Hospices; Hospitals including Psychiatric Hospitals; Clinics, Rehabilitation Agencies, and Public Health Agencies as Providers of Outpatient Physical Therapy and Speech-Language Pathology Services (OPT/OSP); and Rural Health Clinics (RHCs).

NOTE: Excluded are the following provider/supplier types who currently are not recognized as a deemed program under a CMS-approved Accrediting Organization (AO) - Community Mental Health Centers (CMHCs); Comprehensive Outpatient Rehabilitation Facilities (CORF); Federally Qualified Health Centers (FQHCs); Intermediate Care Facilities for Individuals with Intellectual Disabilities (ICF/IID); Nursing Facilities (NFs); Organ Procurement Organizations (OPOs); Portable X-Ray (PXR); Psychiatric Residential Treatment Facilities (PRTFs); Religious Nonmedical Health Care Institutions (RNHCIs); Rural Emergency Hospitals (REH); Skilled Nursing Facilities (SNF); and Transplant Programs.

BACKGROUND: Health care facilities must demonstrate compliance with the Medicare conditions of participation (CoPs), conditions for coverage (CfCs), or conditions for certification (depending on the type of facility) to be eligible to receive Medicare reimbursement. Section 1865 of the Social Security Act (the Act) allows health care facilities that are "provider entities" to demonstrate this compliance through accreditation by CMS-approved national AOs, known as deeming authority. CMS is responsible for the oversight of the national AOs' Medicare accreditation programs, and for ensuring that providers or suppliers under CMS-approved deeming programs meet the minimum quality and patient safety standards required by the Medicare conditions.

Section 1864(c) of the Social Security Act permits validation surveys of provider and supplier types deemed for Medicare participation under Section 1865(a) of the Act as a means of validating the AOs' accreditation processes. A facility is certified based on being "deemed" to meet the Medicare conditions based on accreditation by a CMS-approved AO recommendation for deemed status. These deemed status facilities are not subject to routine surveys by SAs to determine compliance with all applicable Medicare conditions.

Historically, CMS has measured the effectiveness of AOs by choosing a sample of facilities, performing state-conducted "look back" surveys within 60 days following AO surveys, and comparing results of the state surveys with the AO surveys. In 2018-2019, CMS piloted a streamlined way to eliminate the second state-conducted validation survey and instead use direct observation during the original AO-run survey to evaluate AOs' ability to assess compliance with the Medicare conditions.

Direct Observation Validation Survey Process

- The contractor will perform DOVS utilizing survey observers. DOVS will be performed on a random sample of selected reaccreditation surveys which are sent to the contractor by CMS.

- Contractor survey observers will enter the facility at the same time as the AO and will remain present while the AO surveyors perform a reaccreditation survey. Survey observers will present the facility with identification and a CMS authorization letter explaining the process.

- Contractor survey observers are <u>not</u> performing a separate survey of the facility. The AO will lead and run the survey. Survey observers are not surveying the facility or assessing their compliance with the Medicare requirements. Rather, they are directly observing and evaluating the AO's ability to assess the Medicare conditions.

- Contract survey observers will be assigned to the AO surveyors on a 1:1 basis, matching the experience of the AO surveyor where possible. Whenever a less than 1:1 match is necessary, this will be reviewed and approved by CMS.

- The survey observers will utilize a CMS developed, program specific, Direct Observation Scoring Worksheet to evaluate the AO survey in accordance with CMS established policies and procedures. The contractor is not required to complete a CMS-2567.

- Contractor survey observers will observe and evaluate the entire survey and then exit with the AO surveyors when finished.

- Completed worksheets will be submitted to CMS Baltimore after the survey exit.