



Center for Clinical Standards and Quality/Survey & Certification Group

Ref: S&C: 17-40-AO

DATE: July 28, 2017

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: FY 2016 Report to Congress (RTC): Review of Medicare's Program Oversight of Accrediting Organizations (AOs) and the Clinical Laboratory Improvement Amendments of 1988 (CLIA) Validation Program

Memorandum Summary

Annual Report to Congress: The 2016 annual RTC details the review, validation, and oversight of the FY 2015 activities of the approved AOs Medicare accreditation programs as well as the CLIA Validation Program.

- Section 1875(b) of the Social Security Act (the Act) requires the Centers for Medicare & Medicaid Services (CMS) to submit an annual report to Congress on its oversight of national AOs and their CMS-approved accreditation programs.
- Section 353(e)(3) of the Public Health Service Act (PHSA) requires CMS to submit an annual report of the CLIA validation program results.

Background

The Social Security Act, Section 1875(b) requires a performance evaluation of each CMS-approved Accreditation Organization (AO) to verify that accredited provider entities demonstrate compliance with the Medicare Conditions of Participation (CoPs). The Clinical Laboratory Improvement Amendments of 1988 (CLIA), under Section 353 of the Public Health Service Act, requires that any laboratory performing testing on human specimens for health purposes, must meet the requirements established by HHS and have in effect an applicable certificate. The CMS annual Report to Congress (RTC) details the review, validation, and oversight of the AOs Medicare accreditation programs as well as those under CLIA.

State Agency surveyors conduct the validation surveys that are the basis for the analysis in the RTC. We appreciate the tremendous work of the State surveyors that has made it possible for CMS to fulfill its AO oversight responsibilities and complete the annual report to Congress.

Currently, CMS has approved accreditation programs for the following Medicare facility types: hospitals, psychiatric hospitals, critical access hospitals (CAHs), home health agencies (HHAs), hospices, ambulatory surgery centers (ASCs), outpatient physical therapy and speech-language pathology services (OPTs), and rural health clinics (RHCs). There are currently nine CMS approved Medicare accreditation organizations (AO) identified in the report:

- Accreditation Association for Ambulatory Health Care (AAAHC)
- Accreditation Commission for Health Care, Inc. (ACHC)
- American Association for Accreditation of Ambulatory Surgery Facilities (AAAASF)
- American Osteopathic Association / Healthcare Facilities Accreditation Program (AOA/HFAP)
- Community Health Accreditation Program (CHAP)
- Center for Improvement in healthcare (CIHQ)
- DNV GL – Healthcare (DNV GL)
- The Compliance Team (TCT)
- The Joint Commission (JC)

There are currently another seven AOs approved under CLIA, which are:

- AABB
- American Association for Laboratory Accreditation (A2LA)
- American Osteopathic Association / Healthcare Facilities Accreditation Program (AOA/HFAP)
- American Society for Histocompatibility and Immunogenetics (ASHI)
- COLA
- College of American Pathologists (CAP)
- The Joint Commission (TJC)

Effective Date: Immediately. This report should be communicated with appropriate survey and certification staff, their managers and the State/Regional Office training coordinators within 30 days of this memorandum.

/s/
David Wright

Attachment: Review of Medicare's Program for Oversight of Accrediting Organizations and the Clinical Laboratory Improvement Validation Program Fiscal 2016

cc: Survey and Certification Regional Office Management