DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop C2-21-16
Baltimore, Maryland 21244-1850

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

Ref: QSO-22-06-AO/CLIA

DATE: December 15, 2021

TO: State Survey Agency Directors

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

SUBJECT: FY 2020 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 2020 annual RTC details the review, validation, and oversight of the FY 2019 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 certain testing on human specimens for health purposes, must meet the requirements established by The Department of Health & Human Services 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. Currently, CMS has approved accreditation programs for the following Medicare facility type: 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), rural health clinics (RHCs) and End Stage Renal Disease (ESRD). The OPT, RHC and ESRD providers were not part of the validation sample surveys during this reporting period.

Discussion

There are 11 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 (TJC)
- Institute of Medical Quality (IMQ)
- National Dialysis Accreditation Commission (NDAC)

There are another seven AOs approved under CLIA identified in the report, including:

- 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)

Additional Oversight Initiatives:

In FY 2019, CMS announced additional oversight initiatives to increase oversight of the AOs.[1] To increase transparency for consumers, CMS will post new information on a CMS website[2], including: The latest quality-of-care deficiency findings following complaint surveys at facilities accredited by AOs; a list of providers determined by CMS to be out of compliance, with information included on the provider's AO; and overall performance data for AOs themselves.

CMS is also engaged in a process to redesign the assessment of AO performance through validation surveys. In 2019, CMS implemented a direct observation validation survey pilot, in addition to the current 60-day post AO (look behind) validation survey process. This "direct observation" survey is designed to assess the AO performance in real time for determining compliance with the Medicare requirements. CMS has completed 30 of these surveys across several provider types while continuing to refine the process through the ongoing pilot program. CMS is also looking at enhancing the traditional 60-day look behind validation survey.

[1] https://www.cms.gov/newsroom/press-releases/cms-strengthen-oversight-medicares-accreditation-organizations
[2] https://qcor.cms.gov/

Contact: For questions or concerns relating to this memorandum, please contact:
Medicare AO oversight – QSOGAccreditationCO@cms.hhs.gov
CLIA AO oversight – 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

Attachment: FY2020 Report to Congress

cc: Survey & Operations Group Management

REVIEW OF MEDICARE'S PROGRAM FOR OVERSIGHT OF ACCREDITING ORGANIZATIONS AND THE CLINICAL LABORATORY IMPROVEMENT VALIDATION PROGRAM

FISCAL YEAR 2020

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Review of Medicare's Program for Oversight of Accrediting Organizations

Introduction

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"[1] to demonstrate this compliance through accreditation by a Centers for Medicare & Medicaid Services (CMS)-approved accreditation program of a private, national Accrediting Organization (AO).[2] AOs may voluntarily submit provider- and supplier-specific accreditation programs intended to demonstrate compliance with the applicable Medicare standards for CMS review and approval. AOs charge fees to facilities that seek their accreditation. Generally, AOs offer facilities at least two accreditation options: accreditation alone, or accreditation under a CMS-approved program for the purpose of participating in Medicare. CMS reviews and provides oversight only for those accreditation programs submitted by an AO requesting to have the program recognized as a Medicare accreditation program. Accordingly, this report addresses AO activity only as it relates to CMS-approved Medicare accreditation programs.

CMS has responsibility for oversight and approval of AO accreditation programs used for Medicare certification purposes, and for ensuring that providers or suppliers that are accredited under an approved AO accreditation program meet the quality and patient safety standards required by the Medicare conditions.[3],[4] A thorough review of each Medicare accreditation program voluntarily submitted by an AO is conducted by CMS, including a review of the equivalency to the Medicare standards of its accreditation requirements, survey processes and procedures, training, oversight of provider entities, and enforcement.

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[1] Section 1865(a)(4) of the Act defines "provider entity" to include a provider of services, supplier, facility, clinic, agency, or laboratory. Section 1861(d) defines a "supplier" to mean a physician or other practitioner, a facility, or other entity other than a provider. Section 1861(u) defines a "provider" to mean a hospital, critical access hospital, skilled nursing facility, comprehensive outpatient rehabilitation facility, home health agency, or hospice program. Note that "provider entities" do not include advanced diagnostic imaging (ADI) or durable medical equipment (DME) suppliers, which are required to be accredited under Section 1834 of the Act. Oversight of ADI and DME accreditation programs are administered separately by CMS and not subject to the Section 1875 reporting requirements.

[2] Accreditation for provider entities in accordance with Section 1865 is voluntary and not required for Medicare participation. Generally, accreditation by a CMS-approved national AO's Medicare accreditation program is an alternative to being subject to assessment of compliance by the applicable State Survey Agency.

[3] CoPs apply to providers; CfCs apply to suppliers; "Requirements" apply to long-term care facilities; and Conditions for Certification apply to rural health clinics. In this report, the term "facility" is used to cover all types of institutional health care providers which require certification in order to participate in Medicare and the term "Medicare conditions" is used to cover CoPs, CfCs, Requirements, and Conditions for Certification.

[4] The Act mandates the establishment of minimum health and safety standards that must be met by most providers and suppliers participating in the Medicare and Medicaid programs. These standards are found in Title 42 of the Code of Federal Regulations for each applicable provider/supplier type. The intention of the health and safety CoPs is to stipulate that each patient receives safe care. This often includes providing protection to the patient's emotional health and safety as well as physical safety.

Also reviewed are the qualifications of the surveyors, staff, and the AO's financial status. Upon approval, any provider or supplier accredited by the AO's approved program could be "deemed" by CMS to have met the applicable Medicare conditions and are referred to as having deemed status.[5]

Pursuant to Section 1875(b) of the Act, the Secretary of Health and Human Services (HHS) shall make a continuing study of the national accreditation bodies under Section 1865(a) and transmit to the Congress annually a report concerning the operation and oversight of all CMS-approved AO Medicare accreditation programs. CMS has implemented a comprehensive approach to the review and approval of an AO's Medicare accreditation program and its ongoing oversight of AO activities. The primary goal of this review is to ensure that the AO's standards meet or exceed the Medicare conditions for each program type and that the organization has the capacity to adequately administer the program and provide ongoing oversight of facilities it accredits.

Currently, CMS has approved accreditation programs under 42 CFR Part 488 for the following 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), rural health clinics (RHCs), and End-Stage Renal Disease (ESRD) facilities.[6] CMS maintains a comprehensive AO Medicare accreditation oversight program and continually strives to strengthen and enhance its ongoing oversight. The program includes:

Deeming application review – CMS rigorously reviews each Medicare accreditation program submitted by an AO initially and then periodically thereafter to determine whether the AO can adequately ensure that facilities comply with Medicare requirements;

Ongoing review – CMS evaluates the performance of each CMS-approved accreditation program on an ongoing basis through performance, comparability, and accreditation program reviews;

Electronic reporting systems – CMS builds, implements, and updates electronic systems for AO reporting on activities related to deemed facilities;

Performance measurement – CMS develops and implements performance measures which reflect each AO's compliance with administrative reporting requirements;

Validation survey program – CMS has expanded efforts across a growing number of AO programs and types of facilities to measure the effectiveness of the AO survey process in identifying areas of serious non-compliance with Medicare conditions. In the validation program, CMS conducts a survey of a facility within 60 days of an AO survey and compares the findings of the two surveys to evaluate the adequacy of the AO survey process[7];

[5] In accordance with Section 1865 of the Act, 42 CFR §§ 488.5(a)(4)(i) states that AOs may award accreditation under a CMS-approved Medicare accreditation program for 3 years. The AOs will re-survey every accredited provider through unannounced surveys, no later than 36 months after the prior accreditation effective date.

[6] Note that other types of facilities may also participate in Medicare via an approved accreditation program, but to date, no AO has sought and received approval for any of these additional non-listed facility types. CMS also accredits suppliers of Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) and the technical component of ADI under other accreditation statutes.

[7] State standard survey frequencies for all provider types is addressed in CMS' Mission and Priority Document

Validation redesign program (VRP) pilot – CMS has developed a pilot that utilizes the SAs in an observational capacity to observe and evaluate the ability of the AO surveyors to survey for compliance to CMS regulations versus conducting a second survey of the facility. The VRP pilot was placed on hold in August 2019 to make enhancements based on lessons learned. The VRP pilot is tentatively scheduled to start back up in FY 2022.

Education – CMS conducts ongoing education for AO staff that includes, but is not limited to, quarterly conference calls, monthly liaison calls with each AO, an annual on-site training for all AOs with approved programs at CMS, provision of an AO resource manual, as well as availability of CMS surveyor training opportunities.

Overview

This report reviews AO activities in fiscal year (FY) 2019 (October 1, 2018 – September 30, 2019), compares this activity to past years, and outlines the current CMS oversight of approved Medicare accreditation programs organized in the following sections:

Section 1 – Centers for Medicare & Medicaid Services' Approval of Medicare Accreditation Programs
The process used for CMS approval and renewal of AO Medicare accreditation programs; the types of CMS reviews and decisions; the number of reviews that were performed and decisions made since FY 2011; the current AOs with approved Medicare accreditation programs; and the most recent CMS approval or review status for each AO Medicare accreditation program.

Section 2 – Scope of Accrediting Organization Medicare Accreditation Programs
The current number of deemed status and non-deemed Medicare-certified facilities by program type; the growth in deemed status facilities within the Medicare program since FY 2008; and the overall Medicare accreditation survey activities of each AO in FY 2019, including the number of initial and renewal accreditation surveys performed, the number of facilities denied and the number of facilities that voluntarily withdrew from an accreditation program.

Section 3 – Accrediting Organization Performance Measures
The AO reporting requirements and CMS methods for collecting AO quarterly data on Medicare accreditation program activities and deemed facilities; the FY 2019 AO performance measures; and comparison of FYs 2018 and 2019 performance measure results.

Section 4 – Validation of Accrediting Organization Surveys
The AO Validation Program, the disparity rate for each program type nationally and by AO, and the number of representative sample validation surveys that have been performed for hospital and non-hospital facilities since FY 2007. The section also describes the comparative analysis process conducted for the 60-day validation surveys completed to assess the ability of each AO Program to evaluate and ensure compliance with the applicable Medicare conditions. The validation performance results for FYs 2017–2019 are presented by facility type for each AO. The FY 2019 AO and State Agency (SA) condition-level citations for each facility type are

(MPD) tier system. The State standard survey frequencies are resource driven and depend on CMS's annual funding level and specific criteria. Typically, State survey frequency is between 3–5 years (no more than 6 years) based on the provider type, tier priority, the number of specific providers in the state, and the budget.

presented and compared. For hospital accreditation programs, validation performance results provide separate comparisons for short-term acute care and long-term care hospitals (LTCHs).

Section 5 – Life Safety Code, Health & Safety Disparity Rates Analysis and Complaint Survey Citations
The most frequently disparate 60-day validation survey condition-level deficiencies, Life Safety Code (LSC) and health and safety disparity rates; the top five complaint survey condition-level deficiencies by program type; the limitations surrounding the disparity rates; and conclusions and recommendations for decreasing the disparity rates.

Section 6 – Centers for Medicare & Medicaid Services Improvements
CMS executed and improved program management and oversight activities for FY 2019.

Section 7 – Clinical Laboratory Improvement Amendments Validation Program
Clinical Laboratory Improvement Amendments of 1988 (CLIA) includes statutory requirements for deeming by AOs, and for conducting AO validation reviews.

Appendix A – Performance Measures
Table 1 outlines the performance measure results by AO for comparable FYs 2018–2019 measures.

Appendix B – Fiscal Year 2019 Life Safety Code and Health & Safety Disparity Rates
Detailed FY 2019 LSC and health and safety statistics for each program type as discussed in Section 5 and AO specific statistics.

Appendix C – Life Safety Code Category Definitions
LSC terminology and definitions.

SECTION 1: Centers for Medicare & Medicaid Services' Approval of Medicare Accreditation Programs

Application and Renewal Process

Approval of a National Accrediting Organization's Medicare Accreditation Program

The process for CMS approval of a national AO's Medicare accreditation program is voluntary and, therefore, applicant-driven. In order to gain approval of an accreditation program for Medicare deemed status purposes, an AO must demonstrate the ability to effectively evaluate a facility using accreditation standards which meet or exceed the applicable Medicare conditions, as well as survey processes that are comparable to those outlined in the State Operations Manual (SOM). Among other things, the SOM contains CMS' policy, interpretation of regulations, and instructions to SAs for conducting survey activities on behalf of CMS. Section 1865(a)(2) of the Act requires that CMS base its decision to approve or deny an AO's Medicare accreditation program application after considering the following factors:

- Program requirements for the accreditation program to meet or exceed Medicare requirements;
- Survey procedures are comparable to those of Medicare as outlined in the SOM;
- Ability to provide adequate resources for conducting surveys;
- Capacity to furnish information for use by CMS in enforcement activities;
- Monitoring procedures for providers or suppliers identified as being out of compliance with conditions or requirements; and
- Ability to provide the necessary data for validation surveys to CMS.

Section 1865(a)(3)(A) of the Act further requires that CMS publish a proposed notice in the *Federal Register*. This notice must be published within 60 days of receipt of an AO's complete application requesting approval of a Medicare accreditation program. The notice identifies the national AO making the request, describes the nature of the request, and provides at least a 30-day public comment period. CMS has 210 days from receipt of a complete application to publish a *Federal Register* notice of approval or denial of the request.

The regulations at 42 CFR § 488.5 set forth the detailed requirements that an AO must satisfy to receive and maintain CMS recognition and approval of a Medicare accreditation program. This section also details the procedures CMS follows in reviewing AO applications.

Renewal applications are subject to the same criteria and scrutiny as initial applications for approval of an AO's Medicare accreditation program. Approval of an AO's Medicare accreditation program is for a specified time period, with a 6-year maximum. Initial applications are generally provided a 4-year term of approval. This allows CMS to conduct a comprehensive review and evaluation of the renewal application within a shorter period of time to ensure that the accreditation program continues to meet CMS requirements. Some AOs are given approval on a conditional basis, while CMS reviews and monitors the accreditation program during a probationary period to determine if the program continues to meet or exceed Medicare requirements.

The application and renewal process provide the opportunity for a comprehensive evaluation of an AO's Medicare accreditation program performance. This process includes the AO's ability to ensure compliance with Medicare conditions for deemed status facilities, and the ability to comply with CMS' administrative requirements that facilitate ongoing oversight of the AO's CMS-approved accreditation program(s). CMS' evaluation process includes, but is not limited to, the following components:

- On-site observations are conducted to ensure that the accreditation program is fully implemented and operational as described in the written application:
  - Corporate on-site review; and
  - Survey observation.
- Comprehensive review of AO accreditation standards to ensure that the AO standards meet or exceed those of Medicare.
- Comprehensive review of the AO's:
  - Policies and procedures to ensure comparability with those of CMS;
  - Adequacy of resources to perform required surveys to ensure comparability with those of CMS;
  - Survey processes and enforcement to ensure comparability with those of CMS;
  - Surveyor evaluation and training to ensure comparability with those of CMS;
  - Electronic databases to ensure the AO has the capacity to provide CMS with the necessary facility demographic, survey-related, deficiency, adverse action, and accreditation decision data, etc.; and
  - Financial status to ensure organizational solvency and ability to support operations.

Focused Reviews of Accrediting Organization Medicare Accreditation Programs

CMS performs focused reviews in the following areas:

- *Standards and Survey Process Reviews:* Once approved, any subsequent changes in the AO's Medicare accreditation program standards or survey process must also be reviewed and approved by CMS prior to implementation by the AO. The purpose is to ensure that the program continues to meet or exceed Medicare requirements or remains comparable to Medicare survey processes and policies. Such reviews are conducted in accordance with 42 CFR § 488.5(a)(18) and 42 CFR § 488.5(a)(19).

- *Issue Review and Resolution:* AOs must demonstrate that their standards and review processes meet or exceed all applicable conditions of Section 1865 of the Act. CMS works with AOs to resolve issues when they are identified during the approval period.

- *Performance Review:* CMS reviews AO performance on an ongoing basis in accordance with Section 1875(b) of the Act. This includes, but is not limited to, review of the AO's survey activity, analysis of validation surveys, and review of the AO's continued fulfillment of the requirements at 42 CFR § 488.5.

Table 1 below summarizes the initial, renewal, and other reviews conducted by CMS.

Table 1
CMS Review of AO Medicare Accreditation Programs
FYs 2011–2019

Type of Review and CMS Decision	FY 2011	FY 2012	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017	FY 2018	FY 2019
Initial Applications									
• Decision: Full approval	3	1	1	1	0	1	0	2	0
• Decision: Denied	0	0	0	0	0	0	0	0	0
• Incomplete application	0	2	0	0	1	1	0	1	3
• Application withdrawn	1	1	1	0	0	0	0	0	0
Renewal Applications									
• Decision: Full approval	0	3	6	4	6	1	5	8	1
• Decision: Denied	0	0	0	0	0	0	0	0	0
• Decision: Conditional approval	0	0	0	0	0	0	0	0	0
• Decision: Final approval removing conditional status	0	0	0	0	0	0	0	0	0
Total Reviews of Initial and Renewal Applications	**4**	**7**	**8**	**5**	**7**	**3**	**5**	**11**	**4**
Focused Reviews									
• Standards review*	18	20	3	25	12	23	78	32	16
• Survey process review	10	5	0	1	5	5	18	3	18
• Issue review and resolution	44	22	41	11	3	16	9	2	1
• Performance review	3	3	0	4	3	1	2	1	0
Total Focused Reviews	**75**	**50**	**44**	**41**	**23**	**45**	**107**	**38**	**35**

Note: The Institute for Medical Quality's (IMQ's) application to serve as an AO for ASCs was received in FY 2019. The decision to withdraw was made in FY 2020; therefore, is not reflected in this report.
*In FY 2017, CMS's increase in focused standard reviews increased drastically due to several regulatory changes (e.g., 2016 Emergency Preparedness Final Rule; the Medicare and Medicaid Programs; Fire Safety Requirements for Certain Health Care Facilities Final Rule.

From FY 2011 through FY 2019, CMS completed 54 reviews of renewal and initial applications (which included approvals published in the *Federal Register* as well as initial applications withdrawn by the AO prior to publication). In this same timeframe, CMS completed 458 focused reviews. In total, 512 comprehensive reviews were completed.

Approved Accrediting Organization Medicare Accreditation Programs

CMS reviews and approves separately, each provider or supplier Medicare accreditation program for which an AO seeks CMS approval. AOs currently have CMS approval for nine provider or supplier program types: hospital, psychiatric hospital, CAH, HHA, hospice, ASC, OPT, RHC and ESRD. As of September 30, 2019, there were 11 national AOs with 24 approved Medicare accreditation programs. (See Tables 2 and 3.)

Table 2
AOs with Approved Medicare Accreditation Programs
FY 2019

AO Acronym	Description
AAAASF	American Association for Accreditation of Ambulatory Surgery Facilities, Inc.
AAAHC	Accreditation Association for Ambulatory Health Care, Inc.
ACHC	Accreditation Commission for Health Care
AAHHS/HFAP	Accreditation Association for Hospitals and Health Systems/Healthcare Facilities Accreditation Program
CHAP	Community Health Accreditation Partner
CIHQ	Center for Improvement in Healthcare Quality
DNV GL	DNV GL-Healthcare
IMQ	Institute for Medical Quality
NDAC	National Dialysis Accreditation Commission
TCT	The Compliance Team
TJC	The Joint Commission

Table 3
Approved Medicare Accreditation Programs by AO
FY 2019

AO	Hospital	Psych Hospital	CAH	HHA	Hospice	ASC	ESRD	OPT	RHC	Total
AAAASF						X		X	X	3
AAAHC						X				1
ACHC				X	X		X			3
AAHHS/HFAP	X		X			X				3
CHAP				X	X					2
CIHQ	X									1
DNV GL	X		X							2
IMQ						X				1
NDAC							X			1
TCT									X	1
TJC	X	X	X	X	X	X				6
Total	4	1	3	3	3	5	2	1	2	24

The number of CMS-approved Medicare accreditation programs has grown steadily over the past several years resulting in 24 approved programs in FY 2019.

Approval of Medicare Accreditation Programs

American Association for Accreditation of Ambulatory Surgery Facilities, Inc.

Ambulatory Surgery Center

AAAASF's ASC Medicare accreditation program was initially approved December 2, 1998. AAAASF's current term of approval is effective November 27, 2018 through November 27, 2024. The final notice announcing this decision was published in the *Federal Register* (83 FR 58253) (November 19, 2018), and can be accessed at https://www.govinfo.gov/content/pkg/FR-2018-11-19/pdf/2018-25013.pdf.

Outpatient Physical Therapy and Speech-Language Pathology Services

AAAASF's OPT Medicare accreditation program was initially approved April 22, 2011. AAAASF's current term of approval is effective April 4, 2019 through April 4, 2025. The final notice announcing this decision was published in the *Federal Register* (84 FR 12260) (April 1, 2019), and can be accessed at https://www.govinfo.gov/content/pkg/FR-2019-04-01/pdf/2019-06149.pdf.

Rural Health Clinic

AAAASF's RHC Medicare accreditation program was initially approved March 23, 2012. AAAASF's RHC Medicare accreditation program was granted a 4-year term of approval effective March 23, 2016 through March 23, 2022. The final notice was published in the *Federal Register* (81 FR 9481) (February 25, 2016), and can be accessed at https://www.govinfo.gov/content/pkg/FR-2016-02-25/pdf/2016-04092.pdf .

Accreditation Association for Ambulatory Health Care, Inc.

Ambulatory Surgery Center

AAAHC's ASC Medicare accreditation program was initially approved December 19, 1996. AAAHC's current term of approval is effective December 20, 2018 through December 20, 2024. The final notice announcing this decision was published in the *Federal Register* (83 FR 65676) (December 21, 2018), and can be accessed at https://www.govinfo.gov/content/pkg/FR-2018-12-21/pdf/2018-27592.pdf.

Accreditation Commission for Health Care, Inc.

End Stage Renal Disease

ACHC's ESRD Medicare accreditation program was initially approved April 11, 2019. ACHC's current term of approval is effective April 11, 2019 through April 11, 2023. The final notice announcing this decision was published in the *Federal Register* (84 FR 14381) (April 10, 2019), and can be accessed at https://www.govinfo.gov/content/pkg/FR-2019-04-10/pdf/2019-07135.pdf.

Home Health Agency

ACHC's HHA Medicare accreditation program was initially approved February 24, 2006. ACHC's current term of approval is effective February 24, 2015 through February 24, 2021. The final notice announcing this decision was published in the *Federal Register* (80 FR 2708) (January 20, 2015), and can be accessed at https://www.govinfo.gov/content/pkg/FR-2015-01-20/pdf/2015-00699.pdf.

Hospice

ACHC's hospice Medicare accreditation program was initially approved November 27, 2009. ACHC's current term of approval is effective November 27, 2019 through November 27, 2025. The final notice announcing this decision was published in the *Federal Register* (84 FR 64902) (November 25, 2019), and can be accessed at https://www.govinfo.gov/content/pkg/FR-2019-11-25/pdf/2019-25429.pdf.

Accreditation Association for Hospitals and Health Systems/Healthcare Facilities Accreditation Program

Hospital

AAHHS/HFAP has had an approved hospital Medicare accreditation program since February 22, 2000. Although its hospital program is mentioned by name in the Act, it is also explicitly subject to the Secretary's review and approval. AAHHS/HFAP's current term of approval is effective September 25, 2019 through September 25, 2023. The final notice announcing this decision was published in the *Federal Register* (84 FR 9799) (March 18, 2019) and can be accessed at https://www.govinfo.gov/content/pkg/FR-2019-03-18/pdf/2019-05037.pdf.

Critical Access Hospital

AAHHS/HFAP's CAH Medicare accreditation program was initially approved December 27, 2001. AAHHS/HFAP's current term of approval is effective December 27, 2019 through December 27, 2025. The final notice announcing this decision was published in the *Federal Register* (84 FR 70975) (December 26, 2019), and can be accessed at https://www.govinfo.gov/content/pkg/FR-2019-12-26/pdf/2019-27836.pdf.

Ambulatory Surgery Center

AAHHS/HFAP's ASC Medicare accreditation program was initially approved January 30, 2003. AAHHS/HFAP's current term of approval is effective September 22, 2017 through September 22, 2023. The final notice announcing this approval was published in the *Federal Register* (82 FR 44414) (September 22, 2017), and can be accessed at https://www.govinfo.gov/content/pkg/FR-2017-09-22/pdf/2017-20281.pdf.

Community Health Accreditation Partner

Home Health Agency

CHAP's HHA Medicare accreditation program was initially approved August 27, 1992. CHAP's current term of approval is effective March 31, 2018 through March 31, 2024. The final notice announcing this decision was published in the *Federal Register* (83 FR 12769) (March 23, 2018) and can be accessed at https://www.govinfo.gov/content/pkg/FR-2018-03-23/pdf/2018-05891.pdf.

Hospice

CHAP's hospice Medicare accreditation program was initially approved April 20, 1999. CHAP's current term of approval is effective November 20, 2018 through November 20, 2024. The final notice announcing this decision was published in the *Federal Register* (83 FR 57727) (November 16, 2018), and can be accessed at https://www.govinfo.gov/content/pkg/FR-2018-11-16/pdf/2018-25066.pdf.

Center for Improvement in Healthcare Quality

Hospital

CIHQ's hospital Medicare accreditation program was initially approved July 26, 2013 for a 4-year term. CIHQ's current term of approval is effective July 26, 2017 through July 26, 2023. The final notice announcing this approval was published in the *Federal Register* (82 FR 28853) (June 26, 2017), and can be accessed at https://www.govinfo.gov/content/pkg/FR-2017-06-26/pdf/2017-13207.pdf.

DNV GL-Healthcare

Hospital

DNV GL's hospital Medicare accreditation program was initially approved September 29, 2008. DNV GL's current term of approval is effective August 17, 2018 through September 26, 2022. The final notice announcing this decision was published in the *Federal Register* (83 FR 41073) (August 17, 2018), and can be accessed at https://www.govinfo.gov/content/pkg/FR-2018-08-17/pdf/2018-17815.pdf.

Critical Access Hospital

DNV GL's CAH Medicare accreditation program was initially approved December 23, 2010. DNV GL's current term of approval is effective December 23, 2014 through December 23, 2020. The final notice announcing this decision was published in the *Federal Register* (79 FR 69482) (November 21, 2014), and can be accessed at https://www.govinfo.gov/content/pkg/FR-2014-11-21/pdf/2014-27576.pdf.

Institute for Medical Quality

Ambulatory Surgery Center

IMQ's ASC Medicare accreditation program was initially approved for a 4-year term effective April 29, 2016 through April 29, 2020. The final notice announcing this approval was published in the *Federal Register* (81 FR 25675) (April 29, 2016), and can be accessed at https://www.govinfo.gov/content/pkg/FR-2016-04-29/pdf/2016-10165.pdf.

National Dialysis Accreditation Commission

End Stage Renal Disease

NDAC's ESRD Medicare accreditation program was initially approved January 4, 2019. NDAC's current term of approval is effective January 4, 2019 through January 4, 2023. The final notice announcing this approval was published in the *Federal Register* (84 FR 1737) (February 5, 2019), and can be accessed at https://www.govinfo.gov/content/pkg/FR-2019-02-05/pdf/2019-01103.pdf.

The Compliance Team

Rural Health Clinics

TCT's RHC Medicare accreditation program was initially approved July 18, 2014. TCT's current term of approval is effective July 18, 2018 through July 18, 2024. The final notice announcing this approval was published in the *Federal Register* (83 FR 29118) (June 22, 2018), and can be accessed at https://www.govinfo.gov/content/pkg/FR-2018-06-22/pdf/2018-13436.pdf.

The Joint Commission

Hospital

TJC's hospital Medicare accreditation program was initially approved July 15, 2010. Prior to July 15, 2010, TJC's hospital accreditation program had statutory status and did not require CMS review and approval. TJC's current term of approval is effective July 15, 2020 through July 15, 2022. The final notice announcing this decision was published in the *Federal Register* (85 FR 43582) (July 17, 2020), and can be accessed at https://www.govinfo.gov/content/pkg/FR-2020-07-17/pdf/2020-15599.pdf.

Psychiatric Hospital

TJC's psychiatric hospital Medicare accreditation program was initially approved February 25, 2011. TJC's current term of approval is effective February 25, 2019 through February 25, 2023. The final notice announcing this decision was published in the *Federal Register* (84 FR 4818) (February 19, 2019), and can be accessed at https://www.govinfo.gov/content/pkg/FR-2019-02-19/pdf/2019-02673.pdf.

Critical Access Hospital

TJC's CAH Medicare accreditation program was initially approved November 21, 2002. TJC's current term of approval is effective November 21, 2017 through November 21, 2023. The final notice announcing this decision was published in the *Federal Register* (82 FR 49817) (October 27, 2017), and can be accessed at https://www.govinfo.gov/content/pkg/FR-2017-10-27/pdf/2017-23449.pdf.

Home Health Agency

TJC's HHA Medicare accreditation program was initially approved September 28, 1993. TJC's current term of approval is effective March 31, 2020 through March 31, 2026. The final notice announcing this decision was published in the *Federal Register* (85 FR 18245) (April 1, 2020), and can be accessed at https://www.govinfo.gov/content/pkg/FR-2020-04-01/pdf/2020-06792.pdf.

Hospice

TJC's hospice Medicare accreditation program was initially approved June 18, 1999. TJC's current term of approval is effective June 18, 2015 through June 18, 2021. The final notice announcing this decision was published in the *Federal Register* (80 FR 29714) (May 22, 2015) and can be accessed at https://www.govinfo.gov/content/pkg/FR-2015-05-22/pdf/2015-12524.pdf.

Ambulatory Surgery Center

TJC's ASC Medicare accreditation program was initially approved December 19, 1996. TJC's current term of approval is effective December 20, 2014 through December 20, 2020. The final notice announcing this decision was published in the *Federal Register* (79 FR 69486) (November 21, 2014), and can be accessed at https://www.govinfo.gov/content/pkg/FR-2014-11-21/pdf/2014-27577.pdf.

SECTION 2: Scope of Accrediting Organization Medicare Accreditation Programs

Medicare-Participating Facilities by Program Type:

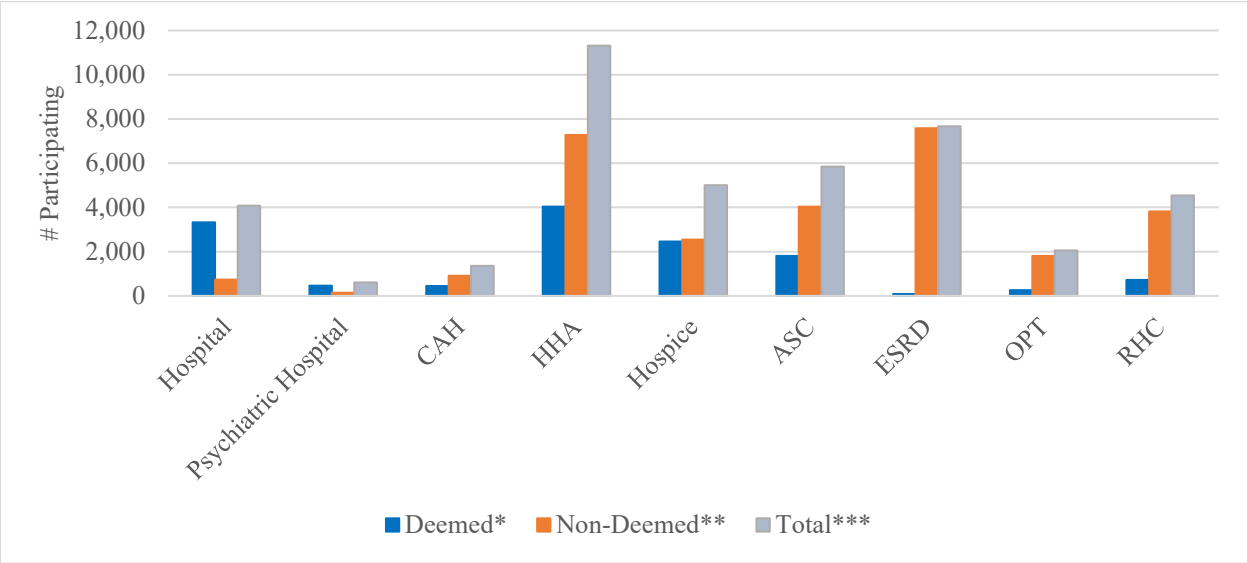
In FY 2019, AOs were responsible for assuring compliance with Medicare conditions for 32 percent (13,608) of all Medicare-participating facilities in the nine program types for which there was a CMS-approved AO Medicare accreditation program. (See Table 4 and Graph 1.)

Table 4
Deemed & Non-Deemed Medicare-Participating Facilities and Program Types with a Medicare Accreditation Program Option
FY 2019

Program Type	Deemed* (percentage)	Non-Deemed** (percentage)	Total***
Hospital	3,332 (82)	740 (18)	4,072
Psychiatric Hospital	466 (77)	143 (23)	609
CAH	449 (33)	905 (67)	1,354
HHA	4,034 (36)	7,281 (64)	11,315
Hospice	2,458 (49)	2,549 (51)	5,007
ASC	1,803 (31)	4,038 (69)	5,841
ESRD****	89 (1)	7,578 (99)	7,667
OPT	254 (12)	1,802 (88)	2,056
RHC	723 (16)	3,815 (84)	4,538
Total	13,608 (32)	28,851 (68)	42,459

Note: The total number of deemed facilities represents the number of deemed surveys performed. The term facilities includes clinics, rehabilitation agencies, and public health agencies as providers of outpatient physical therapy and speech language pathology services, referred to as OPTs.
*As reported by AOs in Accrediting Organization System for Storing User Recorded Experiences (ASSURE).
**Surveyed by an SA for compliance with Medicare conditions.
***As reported in the Quality Improvement Evaluation System (QIES)/Certification and Survey Provider Enhanced Reports (CASPER) and QIES/ASSURE 4/21/2020.
****Historically, section 1865(a)(1) of the Act previously excluded dialysis facilities from participating in Medicare via a CMS-approved accreditation program; however, section 50403 of the Bipartisan Budget Act of 2018 (Pub. L. No. 115-123, § 50403, 132 Stat. 64, (2018)) amended the Act to include renal dialysis facilities.

Graph 1
Deemed & Non-Deemed Medicare-Participating Facilities and Program Types with a Medicare Accreditation Program Option
FY 2019



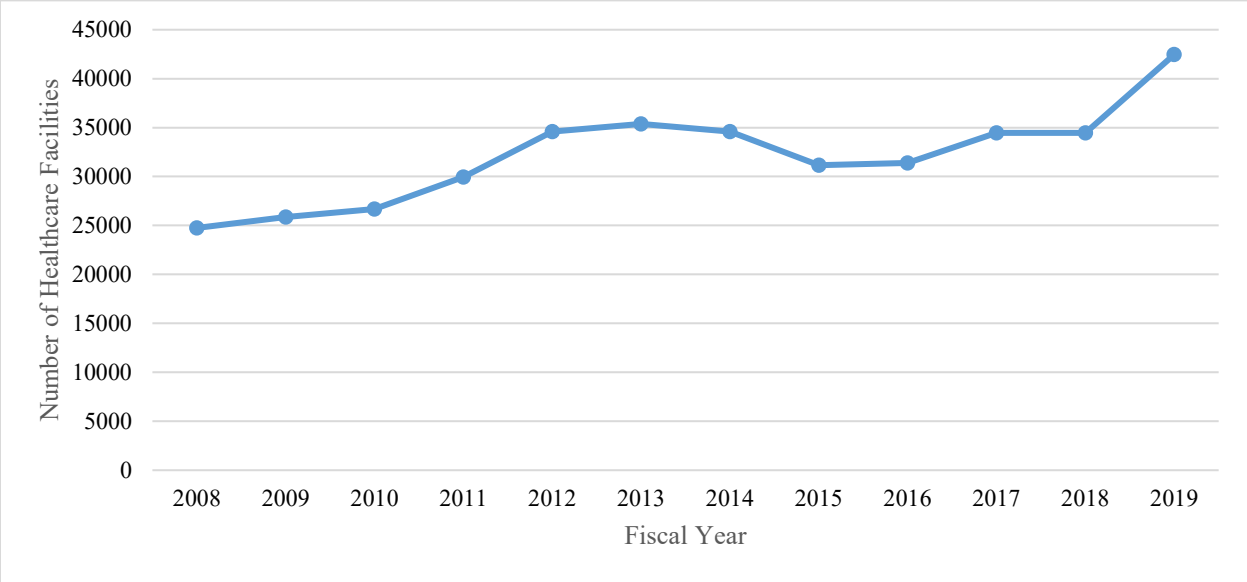
*As reported by AOs in ASSURE.
**Surveyed by an SA for compliance with Medicare conditions.
***As reported in QIES/CASPER and QIES/ASSURE 4/21/2020.

In FY 2019, the AOs with CMS-approved Medicare accreditation programs were responsible for monitoring compliance with health and safety standards for varying percentages of the total number of Medicare-participating facilities for each program type. This percentage ranges from a high of 82 percent for hospitals to a low of 1 percent for ESRD facilities. Hospitals have historically had the largest percentage of facilities participating in Medicare via accreditation and deemed status with one exception. In FY 2015, both hospitals and psychiatric hospitals had a high of 89 percent.

Growth in Medicare Deemed Facilities

The total number of Medicare-participating health care facilities (among those that have the option of being certified via a CMS-approved accreditation program) has increased 72 percent from 24,752 in FY 2008 to 42,459 in FY 2019. (See Graph 2) Note that this increase is partially attributed to the inclusion of ESRD facilities for the first time in this report. ESRD facilities were not able to be certified by a CMS-approved accreditation program until a provision in the Bipartisan Budget Act of 2018 amended the law to allow this. Since FY 2008, the majority of those newly participating facilities with an accreditation option, enrolled and became certified in the Medicare program via accreditation from a CMS-approved Medicare accreditation program and deemed status. This number of deemed Medicare-participating health care facilities via a Medicare accreditation program option increased 91 percent from 7,128 in FY 2008 to 13,608 in FY 2019.

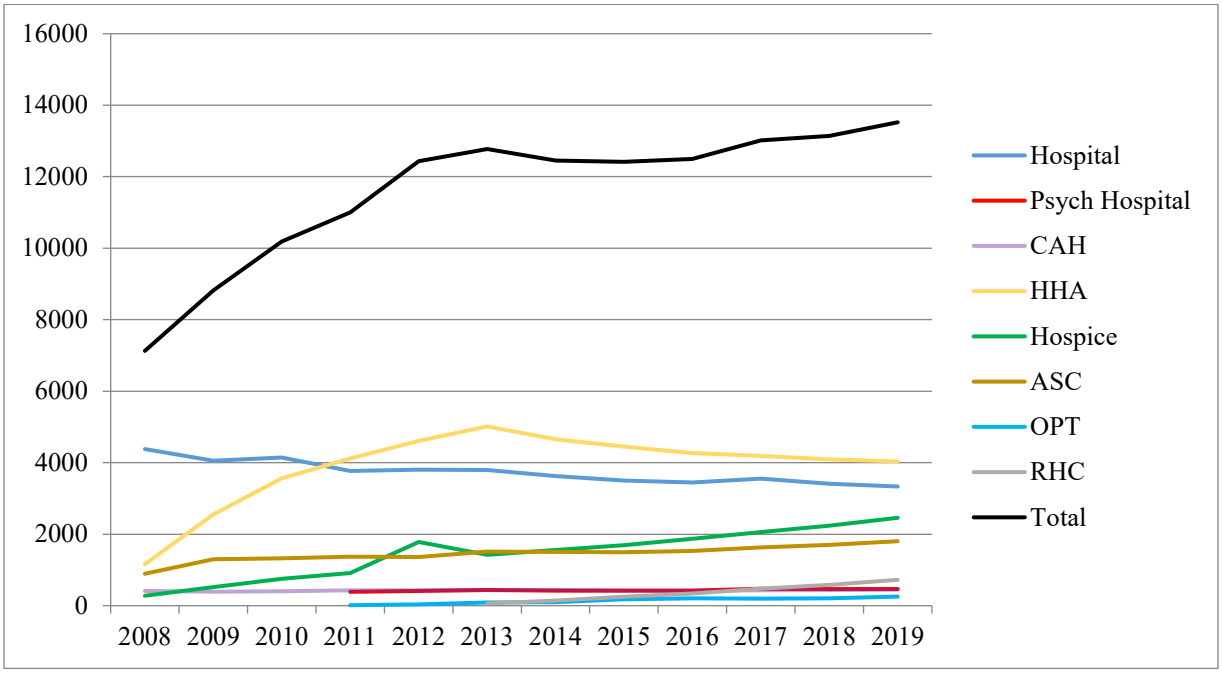
Graph 2
Medicare-Participating Health Care Facilities
FYs 2008–2019



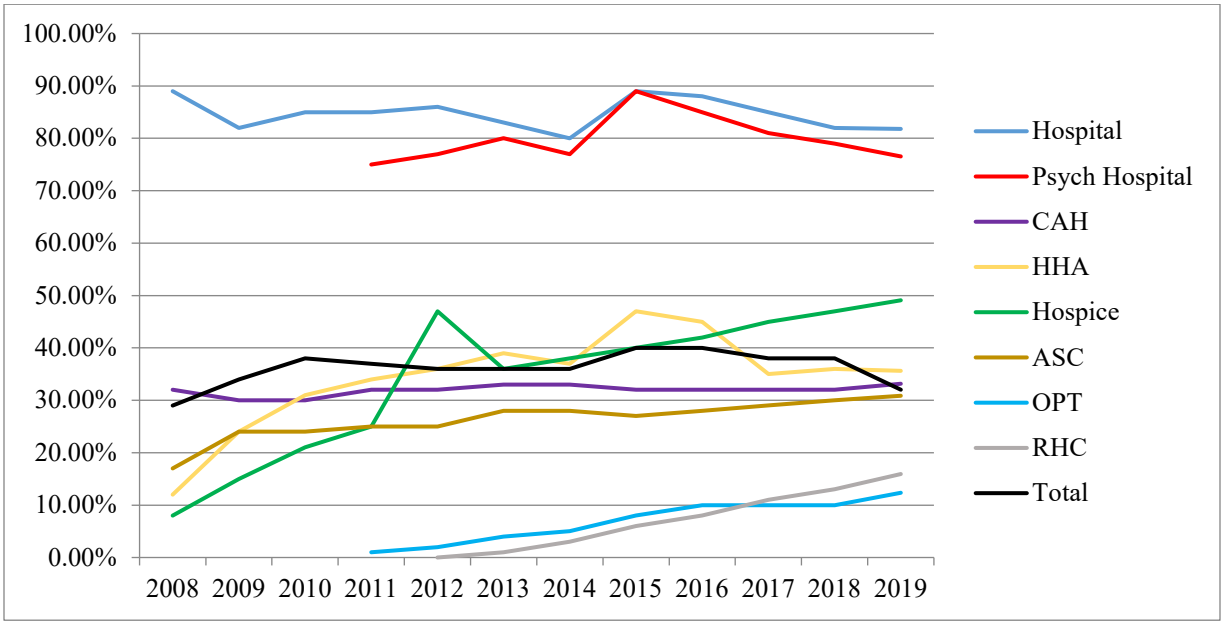
The growth in the number of deemed facilities is likely attributable, in part, to CMS' workload priorities for SAs. The long-standing CMS policy for SAs has been that initial surveys for newly enrolling facilities with an approved accreditation option have a lower priority as compared to statutorily mandated recertification surveys of participating nursing homes, HHAs, and hospices; validation surveys; complaint investigations; other recertification surveys; and initial surveys of new applicants for which no accreditation option exists. As a result, an increasing number of facilities seeking initial Medicare participation have used CMS-approved Medicare accreditation programs to demonstrate their compliance with Medicare requirements to facilitate a faster enrollment and certification process.

Graphs 3 and 4 below show the number of facilities certified each year by CMS by virtue of a CMS-recognized Medicare accreditation program, and the percentage of all Medicare-certified facilities that these deemed facilities represent. These graphs represent the nine program types for which there is currently more than 1 year of data. (Note: CMS approved the first Medicare ESRD accreditation program in January 2019; therefore, the ESRD data isn't depicted in graphs 3 and 4.)

Graph 3
Number of Deemed Facilities by Program Type
FYs 2008–2019



Graph 4
Deemed Facilities as Percentage of Medicare-Participating Facilities by Program Type
FYs 2008-2019



- **Total:** Since the introduction of the original AO Medicare accreditation programs (hospitals, CAHs, HHAs, hospices, and ASCs), four more types of accreditation programs have been approved since FY 2008. The first OPT and psychiatric hospital Medicare accreditation programs were approved in FY 2011.[8] The first RHC Medicare accreditation program was approved in FY 2012. The first ESRD Medicare accreditation program was approved in FY 2019. From FY 2008 to FY 2019, the total number of Medicare-participating facilities increased from 24,752 to 42,459, a 72 percent increase. During that same time, the growth in the number of facilities accredited by a CMS-approved Medicare accreditation program was much larger. From FY 2008 to FY 2019, the number of deemed facilities increased from 7,128 to 13,608, a 91 percent increase.
  - From FY 2008 to FY 2018, the number of facilities participating in Medicare via deemed status increased from 7,128 to 13,137, an 84 percent increase.
  - From FY 2018 to FY 2019, the number of facilities participating in Medicare via deemed status increased from 13,137 to 13,608, a 4 percent increase.
  - While the SAs continue to survey and monitor the majority of Medicare-participating facilities, in FY 2019, there were 13,608 (32 percent) facilities participating in Medicare via their accreditation from a CMS-approved Medicare accreditation program and deemed status.

- **Hospital:** The number of Medicare-participating hospitals was largely unchanged between FYs 2008 and 2019. The hospital and psychiatric hospital programs are the only categories in which the majority of facilities participate in Medicare by virtue of accreditation under an approved Medicare accreditation program.
  - From FY 2008 to FY 2018, the number of deemed hospitals decreased from 4,381 to 3,409, a decrease of 22 percent.
  - From FY 2018 to FY 2019, the number of deemed hospitals decreased from 3,409 to 3,332, a 2 percent decrease.
  - The proportion of all Medicare-participating hospitals that were deemed was unchanged from FY 2018 to FY 2019.

- **Psychiatric Hospital:** The number of Medicare-certified psychiatric hospitals increased from 516 in FY 2011 to 609 in FY 2019, an 18 percent increase.
  - From FY 2011 to FY 2018, the number of deemed psychiatric hospitals increased from 388 to 469, a 21 percent increase.
  - From FY 2018 to FY 2019, the number of deemed psychiatric hospitals slightly decreased from 469 to 466, a 1 percent decrease.
  - The proportion of all Medicare-participating psychiatric hospitals which were deemed increased slightly from 75 percent in FY 2011 to 77 percent in FY 2019.

- **CAH:** The number of Medicare-certified CAHs was increased slightly from 1,310 in FY 2008 to 1,354 in FY 2019, a 3 percent increase.
  - From FY 2008 to FY 2018, the number of deemed CAHs increased slightly from 415 to 438, a 6 percent increase.

[8] Prior to FY 2011, the number of psychiatric hospitals participating in Medicare through a CMS-approved accreditation program were included in the total number of hospitals.

  - From FY 2018 to FY 2019, the number of deemed CAHs increased slightly from 438 to 449, a 3 percent increase.
  - The proportion of all Medicare-certified deemed CAHs which were deemed increased slightly from 32 percent in FY 2008 to 33 percent in FY 2019.

- **HHA:** The number of Medicare-certified HHAs increased from 9,893 in FY 2008 to 11,315 in FY 2019, a 14 percent increase.
  - From FY 2008 to FY 2018, the number of deemed HHAs increased from 1,161 to 4,095, a 253 percent increase.
  - From FY 2018 to FY 2019, the number of deemed HHAs decreased from 4,095 to 4,034, a 1 percent decrease.
  - The proportion of all Medicare-certified HHAs which were deemed tripled from 12 percent in FY 2008 to 36 percent in FY 2019.

- **Hospice:** There has been significant growth in the Medicare hospice program as well. The number of Medicare-certified hospices increased from 3,388 in FY 2008 to 5,007 in FY 2019, a 48 percent increase. There has also been corresponding significant growth in the number and proportion of deemed hospices.
  - From FY 2008 to FY 2018, the number of deemed hospices increased from 278 to 2,238, a 705 percent increase.
  - From FY 2018 to FY 2019, the number of deemed hospices increased from 2,238 to 2,458, a 10 percent increase.
  - The proportion of all Medicare-certified hospices which were deemed increased six-fold from 8 percent in FY 2008 to 49 percent in FY 2019.

- **ASC:** The number of Medicare-certified ASCs increased from 5,217 in FY 2008 to 5,841 in FY 2019, a 12 percent increase.
  - From FY 2008 to FY 2018, the number of deemed ASCs increased significantly from 893 to 1,699, a 90 percent increase.
  - From FY 2018 to FY 2019, the number of deemed ASCs increased slightly from 1,699 to 1,803, a 6 percent increase.
  - The proportion of all Medicare-certified ASCs which were deemed increased from 17 percent in FY 2008 to 31 percent in FY 2019.

- **OPT:** The number of Medicare-certified OPTs decreased from 2,471 in FY 2011 to 2,056 in FY 2019, a 17 percent decrease. Note, for the purposes of this report, CMS includes clinics, rehabilitation agencies, and public health agencies as providers of outpatient physical therapy and speech language pathology services, referred to as OPTs, in the term "facilities".
  - From FY 2011 to FY 2018, the number of deemed OPTs increased from 13 to 204, a 1,469 percent increase. This large percentage increase is due to the relatively recent availability of an accreditation option for OPTs. CMS approved the first Medicare OPT accreditation program in April 2011; therefore, there was a small number of deemed OPTs in FY 2011.
  - From FY 2018 to FY 2019, the number of deemed OPTs increased from 204 to 254, a 25 percent increase.

- The proportion of all Medicare-certified OPTs which were deemed increased from 1 percent in FY 2011 to 12 percent in FY 2019.

- **RHC:** The number of Medicare-certified RHCs increased from 4,108 in FY 2012 to 4,538 in FY 2019, a 10 percent increase.
  - From FY 2012 to FY 2018, the number of deemed RHCs increased from 3 to 585, a 19,400 percent increase. This large percentage increase is due to the relatively recent availability of an accreditation option for RHCs. CMS approved the first Medicare RHC accreditation program in May 2012; therefore, there was an extremely low number of deemed RHCs in FY 2012.
  - From FY 2018 to FY 2019, the number of deemed RHCs increased from 585 to 723, a 24 percent increase.
  - The proportion of all Medicare-certified RHCs which were deemed increased from less than 1 percent in FY 2012 to 16 percent in FY 2019.

- **ESRD:** The number of Medicare-certified ESRD facilities was 7,667 in FY 2019.
  - In FY 2019, there were 89 deemed ESRD facilities.
  - In FY 2019, the percentage of deemed ESRD facilities was 1 percent.

Medicare Accreditation Program Survey Activity

An AO with a CMS-recognized Medicare accreditation program is responsible for evaluating a facility through an on-site survey to determine whether the facility complies with the health care quality and patient safety standards required by the Medicare conditions. The evaluation performed by the AO includes, but is not limited to, observation and review of the following: care and treatment of patients; care processes in the facility; the physical environment (PE) including compliance with the LSC when applicable; emergency preparedness; administrative and patient medical records; and staff qualifications. The AO performs an initial survey for a facility that is being reviewed by the AO for the first time. Initial surveys include surveys of facilities that are seeking initial Medicare certification as well as those facilities currently participating in Medicare and previously overseen by an SA or another AO. The AO may award accreditation under a CMS-approved Medicare accreditation program for up to 3 years. A reaccreditation survey must be completed prior to the expiration date of the facility's Medicare accreditation to ensure that the facility remains in compliance with CMS requirements.

In addition, facilities seeking initial deemed status with an AO must be found to be in compliance with *all* conditions through the on-site survey activity. "Condition-level" deficiencies are the most serious type of deficiency cited, indicating a provider or supplier is not in compliance with an entire CoP or CfC. A "standard-level" deficiency means that the provider or supplier may be out of compliance with one aspect of the regulations but is considered less serious than a condition-level finding. If a facility is found to have condition-level non-compliance on an initial survey, the facility must be denied accreditation. A second deemed status survey must be conducted once the facility has submitted an acceptable POC and corrected all deficiencies. Through the process of reviewing survey reports and findings made by the AOs, CMS has identified that in some cases, an AO may not have cited certain findings at the

appropriate level (e.g., deficiencies were cited inappropriately at the "standard" or "condition" level, instead of at the "condition" or "immediate jeopardy" level based on the surveyor documentation contained in the survey report). This issue may also create a "false low" in the reporting of denials. In identifying these issues, CMS is actively involved in reinforcing the decision-making process related to identification of the appropriate level of citation with the AOs. CMS Regional Offices (ROs), now known as CMS Survey & Operations Group (SOG) Locations, review all initial AO Medicare survey reports. Based on surveyor observations and evidence of non-compliance documented in the survey report, and follow-up with the AO, the RO has the authority to question the level of citation of a deficiency, raise it to the condition level as appropriate, and deny certification and the facility's application for participation in the Medicare program. Citing deficiencies at the appropriate level is an essential component to assuring the health and safety of patients receiving care in Medicare facilities.

In FY 2019, the AOs reported having performed 1,869 initial surveys and 4,112 renewal surveys. The total number of deemed status facilities including dually accredited facilities in FY 2019 was 13,6011. The total number of facilities denied was 370. (See Table 5.)

Table 5
Total Number of Deemed Facilities
Initial Surveys and Renewal Surveys
Denials by AO Accreditation Program
FY 2019

Program Type/ AOs	Total Deemed Facilities	Initial Surveys	Renewal Surveys	Denials
Hospital				
AAHHS/HFAP	89	3	37	1
CIHQ	68	21	13	6
DNV GL	286	30	99	10
TJC	2,891	34	1,110	8
Hospital Total	**3,334**	**88**	**1,259**	**25**
Psychiatric Hospital				
TJC	466	27	186	6
Psychiatric Hospital Total	**466**	**27**	**186**	**6**
CAH				
AAHHS/HFAP	25	1	5	1
DNV GL	98	8	23	2
TJC	326	9	97	3
CAH Total	**449**	**18**	**125**	**6**
HHA				
ACHC	1,024	269	181	50
CHAP	1,452	153	489	45
TJC	1,559	181	520	49
HHA Total	**4,035**	**603**	**1,190**	**144**

Program Type/ AOs	Total Deemed Facilities	Initial Surveys	Renewal Surveys	Denials
Hospice				
ACHC	553	160	96	24
CHAP	776	124	256	9
TJC	1,129	139	330	24
Hospice Total	**2,458**	**423**	**682**	**57**
ASC				
AAAASF	200	27	71	16
AAAHC	870	165	214	60
AAHHS/HFAP	35	11	7	0
IMQ	49	30	0*	2
TJC	649	90	196	16
ASC Total	**1,803**	**323**	**488**	**94**
ESRD				
ACHC	1	2	0**	0
NDAC	88	92	0**	3
ESRD Total	**89**	**94**	**0**	**3**
OPT				
AAAASF	254	66	54	13
OPT Total	**254**	**66**	**57**	**13**
RHC				
AAAASF	267	51	65	1
TCT	456	176	62	21
RHC Total	**723**	**227**	**127**	**22**
Total	**13,611**	**1,869**	**4,114**	**370**

Source: As reported by the AOs in ASSURE.
*The IMQ ASC accreditation program received initial approval FY 2016. Therefore, no renewal surveys were due to be conducted.
**The NDAC and ACHC ESRD accreditation programs received initial approval in FY 2019. Therefore, no renewal surveys were due to be conducted.
Note: The total number of deemed facilities represents the number of deemed surveys performed. The total number of deemed facilities in this table includes 3 facilities that are dually accredited; therefore, the total number of deemed facilities listed in Table 4 is less than this total.

SECTION 3: Accrediting Organization Performance Measures

Accrediting Organization Reporting Requirements

A major focus of CMS' ongoing work with each AO is monitoring and improving the AO's ability to provide CMS with complete, timely, and accurate information regarding deemed status facilities, as required at 42 CFR § 488.5(a)(4)(viii). It is important that AOs and CMS be able to accurately determine a facility's Medicare accreditation status on an ongoing basis. This information is vital for CMS to be able to identify which facilities participate in Medicare via their deemed status and are, therefore, subject to AO versus SA oversight. Additionally, when an AO makes an adverse Medicare accreditation program decision based on a facility's failure to satisfy the AO's health and safety standards or LSC requirements, it is imperative that CMS be notified promptly in order to take appropriate follow-up enforcement action. It is also essential for CMS to have information concerning upcoming AO survey schedules to effectively implement the validation program. To this end, AOs must submit the following to CMS:

- Monthly survey schedules which document the surveys that were completed for the previous month, and those scheduled for the current and following months;
- A report of all data pertaining to all Medicare accreditation and enforcement activity for each month;
- Facility notification letters for all Medicare accreditation program actions and any follow-up communication associated with those facility notification letters; and
- Responses to any formal correspondence from CMS.

In 2008, CMS directed the development of an electronic data collection tool that would enable the AOs to provide CMS with demographic and survey activity information for deemed facilities. The database, ASSURE, provides a method to collect, analyze, and manage data regarding deemed facilities. In 2013, the system moved to a web-based version. ASSURE centralizes data capture and reporting; supports the integration of AO data into the existing QIES infrastructure for network access; ensures that data conforms to the national data structures framework; and allows for CASPER authentication and reporting.

CMS employs several methods to facilitate obtaining this information. In addition to providing AOs access to and implementing ongoing improvements to ASSURE, CMS provides the AOs with:

- Information on the essential elements that should be included in an AO facility notification letter regarding a facility's Medicare accreditation status, which facilitates AO communication with CMS;
- Dedicated Central Office (CO) and RO electronic mailboxes for AO submission of copies of facility notification letters concerning their Medicare accreditation program status; and
- Comparative analysis and feedback on the deemed facility data contained in ASSURE. This includes whether the facilities in ASSURE could be matched to certified facilities in CMS' national Medicare certification database.

Accrediting Organization Performance Measures and Scoring

In FY 2009, CMS instituted performance measures for AOs. These measures are reviewed and updated annually. These measures provide CMS with a method of assessing each AO's ability to provide CMS with timely, accurate, and complete information regarding the various aspects of facility survey and monitoring activities. They also enable CMS to determine the current Medicare accreditation status of certified health care facilities.

Each performance measure is scored on a quarterly basis. For survey schedule measures, the quarterly score is calculated based on monthly scores. Annual scores are the average of all four quarterly scores. Measures are scored as a percentage of correct submissions for a specific month/quarter.

Fiscal Year 2019 Accrediting Organization Performance Measures

In FY 2019, AOs were scored on their performance on 6 measures in 3 key performance focus areas: ASSURE Database, Facility Notification Letters, and Survey Schedule. In FY 2018, each AO excelled, scoring 100 percent on the ASSURE Database measure "No pending survey > 5 months." In FY 2019, this measure was retired, and no new measures were implemented. (See Table 6.)

Table 6
AO Performance Measures
FY 2019

ASSURE Database: AOs use the ASSURE electronic database to record all AO Medicare accreditation program activity, including enforcement activity, and to submit a quarterly export file of this ASSURE data to CMS. Performance in this area was based on:
• The facilities with condition-level findings denied on initial surveys* • The timeliness of notifying facilities of survey results • The timeliness of notifying CMS of withdrawals
Facility Notification Letters: AOs should electronically submit facility notification letters to CMS for all Medicare accreditation program actions in CMS-approved programs. Performance in this area was based on:
• The notification letters contain all required information. • The data in ASSURE is being updated consistent with the letters.
Survey Schedule: AOs should submit a monthly schedule which documents surveys completed in the past month as well as scheduled surveys for the current month and next 2 months. Performance in this area is based on:
• The accuracy of the data in ASSURE regarding the number of surveys reported as completed for the quarter and the number of surveys actually completed each quarter

*Initial surveys that result in condition-level findings must be denied accreditation. Before being awarded accreditation for the purpose of Medicare deemed status, a facility must demonstrate substantial compliance with the Medicare requirements. Therefore, these facilities are required to correct identified deficiencies and undergo another survey to demonstrate full compliance with all Medicare conditions and an acceptable POC for any less serious, standard-level deficiencies before an AO may grant full accreditation and make a recommendation to CMS that the facility be granted deemed status.

Performance Measure Results

The FY 2018 and FY 2019 performance data for all AOs is presented below in Table 7. The table presents the performance measures according to the key focus areas. All results include quarterly averages utilizing standard rounding rules. The data represent the percent frequency with which the task required by the measure was performed in an accurate, timely, complete manner. A discussion of the performance measure scoring, and results follows the table.

Table 7
Performance Measure Results (Percentage) for All AOs
FYs 2018–2019

Comparable 2016	FY 2018*	FY 2019
Denied initial survey with condition-level findings	95	99
Timeliness of facility notification of survey results	96	94
Timeliness of notifying CMS of withdrawals	93	93
Notification letters contain all required information	92	92
ASSURE is updated consistent with the letters	85	91
Number of surveys performed matches number reported in ASSURE	99	95

Note: IMQ's Medicare accreditation program was initially approved in April 2016. In FY 2018, IMQ didn't have data to calculate the measure "Timeliness of notifying CMS of withdrawals."
*NDAC received initial approval in January 2019; therefore, NDAC is not included in the FY 2018 data.

Scoring Definitions:

- "Excelled" means a 100 percent score.
- "Performed well" means a 95–99 percent score.
- "Opportunity for improvement" means any score below 95 percent.

Highlights

ASSURE Database

1. Denied Initial Surveys with Condition-Level Findings

In FY 2018, five of the AOs excelled on the measure "Denied initial survey with condition-level findings." One AO performed well scoring 95 percent. Two of the AOs demonstrated opportunity for improvement scoring 75 percent and 83 percent respectively. Two of the AOs had sample sizes less than five; therefore, couldn't calculate a score for this measure. One AO didn't have any data to calculate. In FY 2019, seven of the AOs scored 100 percent on the same measure. One AO demonstrated opportunity for improvement scoring 92 percent. Three of the AOs had sample sizes less than five; therefore, couldn't calculate a score for this measure. (See Table 8.)

Table 8
"Denied Initial Surveys with Condition-Level Findings"
Performance Measure Results for All AOs by Scoring Definition
FYs 2018–2019

Scoring Definitions	FY 2018 AOs	FY 2019 AOs
Excelled	• AAAHC • AAHHS/HFAP • ACHC • CHAP • TCT	• AAAASF • AAAHC • ACHC • CHAP • DNV GL • TCT • TJC
Performed Well	• AAAASF	*NA
Opportunity for Improvement	• DNV GL • TJC	• CIHQ
No Data or Sample Size <5	• CIHQ • IMQ • NDAC	• AAHHS/HFAP • IMQ • NDAC

*NA: In FY 2019, none of the AOs performed well.

2. Timely Facility Notification of Survey Results

In FY 2018, three AOs scored 100 percent for the measure "Timeliness of facility notification of survey results." Four of the AOs performed well with scores ranging from 95 percent to 97 percent. Three of the AOs showed opportunity for improvement with two of the AOs scoring 93 percent and the third AO scoring 88 percent. One AO didn't have any data to calculate this measure. In FY 2019, three of the AOs excelled, scoring 100 percent for the same measure. Five of the AOs performed well with scores ranging from 95 percent to 99 percent. Three of the AOs showed opportunity for improvement with scores ranging from 76 percent to 92 percent. (See Table 9.)

Table 9
"Timely Facility Notification of Survey Results"
Performance Measure Results for All AOs by Scoring Definition
FYs 2018–2019

Scoring Definitions	FY 2018 AOs	FY 2019 AOs
Excelled	• ACHC • CIHQ • TJC	• ACHC • DNV GL • TJC
Performed Well	• AAAASF • AAHHS/HFAP • DNV GL • TCT	• AAAASF • AAHHS/HFAP • CHAP • CIHQ • TCT
Opportunity for Improvement	• AAAHC • CHAP • IMQ	• AAAHC • IMQ • NDAC
No Data or Sample Size <5	• NDAC	*NA

*NA: In FY 2019, each of the AOs had data and met the required sample size (<5) to calculate the measure.

3. CMS Notified Timely of Withdrawals

In FY 2018, four of the AOs excelled on the measure "CMS notified timely of withdrawals." One of the AOs performed well scoring 98 percent. Three of the AOs showed opportunity for improvement with scores ranging from 63 percent to 89 percent. Two AOs didn't have any data to calculate. One AO had a sample size less than five; therefore, couldn't calculate a score for this measure. In FY 2019, two of the AOs scored 100 percent on the same measure. Two of the AOs performed well scoring 96 percent and 97 percent. Four of the AOs showed opportunity for improvement with scores ranging from 63 percent to 93 percent. One AO didn't have any data to calculate. Two of the AOs had a sample sizes less than five; therefore, couldn't calculate a score for this measure. (See Table 10.)

Table 10
"CMS Notified Timely of Withdrawals"
Performance Measure Results for All AOs by Scoring Definition
FYs 2018–2019

Scoring Definitions	FY 2018 AOs	FY 2019 AOs
Excelled	• ACHC • AAHHS/HFAP • DNV GL • TJC	• DNV GL • TJC
Performed Well	• AAAASF	• AAAASF • TCT
Opportunity for Improvement	• AAAHC • CHAP • TCT	• AAAHC • ACHC • AAHHS/HFAP • CHAP
No Data or Sample Size <5	• CIHQ • IMQ • NDAC	• CIHQ • IMQ • NDAC

Facility Notification Letters

1. Notification Letters Contain all Required Information

In FY 2018, three of the AOs excelled, scoring 100 percent for the measure "Letters contain all required information." Three of the AOs performed well, each scoring 99 percent. Four of the AOs showed opportunity for improvement with scores ranging from 47 percent to 94 percent. One AO didn't have any data to calculate. In FY 2019, three of the AOs excelled for the same measure. Five of the AOs performed well with scores ranging from 97 percent to 99 percent. Three of the AOs showed opportunity for improvement with scores ranging from 58 percent to 90 percent. (See Table 11.)

Table 11
"Notification Letters Contain all Required Information"
Performance Measure Results for All AOs by Scoring Definition
FYs 2018–2019

Scoring Definitions	FY 2018 AOs	FY 2019 AOs
Excelled	• AAAASF • ACHC • DNV GL	• ACHC • AAHHS/HFAP • CHAP
Performed Well	• AAHHS/HFAP • CHAP • TJC	• AAAASF • CIHQ • DNV GL • TCT • TJC
Opportunity for Improvement	• AAAHC • CIHQ • IMQ • TCT	• AAAHC • IMQ • NDAC
No Data or Sample Size <5	• NDAC	*NA

*NA: In FY 2019, each of the AOs had data and met the required sample size (<5) to calculate the measure.

2. ASSURE is Updated Consistent with Letters

In FY 2018, three of the AOs performed well for the measure "ASSURE is updated consistent with letters," with scores ranging from 95 percent to 98 percent. Seven of the AOs showed opportunity for improvement with scores ranging from 66 percent to 93 percent. One of the AOs didn't have any data to calculate. In FY 2019, two of the AOs excelled for the same measure. Three of the AOs performed well with two of the AOs scoring 98 percent and one AO scoring 99 percent. Six of the AOs showed opportunity for improvement with scores ranging from 67 percent to 91 percent. (See Table 12.)

Table 12
"ASSURE is Updated Consistent with Letters"
Performance Measure Results for All AOs by Scoring Definition
FYs 2018–2019

Scoring Definitions	FY 2018 AOs	FY 2019 AOs
Excelled	*NA	• ACHC • AAHHS/HFAP
Performed Well	• AAHHS/HFAP • ACHC • DNV GL	• AAAASF • CHAP • DNV GL
Opportunity for Improvement	• AAAASF • AAAHC • CHAP • CIHQ • IMQ • TCT • TJC	• AAAHC • CIHQ • IMQ • NDAC • TCT • TJC
No Data or Sample Size <5	• NDAC	**NA

*NA: In FY 2018, none of the AOs excelled on the measure.
**NA: In FY 2019, each of the AOs had data and met the required sample size (<5) to calculate the measure.

Survey Schedule

1) Number of Surveys Performed Matches Number Reported in ASSURE

In FY 2018, four of the AOs excelled, scoring 100 percent for the measure "Number of surveys performed matches number reported in ASSURE." Five of the AOs performed well with scores ranging from 97 percent to 99 percent. One of the AOs showed opportunity for improvement with a score of 93 percent. One of the AOs didn't have any data to calculate. In FY 2019, five of the AOs excelled for the same measure. Four of the AOs performed well with scores ranging from 96 percent to 99 percent. Two of the AOs showed opportunity for improvement scoring 60 percent and 93 percent. (See Table 13.)

Table 13
"Number of Surveys Performed Matches Number Reported in ASSURE"
Performance Measure Results for All AOs by Scoring Definition
FYs 2018–2019

Scoring Definitions	FY 2018 AOs	FY 2019 AOs
Excelled	• AAHHS/HFAP • ACHC • CIHQ • IMQ	• ACHC • CHAP • DNV GL • NDAC • TJC
Performed Well	• AAAASF • CHAP • DNV GL • TCT • TJC	• AAAASF • AAAHC • AAHHS/HFAP • CIHQ
Opportunity for Improvement	• AAAHC	• IMQ • TCT
No Data or Sample Size <5	• NDAC	*NA

*NA: In FY 2019, each of the AOs had data and met the required sample size (<5) to calculate the measure.

CMS reviews the performance measure scores annually to determine which measures, if any, can be retired prior to the next FY. The PM, "No pending survey > 5 months," was the only measure for which the AOs scored consistently. As a result, this PM was retired at the end of FY 2018.

Accrediting Organization Specific Discussion (See Appendix A)

The FY 2018 and FY 2019 performance measure results are presented in Appendix A for all AOs. For all measures where AOs demonstrated an opportunity for improvement, CMS worked with the AO to determine possible causes and provided guidance on improving future scores.

SECTION 4: Validation of Accrediting Organization Surveys

Accreditation Validation Program

Section 1864(c) of the Act permits SA 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 certified on the basis of being "deemed" to meet the Medicare conditions based on accreditation by a CMS-approved Medicare accreditation program and recommendation for deemed status by the AO, is not subject to routine surveys by SAs to determine compliance with all applicable Medicare conditions. However, these deemed status facilities may be subject to validation surveys authorized by CMS and generally conducted by an SA.

The Accreditation Validation Program is one component of CMS oversight of AOs with approved Medicare accreditation programs, and consists of two types of validation surveys:

- Substantial allegation surveys (also called "complaint surveys") – focused surveys based on complaints which, if substantiated, could indicate serious non-compliance with one or more Medicare conditions (see Section 5); and

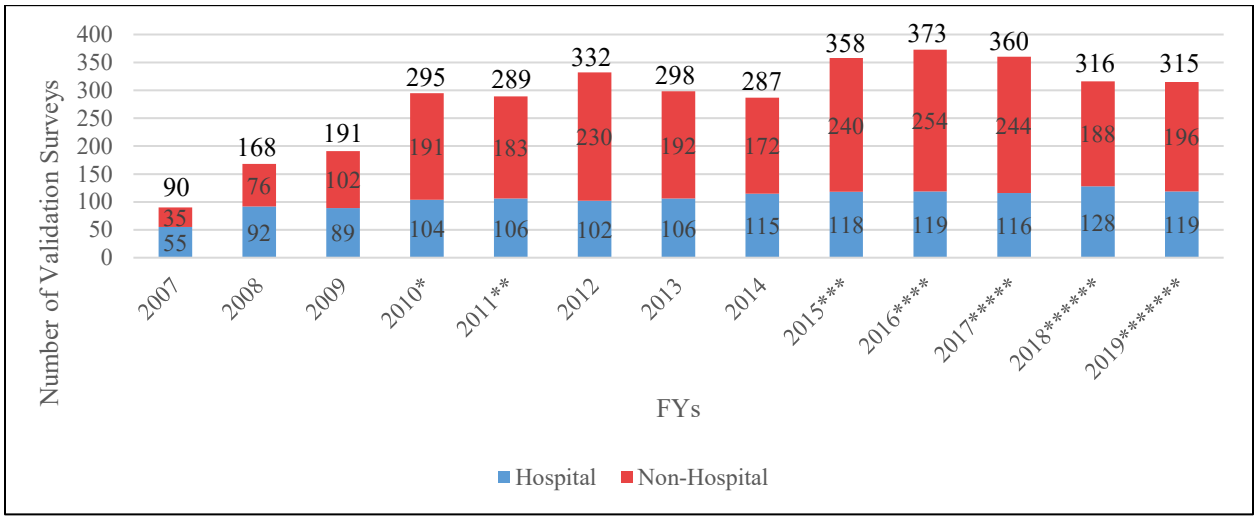
- Representative sample validation surveys – full surveys which are routinely performed for a representative sample of deemed facilities as part of the annual CMS-AO representative sample validation survey program. These surveys must be completed by the SA within 60 days of an AO full accreditation survey for the same facility. In some cases, representative sample "mid-cycle validation surveys" may be conducted independent of a preceding AO survey.

Note: The remaining portion of this section discusses the methodology for and results of CMS validation of the AOs' Medicare accreditation programs which is based only upon analysis of the 60-day representative sample validation surveys.

In 1972, Section 1875 of the Act was amended to require the Health Care Finance Administration (HCFA) (now CMS) to validate TJC survey process for hospitals and report the results to Congress annually.[9] In FY 2007, CMS began conducting 60-day validation surveys for selected non-hospital facility types (CAHs, HHAs, and ASCs), in addition to those already being performed for deemed status hospitals. In FY 2010, hospice 60-day validation surveys were added, and in FY 2011, psychiatric hospital 60-day validation surveys were added. In FY 2019, CMS conducted a total of 315 representative sample 60-day validation surveys for 6 facility types across AOs.[10] This total comprised 119 hospital surveys (including 20 psychiatric hospitals) and 196 non-hospital validation surveys. (See Graph 5.)

[9] Section 125(b)(4) of P.L. 110-275 (2008) revised this provision to apply to all AOs.
[10] OPT and RHC providers were not part of the validation sample.

Graph 5
Number of Representative Sample Validation Surveys for Both Hospital and Non-Hospital Facilities
FYs 2007-2019



*In FY 2010: The non-hospital total of 191 includes 72 mid-cycle ASC validation surveys.
**In FY 2011: The hospital total of 106 includes 33 mid-cycle LTCH validation surveys.
***In FY 2015: The hospital total of 118 includes 16 psychiatric hospital validation surveys.
****In FY 2016: The hospital total of 119 includes 21 psychiatric hospital validation surveys.
*****In FY 2017: The hospital total of 116 includes 21 psychiatric hospital validation surveys.
******In FY 2018: The hospital total of 128 includes 21 psychiatric hospital validation surveys.
*******In FY 2019: The hospital total of 119 includes 20 psychiatric hospital validation surveys.

Since 2007, CMS has worked to strengthen its oversight of AOs and increase the number of validation surveys. The recent history of validation survey samples is as follows:

- 2015: 118 hospital and 240 non-hospital surveys totaling 358 surveys.
- 2016: 119 hospital and 254 non-hospital surveys totaling 373 surveys.
- 2017: 116 hospital and 244 non-hospital surveys totaling 360 surveys.
- 2018: 128 hospital and 188 non-hospital surveys totaling 316 surveys.
- 2019: 119 hospital and 196 non-hospital surveys totaling 315 surveys.

These numbers represent a 250 percent increase in the overall number of validation surveys conducted, from 90 in FY 2007 to 315 in FY 2019. During the same time period, the number of non-hospital validation surveys conducted increased by 460 percent, from 35 surveys in FY 2007 to 196 surveys in FY 2019. The number of hospital validation surveys conducted increased by 116 percent, from 55 surveys in FY 2007 to 119 surveys in FY 2019.

60-Day Validation Surveys

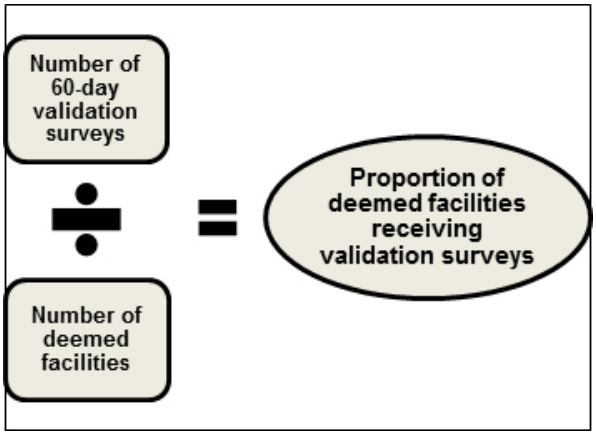
The purpose of 60-day validation surveys is to assess the AO's ability to ensure compliance with Medicare conditions. These validation surveys are on-site full surveys completed by SA surveyors no later than 60 days after the end date of an AO's Medicare accreditation program full survey. The SA performs these surveys without any knowledge of the findings of the AO's accreditation survey.

The composition of the validation sample is driven by a number of factors, including the total number of Medicare accreditation surveys scheduled by the AO and reported on monthly survey schedules furnished to CMS, the accuracy of those schedules, and individual State validation survey volume targets based on the number of deemed providers or suppliers located in the State. CMS determines the number of validation surveys to perform for each AO based on its total number of facilities, as well as the overall budgeted validation survey targets, by State and facility type. In this way, CMS builds a representative national sample for individual accreditation programs.

Proportion of Deemed Facilities Receiving Validation Surveys

The proportion of 60-day validation surveys completed for deemed facilities is calculated by dividing the number of 60-day validation surveys conducted by the total number of deemed facilities. (See Figure 1.)

Figure 1
Proportion of Deemed Facilities Receiving Validation Surveys

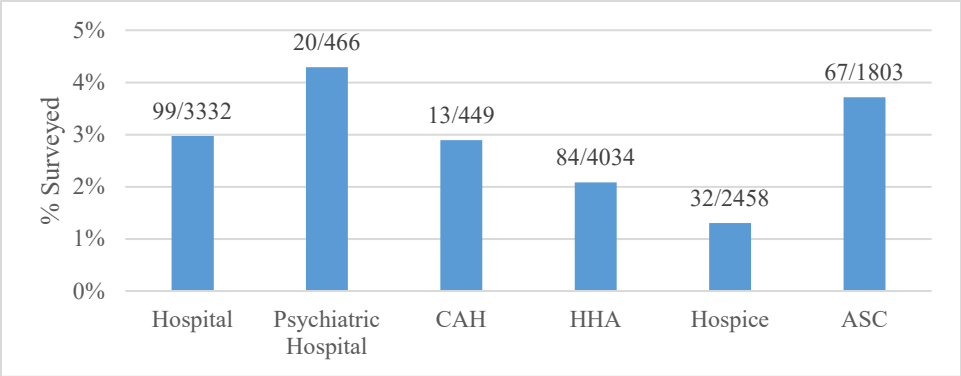


The proportion of deemed facilities that received a 60-day validation survey in FY 2019 is as follows:

- **Hospitals:** Three percent of deemed hospitals received a validation survey in FY 2019 (99 validation surveys conducted out of 3,332 deemed facilities).
- **Psychiatric Hospitals:** Four percent of deemed psychiatric hospitals received a validation survey in FY 2019 (20 validation surveys conducted out of 466 deemed facilities).
- **CAHs:** Three percent of deemed CAHs received a validation survey in FY 2019 (13 validation surveys conducted out of 449 deemed facilities).
- **HHAs:** Two percent of deemed HHAs received a validation survey in FY 2019 (84 validation surveys conducted out of 4,034 deemed facilities).
- **Hospices:** One percent of deemed hospices received a validation survey in FY 2019 (32 validation surveys conducted out of 2,458 deemed facilities).
- **ASCs:** Four percent of deemed ASCs received a validation survey in FY 2019 (67 validation surveys conducted out of 1,803 deemed facilities).

The percentage of 60-day validation surveys performed by provider type is depicted below in Graph 6.

Graph 5
60-Day Validation Surveys Performed by Provider Type
FY 2019



Validation Analysis

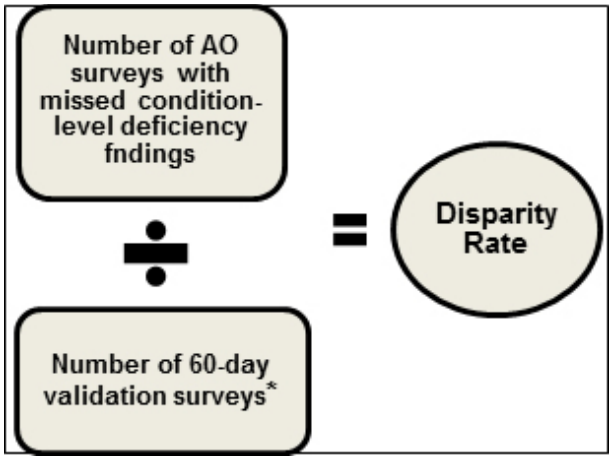
Condition-Level Deficiencies and Disparity Rate

After the 60-day validation surveys are completed, CMS performs a validation analysis and compares the condition-level deficiencies (i.e., serious deficiencies) cited by the SA with all deficiencies cited by the AO on its Medicare accreditation survey. The goal of this validation analysis is to determine whether the AOs are able to accurately identify serious deficiencies in a facility. The premise of the analysis is that condition-level deficiencies cited by the SA during the 60-day validation survey would also have been present 60 days prior, during the AO's Medicare accreditation survey, and should also have been cited by the AO.

When the SA finds a condition-level deficiency in a deemed status facility, CMS removes its deemed status and places it under the jurisdiction of the SA until the facility comes into substantial compliance. If the facility is unable to demonstrate substantial compliance in a timely manner, the facility's participation in Medicare is terminated. If compliance is demonstrated, CMS restores the facility's deemed status and returns the facility to the AO's jurisdiction.

When the SA cites a condition-level deficiency for which the AO has cited no comparable deficiency, the deficiency is considered by CMS to have been "missed" by the AO and is a factor in determining the AO's "disparity rate" for each facility type. (See Figure 2.)

Figure 2
Disparity Rate Calculation



*The number of 60-day validation surveys includes the total number of 60-day validation surveys conducted regardless of whether the SA cited condition-level deficiencies.

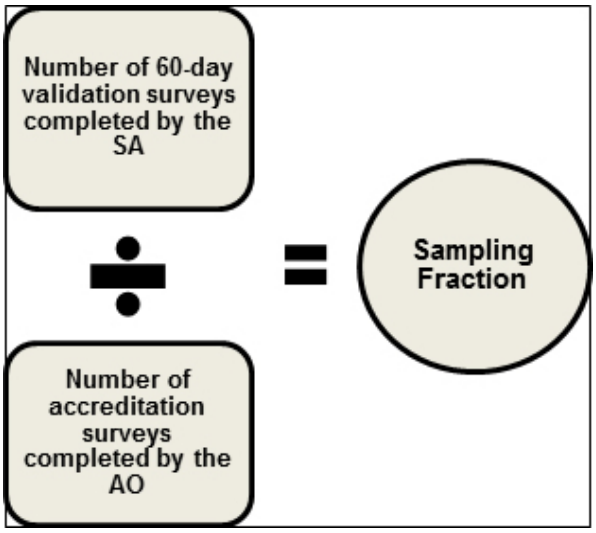
The methodology for the disparity rate is set by regulation at 42 CFR § 488.1. The numerator is the number of surveys where the AO did not cite a comparable serious (condition-level) deficiency as cited by the SA. The denominator is the total number of surveys in the 60-day representative validation sample. The result is the percentage of 60-day validation surveys where the AO did not cite a comparable serious deficiency as cited by the SA. For example, if there are 77 (60-day) validation surveys conducted, and the AO missed 12 condition-level deficiencies cited by the SA, the disparity rate would be 16 percent (12 divided by 77).

There are, however, limitations when discussing disparity rates. The disparity rate does not solely measure the AO's performance. Additionally, a high AO disparity rate does not necessarily indicate unsatisfactory performance by the AO. (See Section 5.)

Sampling Fraction

The sampling fraction is the proportion of AO surveys conducted during the FY for which a representative sample 60-day validation survey was completed. (See Figure 3.)

Figure 3
Sampling Fraction Calculation



For example, if the number of 60-day validation surveys conducted by the SA is 33 and the overall number of accreditation surveys conducted by the AO over the same time period is 638, then the sampling fraction would be 33 divided by 638—which is 5 percent. CMS has worked to increase this sampling fraction for each AO and to include a minimum of five 60-day validation surveys per year for each AO program, to the extent possible.

In summary, the *disparity rate* focuses on the number of 60-day validation surveys where the AO did not cite comparable condition-level deficiencies cited by SAs in relation to the total number of validation surveys completed by the SA. The *sampling fraction* is the proportion of 60-day validation surveys completed by the SA in relation to the number of Medicare accreditation surveys completed by the AO.

Validation Performance Results: Each Facility Type

The table below presents the results of the 60-day validation surveys for all AOs from FY 2017 through FY 2019 by facility type. (See Table 14.)

Table 14
60-Day Validation Survey Results for Each Facility Type
FYs 2017–2019

	FY 2017	FY 2018	FY 2019
HOSPITAL			
60-Day Validation Sample Surveys	95	107	99
SA Surveys with Condition-Level Deficiencies	47	57	48
AO Surveys with Missed Comparable Deficiencies	43	50	42
Disparity Rate	**45%**	**47%**	**42%**
Sampling Fraction	.07	.08	.07
PSYCHIATRIC HOSPITAL			
60-Day Validation Sample Surveys	21	21	20
SA Surveys with Condition-Level Deficiencies	14	13	12
AO Surveys with Missed Comparable Deficiencies	12	8	9
Disparity Rate	**57%**	**38%**	**45%**
Sampling Fraction	.11	.12	.09
CRITICAL ACCESS HOSPITAL			
60-Day Validation Sample Surveys	32	17	13
SA Surveys with Condition-Level Deficiencies	12	7	7
AO Surveys with Missed Comparable Deficiencies	11	7	6
Disparity Rate	**34%**	**41%**	**46%**
Sampling Fraction	.19	.08	.09

	FY 2017	FY 2018	FY 2019
HOME HEALTH AGENCY			
60-Day Validation Sample Surveys	106	81	84
SA Surveys with Condition-Level Deficiencies	16	17	8
AO Surveys with Missed Comparable Deficiencies	13	15	7
Disparity Rate	**12%**	**19%**	**8%**
Sampling Fraction	.07	.04	.05
HOSPICE			
60-Day Validation Sample Surveys	34	32	32
SA Surveys with Condition-Level Deficiencies	4	6	6
AO Surveys with Missed Comparable Deficiencies	4	5	6
Disparity Rate	**12%**	**16%**	**19%**
Sampling Fraction	.04	.03	.03
AMBULATORY SURGERY CENTER			
60-Day Validation Sample Surveys	72	58	67
SA Surveys with Condition-Level Deficiencies	33	28	26
AO Surveys with Missed Comparable Deficiencies	26	24	23
Disparity Rate	**36%**	**41%**	**34%**
Sampling Fraction	.10	.08	.08

The hospice and HHA disparity rates are significantly different than the other facility types due to the lower percentage of surveys with condition-level deficiencies cited by SAs in the 60-day validation samples for both hospice and HHAs for FYs 2017–2019. This lower deficiency rate is primarily due to these facility types not having deficiencies related to PE conditions which has historically been the primary driver for other program types. There is no PE condition for HHAs since these services are provided in the patient's home. Although hospices do have a PE condition for inpatient hospices, a number of hospice services are provided in the patient's home as well.

From FY 2018 to FY 2019, hospitals, HHAs and ASCs had the only decreases in disparity rates of all the program types, with a 5 percentage point, 11 percentage point and 7 percentage point decrease respectively. The disparity rates for psychiatric hospitals increased by 7 percentage points from FYs 2018 to 2019. The disparity rates for CAHs and hospices increased by 5 percentage points and 3 percentage points respectively from FY 2018 to FY 2019.

Validation Performance Results: Individual Accrediting Organizations

Each AO receives feedback on the results of CMS' analysis of 60-day validation surveys for its deemed status facilities. The series of tables below present the results of the 60-day validation surveys by facility type for each of the AO Medicare accreditation programs from FYs 2017 to 2019. (See Tables 15-20.)

When the number of 60-day validation surveys completed by the SA is less than five surveys, the disparity rate is not presented. The small 60-day validation sample sizes limited the analysis of some AO programs. Since 2008, CMS has tried to significantly increase the number of 60-day validation samples. With minimal exception, the sample size for every AO program was either maintained or increased from FYs 2011 to 2012. In FY 2013, the sample size decreased for each program type, except for psychiatric hospitals and CAHs. In FY 2014, the number of validation surveys for CAHs, HHAs, hospices and ASCs decreased. In FYs 2015 and 2016, the number of validation surveys for these same program types increased except for hospices which remained the same. Only hospitals showed a decrease in the number of surveys performed from FY 2014 to FY 2017. In FY 2017, the sample size decreased for each program type except for psychiatric hospitals and hospices. The number of validation surveys for psychiatric hospitals and hospices remained the same from FY 2016 to FY 2017. From FYs 2017 to 2018, the number of validation surveys decreased for CAHs, HHAs, hospices and ASCs. Hospitals was the only program type to increase the number of validation surveys performed during that same time while psychiatric hospitals remained the same. CMS strives to maintain a larger sample size in the future based on the availability of Federal funds. The presentation of validation results over several time periods provides a more complete examination of the consistency of individual AO performance. Therefore, the results for the FYs 2017–2019 60-day validation surveys for individual AOs are outlined in the tables below by program type.

Hospital

The AOs with hospital programs in FY 2019 were AAHHS/HFAP, CIHQ, DNV GL, and TJC. (See Table 15.)

Table 15
Hospital 60-Day Validation Survey Results by AO
FYs 2017–2019

Emp	AAHHS/HFAP			CIHQ			DNV GL			TJC			Total
	FY 2017	FY 2018	FY 2019	FY 2017	FY 2018	FY 2019	FY 2017	FY 2018	FY 2019	FY 2017	FY 2018	FY 2019	FYs 2017–2019
60-Day Validation Sample Surveys	5	9	3	4	0	1	15	19	7	71	78	88	301
SA Surveys with Condition-Level Deficiencies	5	9	*N/A	*N/A	*N/A	*N/A	4	6	3	34	42	43	146
AO Surveys with Missed Comparable Deficiencies	5	9	*N/A	*N/A	*N/A	*N/A	4	5	3	30	36	37	129
Overall Disparity Rate	**100%**	**100%**	***N/A**	***N/A**	***N/A**	***N/A**	**27%**	**26%**	**43%**	**42%**	**46%**	**42%**	**45%**
Health and Safety Disparity Rate	**40%**	**56%**	***N/A**	***N/A**	***N/A**	***N/A**	**13%**	**5%**	**43%**	**23%**	**27%**	**31%**	**27%**
Physical Environment Disparity Rate	**100%**	**44%**	***N/A**	***N/A**	***N/A**	***N/A**	**13%**	**26%**	**29%**	**31%**	**26%**	**23%**	**27%**
Sampling Fraction	.10	.28	*N/A	*N/A	*N/A	*N/A	.15	.14	.05	.06	.07	.08	.08

*N/A: When a minimum sample size of five is not achieved for an AO, no data is reported given the lack of statistical significance.

- **AAHHS/HFAP:** In FY 2019, due to the low number of deemed hospitals due for resurvey, only three validation surveys were conducted. Therefore, no additional data is reported.
- **CIHQ:** In FY 2019, due to the low number of deemed hospitals due for resurvey, only one validation survey was conducted. Therefore, no additional data is reported.
- **DNV GL:** In FY 2019, the overall disparity rate was 43 percent based on the completion of seven validation surveys. The number of validation surveys conducted represents a 5 percent sample of the surveys conducted by DNV GL. The FY 2019 overall disparity rate is 16 percentage points higher than the overall disparity rate for FY 2017. The FY 2017 overall disparity rate was based on a 15 percent sample of the surveys conducted during that period. In FY 2019, DNV GL's health and safety disparity rate was 14 percentage points higher than the PE disparity rate. In FY 2019, the primary drivers of DNV GL's health and safety disparity rate were as follows: Governing Body; Food and Dietetic Services; Infection Control; and Organ, Tissue, and Eye Procurement. The SA cited the Governing Body, the Food and Dietetic Services, and the Organ, Tissue, and Eye Procurement requirements at the condition level one time. In each instance, DNV GL missed one comparable deficiency. The SA cited the Infection Control requirement at the condition level two times. DNV GL missed one comparable deficiency. Each condition yielded a 14 percent disparity rate. The FY 2019 health and safety disparity rate is 30 percentage points higher than the FY 2017 health and safety disparity rate.
- **TJC:** In FY 2019, the overall disparity rate was 42 percent based on the completion of 88 validation surveys. The number of validation surveys conducted represents an 8 percent sample of surveys conducted by TJC. The FY 2017 overall disparity rate was 42 percent based on the completion of 71 validation surveys. The overall disparity rate in FY 2017 was based on a 6 percent sample of surveys conducted during that period. In FY 2019, TJC's health and safety disparity rate was 8 percentage points higher than the PE disparity rate. In FY 2019, the primary drivers of TJC's health and safety disparity rate were as follows: Infection Control; and Patient Rights. The SAs cited the Infection Control requirement at the condition level 15 times. TJC missed 10 comparable deficiencies. The SAs cited the Patient Rights requirement at the condition level 16 times. TJC missed 10 comparable deficiencies. Both conditions yielded an 11 percent disparity rate. The FY 2019 health and safety disparity rate is 8 percentage points higher than the FY 2017 health and safety disparity rate.

Psychiatric Hospital

TJC was the only AO with a CMS-approved psychiatric hospital Medicare accreditation program in FY 2019. The psychiatric hospital program was initially approved by CMS in FY 2011. (See Table 16.)

Table 16
Psychiatric Hospital 60-Day Validation Survey Results by AO
FYs 2017–2019

				Total
	FY 2017	FY 2018	FY 2019	FYs 2017–2019
60-Day Validation Sample Surveys	21	21	20	62
SA Surveys with Condition-Level Deficiencies	14	13	12	39
AO Surveys with Missed Comparable Deficiencies	12	8	9	29
Overall Disparity Rate	**57%**	**38%**	**45%**	**47%**
Health and Safety Disparity Rate	**43%**	**33%**	**30%**	**35%**
Physical Environment Disparity Rate	**38%**	**29%**	**20%**	**31%**
Sampling Fraction	.11	.12	.09	.11

- **TJC:** In FY 2019, the overall disparity rate was 45 percent based on the completion of 20 validation surveys. The number of validation surveys completed represents a 9 percent sample of the surveys conducted by the TJC. The FY 2019 overall disparity rate is 12 percentage points lower than the overall disparity rate for FY 2017. The FY 2017 overall disparity rate was based on an 11 percent sample of the surveys conducted during that period. In FY 2019, TJC's health and safety disparity rate was 10 percentage points higher than the PE disparity rate. The primary driver of TJC's health and safety disparity rate was the Infection Control condition. The SAs cited the Infection Control requirement at the condition level three times. TJC missed all three comparable deficiencies resulting in a 15 percent disparity rate. The FY 2019 health and safety disparity rate is 13 percentage points lower than the FY 2017 health and safety disparity rate.

Critical Access Hospital

The AOs with CAH accreditation programs in FY 2019 were AAHHS/HFAP, DNV GL, and TJC. (See Table 17.)

Table 17
CAH 60-Day Validation Survey Results
by AO
FYs 2017–2019

	AAHHS / HFAP			DNV GL			TJC			Total
	FY 2017	FY 2018	FY 2019	FY 2017	FY 2018	FY 2019	FY 2017	FY 2018	FY 2019	FYs 2017–2019
60-Day Validation Sample Surveys	3	1	0	6	5	4	23	11	9	62
SA Surveys with Condition-Level Deficiencies	*N/A	*N/A	*N/A	1	2	*N/A	10	4	7	24
AO Surveys with Missed Comparable Deficiencies	*N/A	*N/A	*N/A	1	2	*N/A	9	4	6	22
Overall Disparity Rate	***N/A**	***N/A**	***N/A**	**17%**	**40%**	***N/A**	**39%**	**36%**	**67%**	**39%**
Health and Safety Disparity Rate	***N/A**	***N/A**	***N/A**	**17%**	**40%**	***N/A**	**9%**	**18%**	**22%**	**15%**
Physical Environment Disparity Rate	***N/A**	***N/A**	***N/A**	**N/A**	**20%**	***N/A**	**35%**	**27%**	**56%**	**31%**
Sampling Fraction	*N/A	*N/A	*N/A	.17	.10	*N/A	.19	.08	.08	.12

*N/A: When a minimum sample size of five is not achieved for an AO, no data is reported given the lack of statistical significance.

- **AAHHS/HFAP:** In FY 2019, the State Agency did not conduct any validation surveys for AAHHS/HFAP CAHs. Therefore, no additional data is reported.

- **DNV GL:** In FY 2019, due to the low number of deemed CAHs due for resurvey, only four validation surveys were conducted. Therefore, no additional data is reported.

- **TJC:** In FY 2019, the overall disparity rate was 67 percent based on the completion of nine validation surveys. The number of validation surveys conducted represents an 8 percent sample of the surveys conducted by TJC. The FY 2019 overall disparity rate is 28 percentage points higher than the FY 2017 overall disparity rate. The FY 2017 overall disparity rate was based on a 19 percent sample of surveys conducted during that period. In FY 2019, the PE disparity rate was 34 percentage points higher than the health and safety disparity rate. The SA cited PE at the condition level 10 times. TJC missed five comparable deficiencies resulting in a 56 percent disparity rate. The FY 2019 PE disparity rate is 21 percentage points higher than the FY 2017 PE disparity rate.

Home Health Agency

The AOs with HHA accreditation programs in FY 2019 were ACHC, CHAP, and TJC. (See Table 18.)

Table 18
HHA 60-Day
Validation Survey Results by AO
FYs 2017–2019

	ACHC			CHAP			TJC			Total
	FY 2017	FY 2018	FY 2019	FY 2017	FY 2018	FY 2019	FY 2017	FY 2018	FY 2019	FYs 2017–2019
60-Day Validation Sample Surveys	22	12	17	45	36	36	39	33	31	271
SA Surveys with Condition-Level Deficiencies	4	2	0	7	6	6	5	9	2	41
AO Surveys with Missed Comparable Deficiencies	3	2	0	6	6	5	4	7	2	35
Overall Disparity Rate	**14%**	**17%**	***N/A**	**13%**	**17%**	**14%**	**10%**	**21%**	**6%**	**13%**
Sampling Fraction	.08	.03	.04	.08	.05	.06	.06	.04	.04	.05

- **ACHC:** In FY 2019, 17 validation surveys were completed for which no SA condition-level deficiencies were cited. The number of validation surveys completed represents a 4 percent sample of surveys conducted by ACHC.

- **CHAP:** In FY 2019, the overall disparity rate was 14 percent based on the completion of 36 validation surveys. The number of validation surveys completed represents a 6 percent sample of the surveys conducted by CHAP. The FY 2019 overall disparity rate is 1 percentage point higher than the overall disparity rate for FY 2017. The overall disparity rate for FY 2017 was based on an 8 percent sample of surveys conducted during that period. In FY 2019, the primary drivers of CHAP's overall disparity rate were Skilled Professional Services; and Comprehensive Assessment of Patients. The SA cited the Skilled Professional Services and the Comprehensive Assessment of Patients requirements three times. Both times, CHAP missed two comparable deficiencies. Each condition yielded a 6 percent disparity rate.

- **TJC:** In FY 2019, the overall disparity rate was 6 percent based on the completion of 31 validation surveys. The number of validation surveys completed represents a 4 percent sample of the surveys conducted by TJC. The FY 2019 overall disparity rate is 4 percentage points lower than the overall disparity rate for FY 2017. The overall disparity rate for FY 2017 was based on a 6 percent sample of surveys conducted during that period. In FY 2019, the primary drivers of TJC's overall disparity rate were as follows: Compliance with Federal, State, Local Law; Clinical Records; Comprehensive Assessment of Patients; and Care Planning, Coordination, and Quality of Care. The SA cited the Compliance with Federal, State, Local Law and the Comprehensive Assessment of Patients requirements one time. Both times, TJC missed one comparable deficiency. The SA cited the Clinical Records requirement at the condition level two times. TJC missed one comparable deficiency. The SA cited the Care Planning, Coordination, and Quality of Care requirement at the condition level three times. TJC missed one comparable deficiency. Each of the conditions yielded a 3 percent disparity rate.

Hospice

The AOs with hospice accreditation programs in FY 2019 were ACHC, CHAP and TJC. (See Table 19.)

Table 19
Hospice 60-Day Validation Survey Results
by AO
FYs 2017–2019

	ACHC			CHAP			TJC			Total
	FY 2017	FY 2018	FY 2019	FY 2017	FY 2018	FY 2019	FY 2017	FY 2018	FY 2019	FYs 2017-2019
60-Day Validation Sample Surveys	3	8	8	17	17	11	14	7	13	98
SA Surveys with Condition-Level Deficiencies	*N/A	1	2	2	4	1	2	1	3	16
AO Surveys with Missed Comparable Deficiencies	*N/A	0	2	2	4	1	2	1	3	15
Overall Disparity Rate	***N/A**	**0%**	**25%**	**12%**	**24%**	**9%**	**14%**	**14%**	**23%**	**15%**
Sampling Fraction	*N/A	.04	.03	.06	.05	.03	.04	.01	.03	.03

*N/A: When a minimum sample size of five is not achieved for an AO, no data is reported given the lack of statistical significance.

- **ACHC:** In FY 2019, the overall disparity rate was 25 percent based on the completion of eight validation surveys. The number of validation surveys completed represents a 3 percent sample of the surveys conducted by ACHC. The FY 2019 overall disparity rate is 25 percentage points higher than the overall disparity rate for FY 2018. The overall disparity rate for FY 2018 was based on 4 percent sample of surveys conducted during that period. In FY 2019, the primary driver of ACHC's overall disparity rate was the IDG, Care Planning, Coordination of Services condition. The SA cited this requirement at the condition level four times. ACHC missed two comparable deficiencies resulting in a disparity rate of 25 percent.

- **CHAP:** In FY 2019, the overall disparity rate was 9 percent based on the completion of 11 validation surveys. The number of validation surveys completed represents a 3 percent sample of the surveys conducted by CHAP. The FY 2019 overall disparity rate is 3 percentage points lower than the overall disparity rate for FY 2017. The overall disparity rate for FY 2017 was based on a 6 percent sample of surveys conducted during that period. In FY 2019, the primary drivers of CHAP's overall disparity rate were Organizational Environment; and IDG, Care Planning, Coordination of Services. The SA cited the Organizational Environment requirement at the condition level one time. CHAP missed the comparable deficiency. The SA cited the IDG, Care Planning, Coordination of Services requirement at the condition level two times. CHAP missed one comparable deficiency. Both instances yielded a 9 percent disparity rate.

- **TJC:** In FY 2019, the overall disparity rate was 23 percent based on the completion of 13 validation surveys. The number of validation surveys completed represents a 3 percent sample of the surveys performed by TJC. The FY 2019 overall disparity rate is 9 percentage points higher than the overall disparity rate for FY 2017. The overall disparity rate for FY 2017 was based on a 4 percent sample of the surveys conducted during that period. In FY 2019, the primary drivers of TJC's disparity rate were IDG, Care Planning, Coordination of Services; and Quality Assessment & Performance Improvement. The SA cited the IDG, Care Planning, Coordination of Services requirement at the condition level four times. TJC missed two comparable deficiencies. The SA cited the Quality Assessment & Performance Improvement requirement at the condition level two times. TJC missed both comparable deficiencies. Both instances yielded a 15 percent disparity rate.

Ambulatory Surgery Center

The AOs with ASC accreditation programs in FY 2019 were AAAASF, AAAHC, AAHHS/HFAP, IMQ and TJC. (See Table 20.)

Table 20
ASC 60-Day
Validation Survey Results by AO
FYs 2017–2019

	AAAASF			AAAHC			AAHHS/HFAP**			TJC			Total
	FY 2017	FY 2018	FY 2019	FY 2017	FY 2018	FY 2019	FY 2017	FY 2018	FY 2019	FY 2017	FY 2018	FY 2019	FYs 2017–2019
60-Day Validation Sample Surveys	6	7	6	35	30	39	0	0	1	31	21	21	197
SA Surveys with Condition-Level Deficiencies	4	4	3	12	12	16	*N/A	*N/A	*N/A	17	12	6	86
AO Surveys with Missed Comparable Deficiencies	4	4	3	8	11	15	*N/A	*N/A	*N/A	14	9	4	72
Overall Disparity Rate	**67%**	**57%**	**50%**	**23%**	**37%**	**38%**	***N/A**	***N/A**	***N/A**	**45%**	**43%**	**19%**	**37%**
Health and Safety Disparity Rate	**50%**	**57%**	**33%**	**11%**	**30%**	**31%**	***N/A**	***N/A**	***N/A**	**35%**	**14%**	**14%**	**26%**
Physical Environment Disparity Rate	**33%**	**29%**	**33%**	**14%**	**20%**	**13%**	***N/A**	***N/A**	***N/A**	**26%**	**33%**	**10%**	**20%**
Sampling Fraction	.08	.08	.06	.10	.08	.10	*N/A	*N/A	*N/A	.13	.07	.07	.09

*N/A: When a minimum sample size of five is not achieved for an AO, no data is reported given the lack of statistical significance.
**Very few AAHHS/HFAP ASC validation survey selections have been made since FY 2012 due to the low numbers of deemed ASCs.
Note: IMQ's ASC accreditation program received initial CMS approval April 2016. No IMQ selections in FYs 2017-2019.

- **AAAASF:** In FY 2019, the overall disparity rate was 50 percent based on the completion of six validation surveys. The number of validation surveys completed represents a 6 percent sample of the surveys performed by AAAASF. The FY 2019 overall disparity rate is 17 percentage points lower than the overall disparity rate for FY 2017. The overall disparity rate for FY 2017 was based on an 8 percent sample of the surveys conducted during that period. In FY 2019, AAAASF's health and safety disparity rate and PE disparity rate were 33 percent. The primary drivers for AAAASF's health and safety disparity rate were Infection Control; Governing Body and Management; and Quality Assessment and Performance Improvement. The SA cited the Governing Body and Management requirement and the Quality Assessment and Performance Improvement requirement at the condition level two times. In both instances, AAAASF missed both comparable deficiencies resulting in a disparity rate of 33 percent. The SA cited the Infection Control requirement at the condition level three times. AAAASF missed two comparable deficiencies resulting in a disparity rate of 33 percent. The SA cited the PE requirement at the condition level three times. AAAASF missed two comparable deficiencies resulting in a disparity rate of 33 percent. The FY 2019 health and safety disparity rate is 17 percentage points lower than the FY 2017 health and safety disparity rate. The FY 2019 PE disparity rate remained unchanged from the FY 2017 PE disparity rate.

- **AAAHC:** In FY 2019, the overall disparity rate was 38 percent based on the completion of 39 validation surveys. The number of validation surveys completed represents a 10 percent sample of the surveys performed by AAAHC. The FY 2019 overall disparity rate is 15 percentage points higher than the overall disparity rate for FY 2017. The overall disparity rate for FY 2017 was based on a 10 percent sample of the surveys conducted during that period. In FY 2019, AAAHC's health and safety disparity rate was 18 percentage points higher than the PE disparity rate. The primary driver of AAAHC's health and safety disparity rate was Infection Control. The SA cited the Infection Control requirement at the condition level 12 times. AAAHC missed eight comparable deficiencies resulting in a disparity rate of 21 percent. The FY 2019 health and safety disparity rate is 20 percentage points higher than the FY 2017 health and safety disparity rate.

- **AAHHS/HFAP:** Due to the consistently low number of deemed AAHHS/HFAP ASCs, only one validation survey was conducted in FY 2019. Therefore, no additional data is reported.

- **TJC:** In FY 2019, the overall disparity rate was 19 percent based on the completion of 21 validation surveys. The number of validation surveys completed represents a 7 percent sample of the surveys performed by TJC. The FY 2019 overall disparity rate is 26 percentage points lower than the overall disparity rate for FY 2017. The disparity rate for FY 2017 was based on a 13 percent sample of surveys conducted during that period. In FY 2019, TJC's health and safety disparity rate was 4 percentage points higher than the PE disparity rate. The primary driver of TJC's health and safety disparity rate was Governing Body and Management. The SA cited the Governing Body and Management requirement at the condition level 4 times. TJC missed two comparable deficiencies resulting in a disparity rate of 10 percent. The FY 2019 health and safety disparity rate is 21 percentage points

lower than the FY 2017 health and safety disparity rate.

Validation Performance Results: Physical Environment vs. Other Health Conditions Cited

Examining the specific condition-level deficiencies cited by the SAs across all 60-day validation surveys provides an indication of the types of quality problems that exist in these facility types as well as the relationship between SA and AO citations for specific conditions. CMS uses two approaches for this analysis: (1) a review of the types of condition-level citations identified by SAs and the comparable AO deficiency findings; and (2) a comparison of the number of surveys with PE condition-level deficiencies and the number of surveys with other types of condition-level deficiencies. Both approaches highlight the same conclusion: SAs identify more PE condition-level deficiencies than any other type of deficiency on validation surveys; and AOs miss a significant number of these PE deficiencies. These findings are consistent with validation analysis results until FY 2014. In FYs 2014–2016, the SAs identified more health and safety condition-level deficiencies than PE condition-level deficiencies in psychiatric hospitals. In FY 2015, the same is true for ASCs. However, in FY 2016, the SAs identified more PE condition-level deficiencies than health and safety condition-level deficiencies for ASCs. In FY 2017, the SAs identified more PE condition-level deficiencies than health and safety condition-level deficiencies in psychiatric hospitals and ASCs. In FY 2018, the SAs identified more health and safety condition-level deficiencies in psychiatric hospitals. In FY 2019, the SAs identified more PE condition-level deficiencies in hospitals, psychiatric hospitals, CAHs and ASCs.

Comparison of State Agency and Accrediting Organization Condition-Level Citation Findings

The first analysis yields the number of facilities cited by SAs for specific condition-level deficiencies and the number of surveys where the AOs missed citing comparable deficiencies. These results are discussed below by each specific facility type. (See Tables 21-26 and Graphs 7-14.)

Table 21
Number and Type of Condition-Level Deficiencies
Cited on 60-Day Validation Surveys
Hospitals
FY 2019

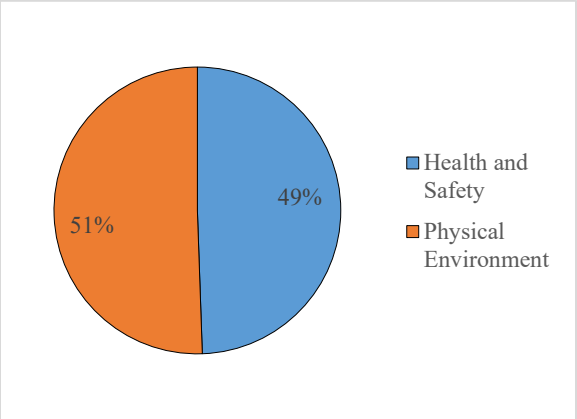
Medicare Conditions* Sample Size - 99	Cited by SA	Missed by AO
***Physical Environment**	**53**	**24**
Infection Control	17	11
Patient Rights	16	10
Governing Body	13	7
QAPI	8	6
Surgical Services	6	3
Medical Record Services	4	2
Food and Dietetic Services	4	3
Nursing Services	3	2
Pharmaceutical Services	2	1
Medical Staff	1	1
Utilization Review	1	1
Organ, Tissue, and Eye Procurement	1	1
TOTAL	129	72

*Most frequently cited deficiency.
Note: The PE condition includes the National Fire Protection Association (NFPA) 2012 edition of the LSC requirements that CMS has adopted as part of its health and safety standards.

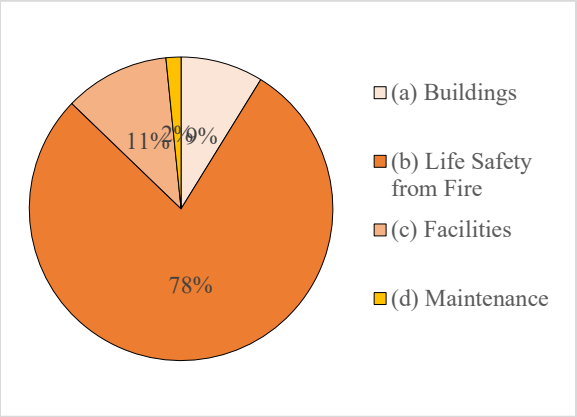
In FY 2019, the hospital sample consisted of 99 validation surveys. In this sample, the SAs cited condition-level deficiencies in 48 facilities. The PE requirement was cited at the condition level by the SAs 53 times. The AOs missed 24 comparable deficiencies for PE. The findings were similar in FYs 2012–2018.

In FY 2019, the next most frequently SA-cited conditions were as follows: Infection Control, cited 17 times by the SAs, and missed 11 times by the AOs; Patient Rights, cited 16 times by the SAs, and missed 10 times by the AOs; and Governing Body, cited 13 times by the SAs, and missed seven times by the AOs.

Graph 7
Percentage of Health and Safety vs PE Condition-Level Deficiencies Cited on 60-Day Validation Surveys
Hospitals
FYs 2017–2019



Graph 8
Percentage of PE Standards Cited on 60-Day
Validation Surveys
Hospitals
FYs 2017–2019



From FY 2017 to FY 2019, there were 152 validation surveys cited with condition-level deficiencies for hospitals. Of the 152 surveys, 90 of the surveys had health and safety citations, 92 of the surveys had PE citations, and 30 of the surveys were cited with both. For hospitals, the PE condition consists of four standards: (a) Buildings, (b) Life Safety from Fire, (c) Facilities, and (d) Maintenance. There were 125 standards cited for the PE condition and 98 of these standards were related to Life Safety from Fire.

Table 22
Number and Type of Condition-Level Deficiencies
Cited on 60-Day Validation Surveys
Psychiatric Hospitals
FY 2019

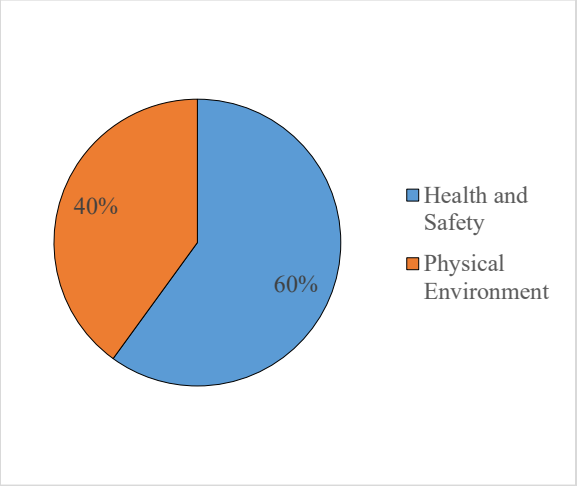
Medicare Conditions Sample Size – 20	Cited by SA	Missed by AO
Physical Environment*	**8**	**4**
Infection Control	3	3
Special Medical Record Reqs for Psych Hospitals	7	2
Governing Body	3	2
Food and Dietetic Services	2	2
Patient Rights	3	1
Nursing Services	2	1
Establishment of the Emergency Program	1	1
Pharmaceutical Services	1	1
TOTAL	30	17

*Most frequently cited deficiency

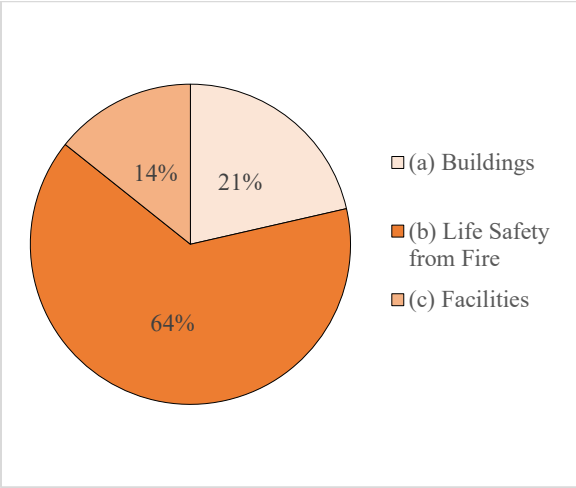
In FY 2019, the psychiatric hospital sample consisted of 20 validation surveys. In this sample, the SAs cited 12 facilities at the condition level. The PE requirement was cited at the condition level by the SAs eight times. The AOs missed four comparable deficiencies for PE. In FY 2018, the following requirements were cited most frequently by the SAs at the condition level for psychiatric hospitals: PE and Special Medical Record Requirements. In FY 2017, the PE requirement was cited most frequently at the condition level by the SAs.

In FY 2019, the next most frequently SA-cited condition was Special Medical Record Requirements for Psychiatric Hospitals, cited seven times by the SAs, and missed two times by the AOs.

Graph 9
Percentage of Health and Safety vs PE Condition-Level Deficiencies Cited on 60-Day Validation Surveys
Psychiatric Hospitals
FYs 2017–2019



Graph 10
Percentage of PE Standards Cited on 60-Day
Validation Surveys
Psychiatric Hospitals
FYs 2017–2019



From FY 2017 to FY 2019, there were 39 validation surveys cited with condition-level deficiencies for psychiatric hospitals. Of the 39 surveys, 30 of the surveys had health and safety citations, 20 of the surveys had PE citations, and 12 of the surveys was cited with both. For psychiatric hospitals, the PE condition consists of three standards: (a) Buildings, (b) Life Safety from Fire, and (c) Facilities. Twenty-eight standards were cited for the PE condition and 18 of these standards were related to Life Safety from Fire.

Table 23
Number and Type of Condition-Level Deficiencies
Cited on 60-Day Validation Surveys
CAHs
FY 2019

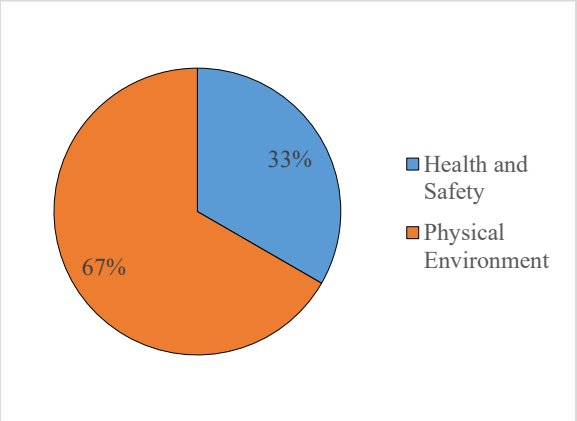
Medicare Conditions Sample Size – 13	Cited by SA	Missed by AO
Physical Plant and Environment*	**10**	**5**
Provision of Services	3	1
Surgical Services	2	1
Organizational Structure	1	1
Special Reqs for CAH Providers of LTC Srvcs	1	1
TOTAL	17	9

*Most frequently cited deficiency

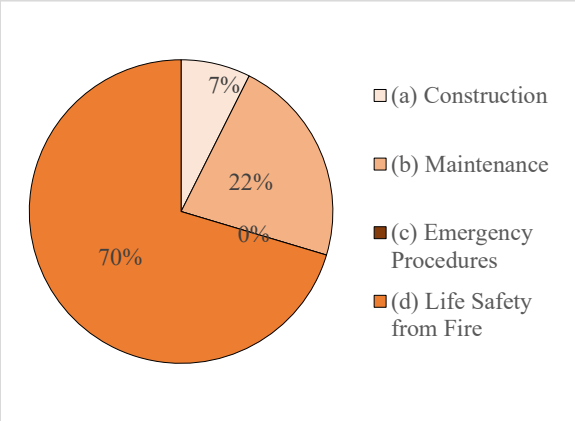
In FY 2019, the CAH sample consisted of 13 validation surveys. In this sample, seven facilities were cited at the condition level by the SAs. The Physical Plant and Environment requirement was cited by the SAs at the condition level 10 times. The AOs missed five comparable deficiencies for PE, which was also the most frequently SA-cited condition in FYs 2012–2018.

In FY 2019, the next most frequently SA-cited condition for CAHs was Provision of Services, cited three times by the SAs, and missed one time by the AOs.

Graph 11
Percentage of Health and Safety vs PE Condition-Level Deficiencies Cited on 60-Day Validation Surveys
CAHs
FYs 2017–2019



Graph 12
Percentage of PE Standards Cited on 60-Day Validation Surveys
CAHs
FYs 2017–2019



From FY 2017 to FY 2019, there were 26 validation surveys cited with condition-level deficiencies for CAHs. Of the 26 surveys, 10 of the surveys had health and safety citations, 20

of the surveys had PE citations, and four of the surveys was cited with both. For CAHs, the PE condition consists of four standards: (a) Construction, (b) Maintenance, (c) Emergency Procedures, and (d) Life Safety from Fire. Twenty-seven standards were cited for the PE condition and 19 of these standards were related to Life Safety from Fire.

Table 24
Number and Type of Condition-Level Deficiencies
Cited on 60-Day Validation Surveys
HHAs
FY 2019

Medicare Conditions Sample Size – 84	Cited by SA	Missed by AO
Comprehensive Assessment of Patients	4	3
Care Planning, Coordination, and Quality of Care*	**6**	**2**
Skilled Professional Services	3	2
Quality Assessment/Performance Improvement	4	1
Establishment of the Emergency Program	3	1
Clinical Records	2	1
Compliance with Federal, State, Local Law	1	1
Establishment of Emergency Program	1	1
Infection Prevention and Control	1	0
TOTAL	25	12

*Most frequently cited deficiency

In FY 2019, the HHA sample consisted of 84 validation surveys. In this sample, the SAs cited condition-level deficiencies in eight agencies. The Care Planning, Coordination, and Quality of Care requirement was cited at the condition level by the SAs six times. The AOs missed two comparable deficiencies. In FY 2018, the Skilled Professional Services requirement was the most frequently SA-cited condition. In FY 2017, the Skilled Nursing Services requirement was cited most frequently by the SAs at the condition level. In FY 2016, the most frequently SA-cited condition was Acceptance of Patients, Plan of Care & Medical Supervision.

In FY 2019, the next most frequently SA-cited conditions were as follows: Comprehensive Assessment of Patients, cited four times by the SAs at the condition level, and missed three times by the AOs; and Quality Assessment/Performance Improvement, cited four times by the SAs at the condition level, and missed one time by the AOs.

Table 25
Number and Type of Condition-Level Deficiencies
Cited on 60-Day Validation Surveys
Hospices
FY 2019

Medicare Conditions Sample Size – 32	Cited by SA	Missed by AO
IDG, Care Planning, Coordination of Services*	**10**	**5**
Quality Assessment & Performance Improvement	4	3
Organizational Environment	3	2
Clinical Records	3	2
Establishment of the Emergency Program	1	1
Patient Rights	1	1
Infection Control	1	1
TOTAL	23	15

*Most frequently cited deficiency

In FY 2019, the hospice sample consisted of 32 validation surveys. In this sample, the SAs cited condition-level deficiencies in six agencies. The IDG, Care Planning, Coordination of Services requirement was cited by the SA at the condition level 10 times. The AOs missed five comparable deficiencies. In FY 2018, the most frequently cited SA-condition level deficiencies were as follows: IDG, Care Planning, Coordination of Services; Quality Assessment & Performance Improvement; Infection Control; and hospice Aide and Homemaker Services. Each of the conditions were cited three times by the SAs and missed two times by the AOs. In FY 2017, the most frequently cited SA-condition level deficiency was the IDG, Care Planning, Coordination of Services condition. In FY 2016, the Quality Assessment & Performance Improvement condition was the most frequently SA-cited condition.

In FY 2019, the next most frequently SA-cited condition was Quality Assessment & Performance Improvement, cited four times by the SAs, and missed three times by the AOs.

Table 26
Number and Type of Condition-Level Deficiencies
Cited on 60-Day Validation Surveys
ASCs
FY 2019

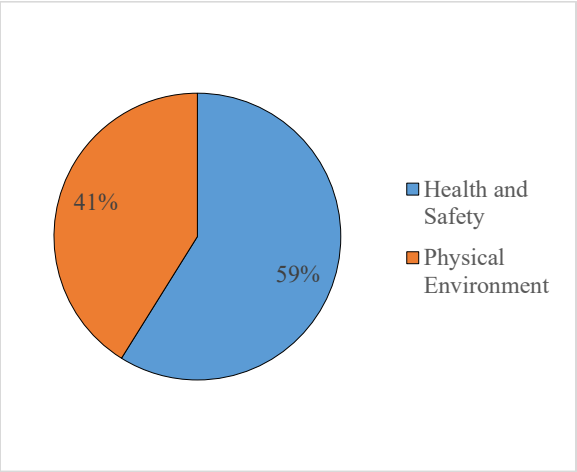
Medicare Conditions Sample Size – 67	Cited by SA	Missed by AO
Environment*	**19**	**10**
Infection Control	17	11
Governing Body and Management	13	9
Quality Assessment & Performance Improvement	6	4
Surgical Services	4	2
Establishment of the Emergency Program	4	2
Pharmaceutical Services	2	2
Patient Admission, Assessment and Discharge	2	1
Basic Requirements	1	1
Medical Staff	1	1
TOTAL	69	43

*Most frequently cited deficiency

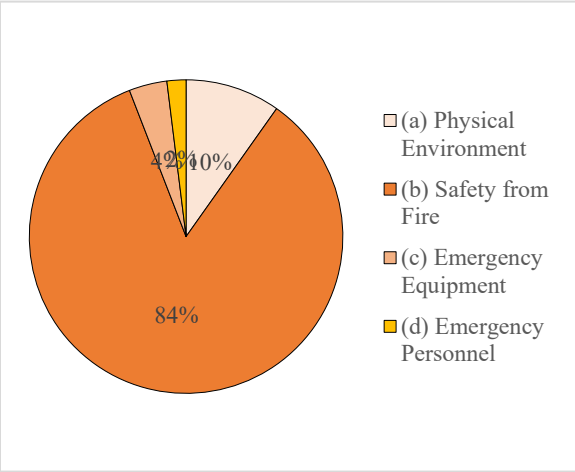
In FY 2019, the ASC sample consisted of 67 validation surveys. In this sample, the SAs cited condition-level deficiencies in 26 facilities. The SAs cited the PE requirement at the condition level 19 times. The AOs missed 10 comparable deficiencies for PE. In FYs 2017-2018, PE was the most frequently cited condition.

In FY 2019, the next most frequently SA-cited conditions were as follows: Infection Control, cited 17 times by the SAs, and missed 11 times by the AOs; and Governing Body and Management, cited 13 times by the SAs, and missed nine times by the AOs.

Graph 13
Percentage of Health and Safety vs PE Condition-Level Deficiencies Cited on 60-Day Validation Surveys
ASCs
FYs 2017–2019



Graph 14
Percentage of PE Standards Cited on 60-Day Validation Surveys
ASCs
FYs 2017–2019



From FY 2017 to FY 2019, there were 87 validation surveys cited with condition-level deficiencies for ASCs. Of the 87 surveys, 63 of the surveys had health and safety citations, 44 of the surveys had PE citations, and 20 of the surveys were cited with both. For ASCs, the PE condition consists of four standards: (a) PE, (b) Safety from Fire, (c) Emergency equipment, and (d) Emergency Personnel. Fifty-one standards were cited for the PE condition and 43 of these standards were related to Safety from Fire.

Comparison of Deficiencies for Physical Environment and Other Health Conditions

The second analysis compares the validation results for condition-level deficiencies for PE conditions with the results for condition-level deficiencies for all other conditions. It also yields two disparity rates for each type of facility and AO. (See Tables 27-28 and Graph 15.)

Table 27
Number of 60-Day Validation Surveys for Facility Types with LSC Requirements
FY 2019

Validation Survey Analysis	Hospital*	Psych Hospital	CAH	ASC
60-Day Validation Sample Surveys	99	20	13	67

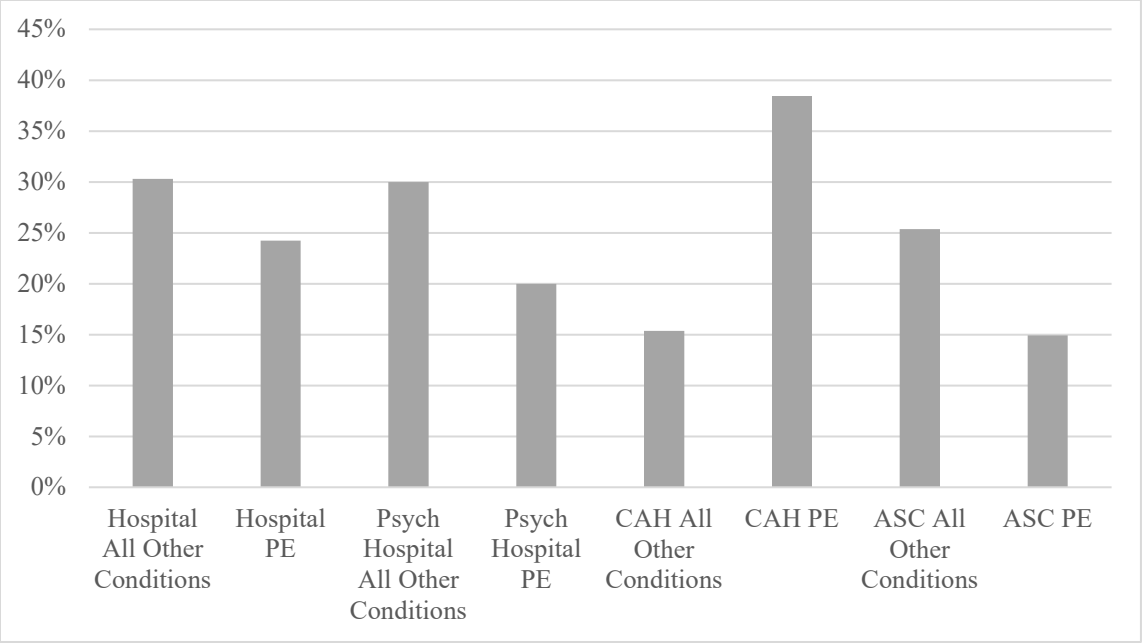
*Acute Care and LTCHs

Table 28
60-Day Validation Survey Results
Comparison between All Other Conditions Cited and
PE for Facility Types with LSC Requirements
FY 2019

	Hospital All Other Conditions	Hospital PE	Psych Hospital All Other Conditions	Psych Hospital PE	CAH All Other Conditions	CAH PE	ASC All Other Conditions	ASC PE
SA Surveys with Condition-Level Deficiencies	31	31	9	4	3	5	19	12
AO Surveys with Missed Comparable Deficiencies	30	26	6	4	2	5	17	10
Disparity Rate	**30%**	**24%**	**30%**	**20%**	**15%**	**38%**	**25%**	**15%**

In FY 2019, the PE condition impacted the overall disparity rate for CAHs. The disparity rate based on the PE condition for CAHs is 23 percentage points higher than the disparity rate based on other health and safety conditions. This is an increase from FY 2018, where the difference in disparity rate was 5 percentage points. In FY 2019, the PE disparity rate for hospitals is 6 percentage points lower than the disparity rate for other health and safety conditions. In FY 2018, the PE disparity rate for hospitals was 2 percentage points higher than the disparity rate for other health and safety conditions. The PE disparity rate for psychiatric hospitals is 10 percentage points lower than the disparity rate for other health and safety conditions compared to 4 percentage points in FY 2018, a decrease of 6 percentage points. In FY 2019, the PE disparity rate for ASCs is 10 percentage points lower than the disparity rate for other health and safety conditions, compared to 2 percentage points in FY 2018, a decrease of 8 percentage points. (See Graph 15.)

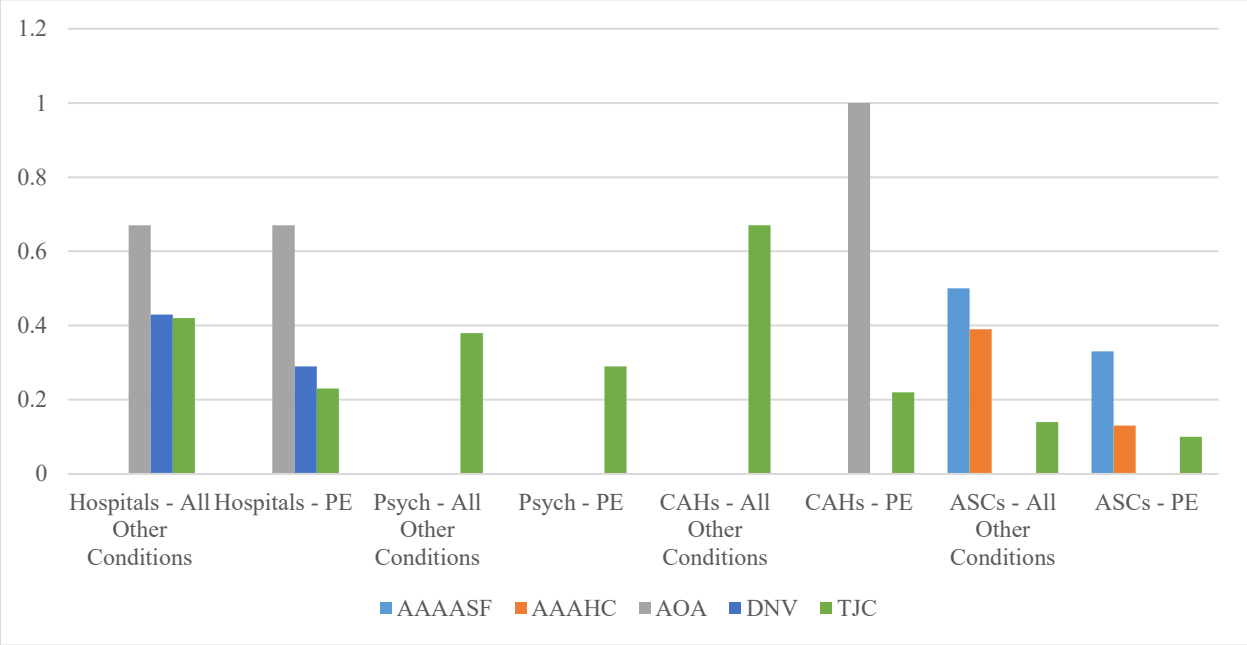
Graph 15
60-Day Validation Survey Disparity Rate Results
Comparison between All Other Conditions Cited and
PE for Facility Types with LSC Requirements
FY 2019



The PE condition consists of PE standards which vary slightly depending upon the program type. However, the life safety from fire standard, or LSC deficiencies, is included in the PE condition for each of the program types with the exception of HHAs and hospices as previously discussed. The majority of the PE disparity rates consist of these LSC deficiencies. CMS generates a report which identifies the top disparate LSC deficiencies as determined by the validation analysis. This report is provided annually to the AOs. These top LSC disparate deficiencies are consistent with deficiencies cited in FYs 2009 through 2019. This report is intended to provide the AOs with an understanding of the emphasis of CMS LSC surveys, which will allow the AOs to ensure their programs are appropriately surveying the same LSC provisions. An emphasis on the top disparate LSC deficiencies should assist the AOs in their efforts to reduce LSC disparities.

In past years, the AOs have had difficulty identifying deficiencies that SAs have cited related to the requirements in the 2012 edition of the LSC, which CMS adopted by regulation. However, in FY 2019, the AO's PE disparity rates have decreased in relation to other health conditions across all program types citing PE except for CAHs. CMS has been working with the AOs to provide guidance on the source of this problem, and possible ways to improve performance and reduce their PE disparity rate. CMS has continued to discuss with the AOs their concerns as well as their performance in the area of evaluating health care facility safety from fire. (See Graph 16.)

Graph 16
60-Day Validation Survey Results
Comparison between All Other Conditions Cited and
PE for Facility Types with LSC Requirements
by AO
FY 2019



Comparison of Deficiencies and Disparity Rates for Long-Term Care Hospitals and Acute Care Hospitals[11]

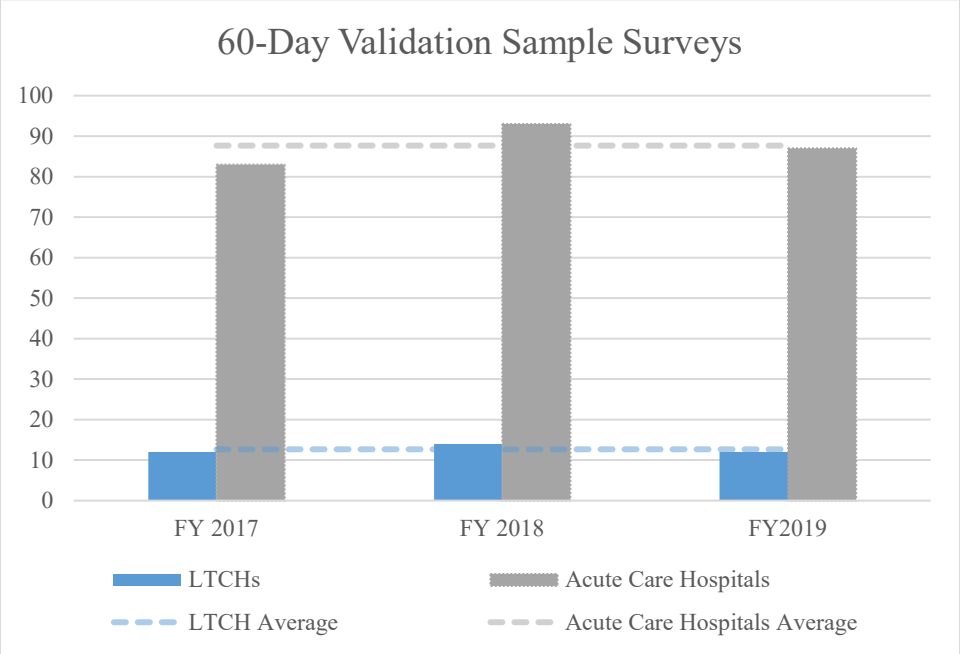
In 2010, CMS became concerned about the quality of care provided in LTCHs based on available SA survey findings. In the 2011 report to Congress, CMS reported on the analysis of mid-cycle validation surveys for 33 LTCHs. The Government Accountability Office (GAO) recommended in a September 2011 report that CMS strengthen oversight of LTCHs by, among other things, increasing the number of LTCH representative validation surveys and calculating a separate disparity rate for them.[12] (See Tables 29-31 and Graphs 17-20.) In FY 2019, CMS increased the LTCH sample size for 60-day representative sample surveys. In FY 2019, the total number of Medicare-participating LTCHs was 365 and the total number of Medicare-participating hospitals minus the LTCHs was 3,707.

[11] LTCHs differ from acute care hospitals in that they furnish extended medical and rehabilitative care to individuals with clinically complex problems, such as multiple acute or chronic conditions, who need hospital-level care for relatively extended periods. Acute care hospitals do not include psychiatric hospitals.
[12] "Long-Term Care Hospitals: CMS Oversight is Limited and Should be Strengthened," GAO, GAO-11-810, September 2011.

Table 29
Number of 60-Day Validation Surveys and Overall Disparity Rate
LTCHs and Acute Care Hospitals
FYs 2017–2019

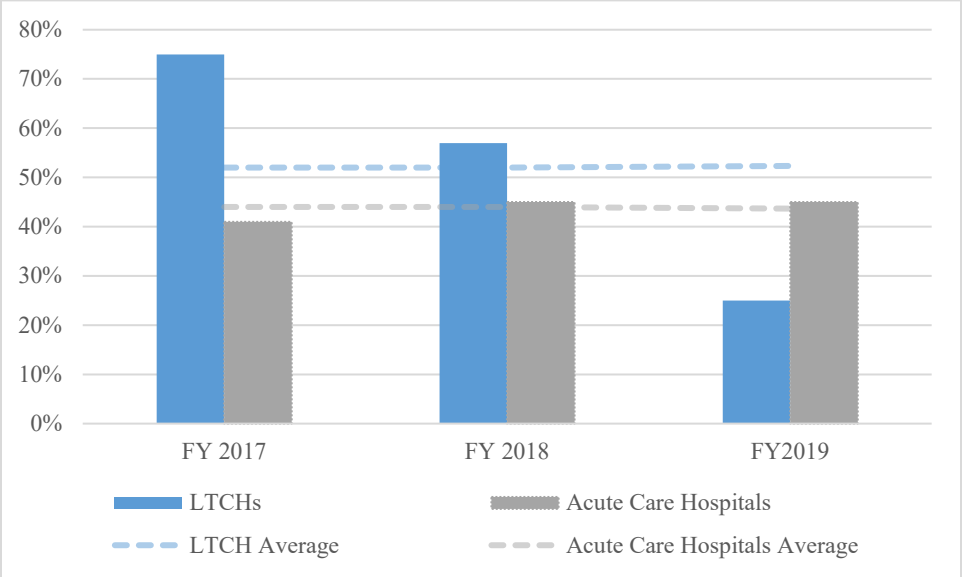
	LTCHs			Acute Care Hospitals			Average LTCHs	Average Acute Care Hospitals
	FY 2017	FY 2018	FY 2019	FY 2017	FY 2018	FY 2019	FYs 2017–2019	FYs 2017–2019
60-Day Validation Sample Surveys	12	14	12	83	93	87	12.67	87.67
Overall Disparity Rate	**75%**	**57%**	**25%**	**41%**	**45%**	**45%**	**52%**	**44%**

Graph 17
Number of 60-Day Validation Surveys and Averages
LTCHs and Acute Care Hospitals
FYs 2017–2019



Note: Total number of Medicare-participating LTCHs is 365 and the total number of Medicare-participating acute care hospitals minus the LTCHs is 3,707.

Graph 18
Overall Disparity Rates and Averages LTCHs and Acute Care Hospitals
FYs 2017–2019



Note: Total number of Medicare-participating LTCHs is 365 and the total number of Medicare-participating acute care hospitals minus the LTCHs is 3,707.

Table 30
Comparison of 60-Day Health and PE Validation Survey Results for LTCHs and Acute Care Hospitals
FYs 2017–2019

	LTCHs - All Other Conditions			LTCHs PE			Acute Care Hospitals - All Other Conditions			Acute Care Hospitals PE		
Validation Survey Analysis	FY 2017	FY 2018	FY 2019	FY 2017	FY 2018	FY 2019	FY 2017	FY 2018	FY 2019	FY 2017	FY 2018	FY 2019
SA Surveys with Condition-Level Deficiencies	8	6	1	3	2	3	20	25	30	26	20	28
AO Surveys with Missed Comparable Deficiencies	8	6	1	3	2	3	16	21	29	26	27	21
Disparity Rate	**67%**	**57%**	**8%**	**25%**	**14%**	**25%**	**19%**	**45%**	**33%**	**31%**	**28%**	**24%**

Graph 19
Comparison of 60-Day Health and PE Validation Survey Disparity Rate Results for LTCHs and Acute Care Hospitals
FYs 2017–2019

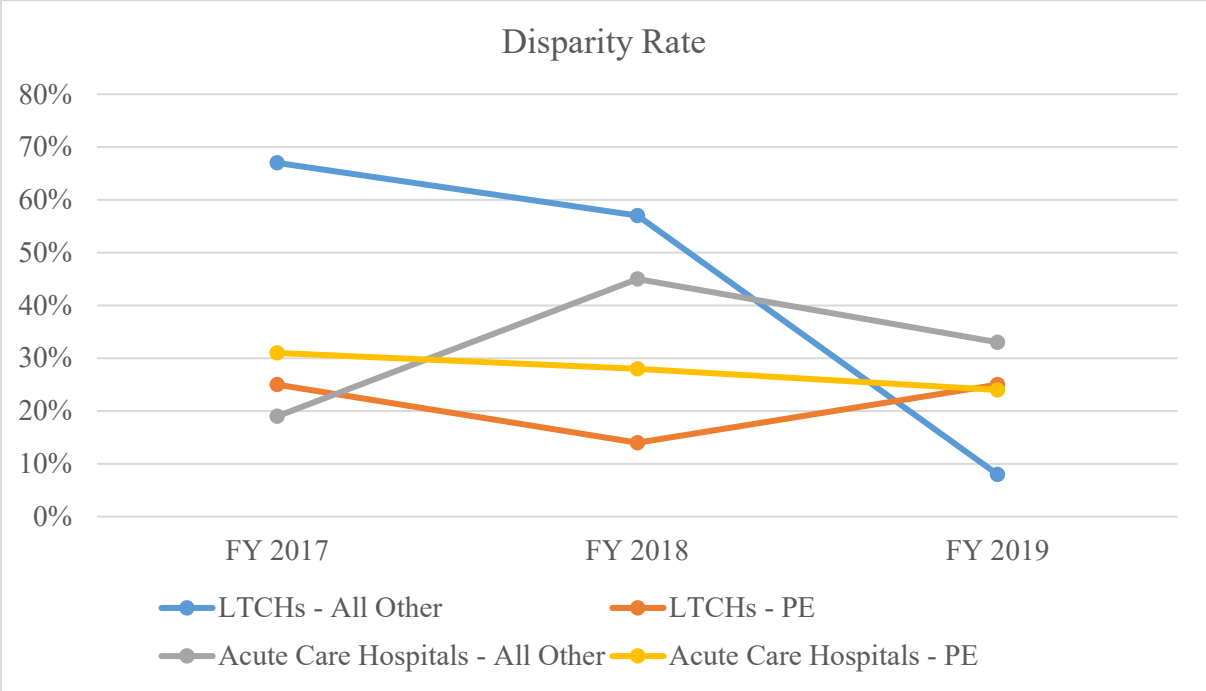


Table 31
Comparison of Averages
60-Day Health and PE Validation Survey Results for LTCHs and Acute Care Hospitals
FYs 2017–2019

	FYs 2017–2019 Average LTCHs All Other Conditions	FYs 2017-2019 Average LTCHs PE	FYs 2017–2019 Average Acute Care Hospitals All Other Conditions	FYs 2017–2019 Average Acute Care Hospitals PE
SA Surveys with Condition-Level Deficiencies	5.00	2.67	25.00	24.67
AO Surveys with Missed Comparable Deficiencies	5.00	2.67	22.00	24.67
Disparity Rate	**44%**	**21%**	**32%**	**28%**

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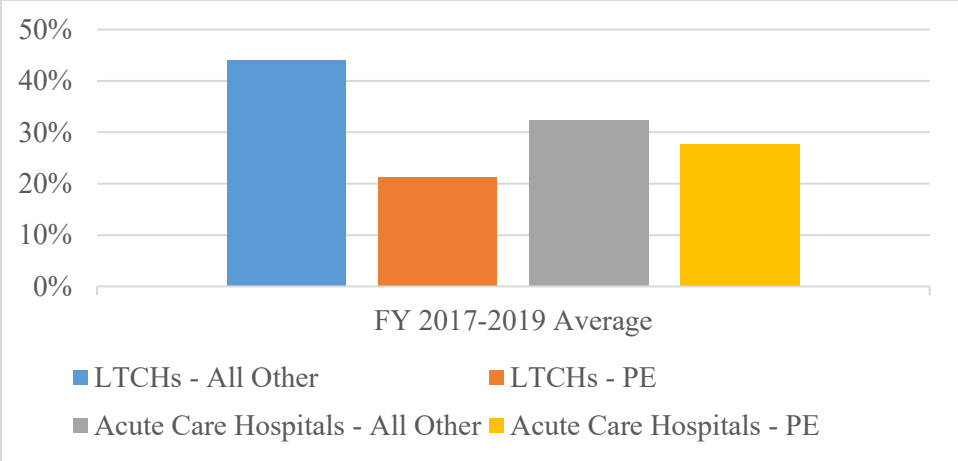
Graph 20
Comparison of Averages
60-Day Health and PE Validation Survey Disparity Rate Results for LTCHs and Acute Care Hospitals
FYs 2017-2019



From FYs 2017–2019, there is a 23 percent difference between the overall average disparity rates in LTCHs' PE and other condition-level deficiencies, and a 4 percent difference in acute care hospitals' PE and other condition-level deficiencies. When comparing the drivers of the average disparity rates, all other conditions is the primary driver for LTCHs and acute care hospitals. In FY 2019, PE is still the primary driver for acute care hospitals, comprising 24 percent of the disparity rate. For LTCHs, PE is the primary driver in FY 2019, comprising 25 percent of the disparity rate.

In FY 2019, the most frequent disparate condition-level deficiencies for acute care hospitals and LTCHs were PE, Infection Control, Governing Body, QAPI, and Patient Rights.

Addressing Disparity Rates

CMS has historically provided AOs with disparity rate analyses and opportunities for discussion on disparity rates across all CMS-approved accreditation programs. While CMS continues to utilize this strategy as an attempt to effect a positive change in disparity rates, CMS has determined that additional interventions are required. Due to the virtual stagnation of disparity rates over the past several years particularly related to PE and LSC, CMS has implemented a number of additional strategies to address this issue. In March 2017, CMS implemented monthly AO Liaison calls during which a number of topics are discussed, including disparity rate findings and possible solutions, as well as overall AO performance in other areas as described in Section 3. In March 2018, CMS initiated a validation redesign pilot (VRP) to overhaul the validation survey process. The VRP workgroup includes CMS central office staff and CMS SOG Location staff, as well as management and staff from State Agencies and the AOs. (See Section 6 for more details). In August 2019, CMS placed the VRP pilot on hold to assess the data and lessons learned to make enhancements as needed. The VRP pilot is tentatively scheduled to restart in FY 2022. CMS has also participated in AO surveyor training sessions, delivering analysis findings directly to the AO's survey cadre. In October 2018, CMS announced additional

oversight initiatives to increase oversight of the AOs.[13] To increase transparency for consumers, CMS will post new information on the CMS.Gov website, including: The latest quality-of-care deficiency findings following complaint surveys at facilities accredited by AOs; a list of providers determined by CMS to be out of compliance, with information included on the provider's AO; and overall performance data for AOs themselves.

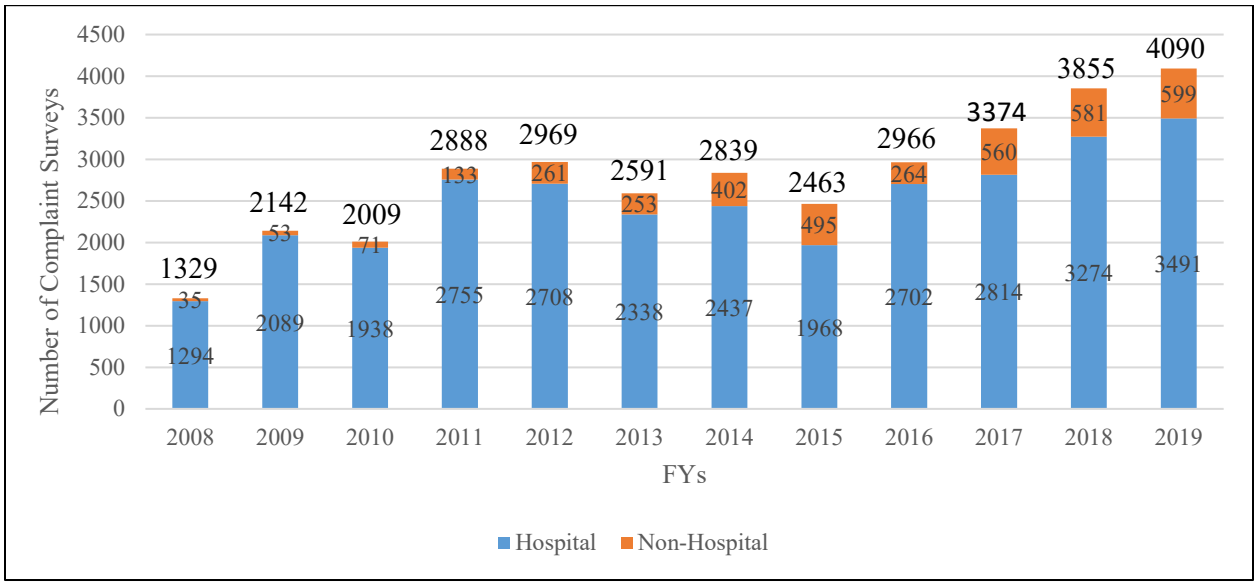
[13] https://www.cms.gov/newsroom/press-releases/cms-strengthen-oversight-medicares-accreditation-organizations

SECTION 5: Life Safety Code, Health & Safety Disparity Rates Analysis and Complaint Survey Citations

Background and Objectives

As discussed in Section 4 of this report, "complaint" surveys and representative sample validation surveys are the two validation survey types that comprise the Accreditation Validation Program. When a complaint is received based on allegations of noncompliance with the Medicare CoPs and CfCs, CMS performs a complaint survey to investigate the allegations. If the CMS SOG Location determines it to be appropriate, a full survey of all the CoPs and CfCs will be conducted. In FY 2019, CMS conducted a total of 4,090 complaint surveys. This total comprised 3,491 hospital surveys, and 599 non-hospital complaint surveys. The non-hospital complaint surveys were specific to CAHs, HHAs, hospices and ASCs. (See Graph 21.)

Graph 21
Number of Complaint Surveys for
Both Hospital and Non-Hospital Facilities
FYs 2008-2019



The recent history of complaint surveys is as follows:

- 2008: 1,294 hospital and 35 non-hospital surveys totaling 1,329 surveys
- 2009: 2,089 hospital and 53 non-hospital surveys totaling 2,142 surveys
- 2010: 1,938 hospital and 71 non-hospital surveys totaling 2,009 surveys
- 2011: 2,755 hospital and 133 non-hospital surveys totaling 2,888 surveys
- 2012: 2,708 hospital and 261 non-hospital surveys totaling 2,969 surveys
- 2013: 2,338 hospital and 253 non-hospital surveys totaling 2,591 surveys
- 2014: 2,437 hospital and 402 non-hospital surveys totaling 2,839 surveys
- 2015: 1,968 hospital and 495 non-hospital surveys totaling 2,463 surveys
- 2016: 2,702 hospital and 264 non-hospital surveys totaling 2,966 surveys
- 2017: 2,814 hospital and 560 non-hospital surveys totaling 3,374 surveys

- 2018: 3,274 hospital and 581 non-hospital surveys totaling 3,855 surveys
- 2019: 3,491 hospital and 599 non-hospital surveys totaling 4,090 surveys

The results of the complaint surveys are stored in the ASPEN Complaints Tracking System (ACTS). CMS has been reviewing and analyzing the data stored in ACTS to provide an additional data source to validate the overall performance of the AOs. Graphs 23, 25, 27, 29, 30, and 31 highlight the top five condition-level deficiencies that were cited during complaint surveys on AO accredited facilities from FYs 2017-2019.

As described in Section 4, a validation survey is a survey completed at a deemed facility by an SA within 60 days of the end date of an AO survey at the same facility. The results of the AO and SA surveys are compared, and a disparity rate is calculated. The disparity rate is the number of AO surveys where the AO did not cite deficiencies that were comparable to serious (condition-level) deficiencies identified during the SA surveys. This number is then divided by the total number of 60-day validation surveys conducted by the SA.

Since FY 2000, disparity rates have consistently been above an acceptable level for most of the program types. The PE condition, specifically LSC requirements, has consistently been the largest driver of the disparity rate for those program types with LSC requirements. This points to limitations in the AO's ability to identify non-compliance with the Medicare CoPs and CfCs LSC requirements.

The objective of this health and safety and LSC analysis is to identify the top categories that are most significantly influencing the disparity rate, identify potential root causes, and present recommendations for minimizing the overall disparity rate.

Methodology

CMS compares the SA validation survey condition-level deficiency citations to the AO survey findings. Separate validation summary reports are then generated for the health and safety conditions, and the PE conditions cited by the SAs. The health and safety summary report identifies each SA-cited condition and identifies the comparable and non-comparable AO deficiency citations. If the AO has findings comparable to each of the identified SA findings, then the survey is determined to be a comparable survey. However, if the AO does not identify a comparable deficiency for each of the SA-cited conditions, the survey is considered disparate.

The PE summary report is similar to the health and safety summary report, but the PE summary report identifies and compares LSC categories and PE CoP requirements. If the AO has comparable findings to the identified PE deficiencies and LSC Categories, then the survey is considered to be a comparable survey. If the AO does not identify the SA-identified PE condition and LSC Category deficiencies, then the survey is considered to be a disparate survey.

The data from the summary reports is collected and stored in a database for analysis. The database contains a record for each facility that identifies the AO, each separate condition and LSC category identified by the SA, and if the AO cited a comparable deficiency. Reports are generated from the analysis of this data to develop individual summaries for each program type and for each AO and the program types in which they survey. These summaries include the

following: (1) the number of validation surveys in the sample; (2) the number of conditions cited by the SAs in the validation surveys; (3) the number of surveys that were not comparable; (4) the overall disparity rate; (5) each condition that was cited by the SA; (6) the number of facilities with the condition cited; (7) the number of matching surveys for each condition; (8) the number of disparate surveys for each condition; and (9) the individual condition disparity rate.

As mentioned in Section 4 of this report, the overall disparity rate is determined by dividing the number of disparate surveys by the total number of validation surveys in the sample. Each individual condition disparity rate is determined by dividing the number of disparate surveys with that individual condition, by the total number of validation surveys in the sample. The LSC Category Disparity rate is determined by dividing the number of LSC Categories that were missed by the AO, by the total number of LSC Categories that were cited by the SA.

Limitations

There are some factors outside the control of CMS that may influence the data and disparity rates resulting from the report calculations. The AO disparity rates are based on the number of validation surveys that have been performed for each AO and program type. The disparity rate is only one way to measure AO performance. In some instances, the validation sample size is too small to provide statistically valid data. For example, if only one validation survey was performed for a particular AO and program type and that validation survey was found to be disparate, the disparity rate would be 100 percent. In order to provide a statistically valid sample size, additional validation surveys are required for each AO and program type. There are a number of factors that play into the number of representative validation surveys that can be performed. While scheduling validation surveys, CMS must consider the number of deemed facilities by state, program type and AO, the number and type of facilities on the AO schedule, the overall targeted sample size by state and program type and AO, the need to spread the survey workload over a year and ensuring that any one state is not overloaded for any given month. Newly approved AOs also pose a challenge when it comes to increasing the sample size. Additionally, CMS resource and budget constraints, as well as state resources, both budget and human resources, may prohibit the ability to perform a greater number of validation surveys for a statistically valid sample.

The SA performs their validation survey within 60 days of the AO survey which may have an effect on the disparate findings. During the 60-day gap between the AO and SA survey, some factors beyond CMS' control may have changed, making it difficult to provide an accurate comparison for the facility surveys.

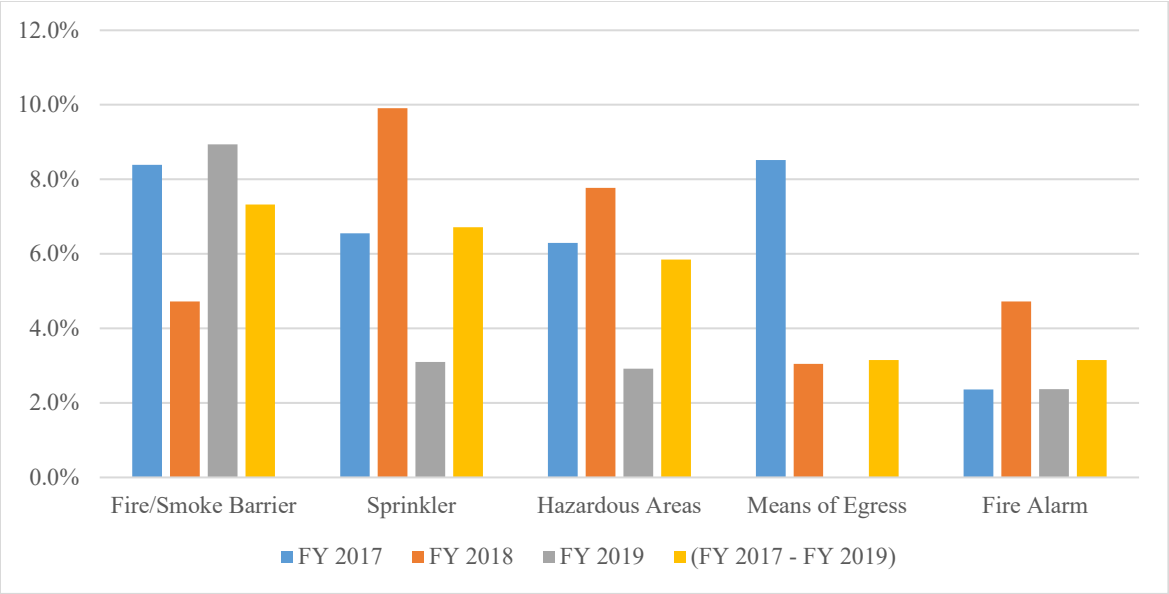
Findings

The PE and Infection Control conditions are the top disparate citations for hospitals, psychiatric hospitals, ASCs, and CAHs. In FYs 2017-2019, the PE condition was the top disparate citation for all four of the program types and the Governing Body and Infection Control conditions were two of the top three disparate citations for hospitals, psychiatric hospitals, and ASCs. The PE condition contains multiple standards; however, a large majority of the PE citations were comprised of the LSC standard within the condition. Within the LSC standard categories, Fire/Smoke Barrier, Hazardous Areas, Sprinklers, and Means of Egress were the top deficiency

citations not cited by AOs, with the Fire/Smoke Barrier category noted in the top five missed citations in FYs 2017-2019 for hospitals, psychiatric hospitals and CAHs and ASCs. The LSC category descriptions can be found in Appendix C. The graphs below present, by program type, the top LSC disparity rates and the top condition-level deficiencies found during complaint surveys. (See Graphs 22-31.)

Hospital and Long-Term Care Hospital

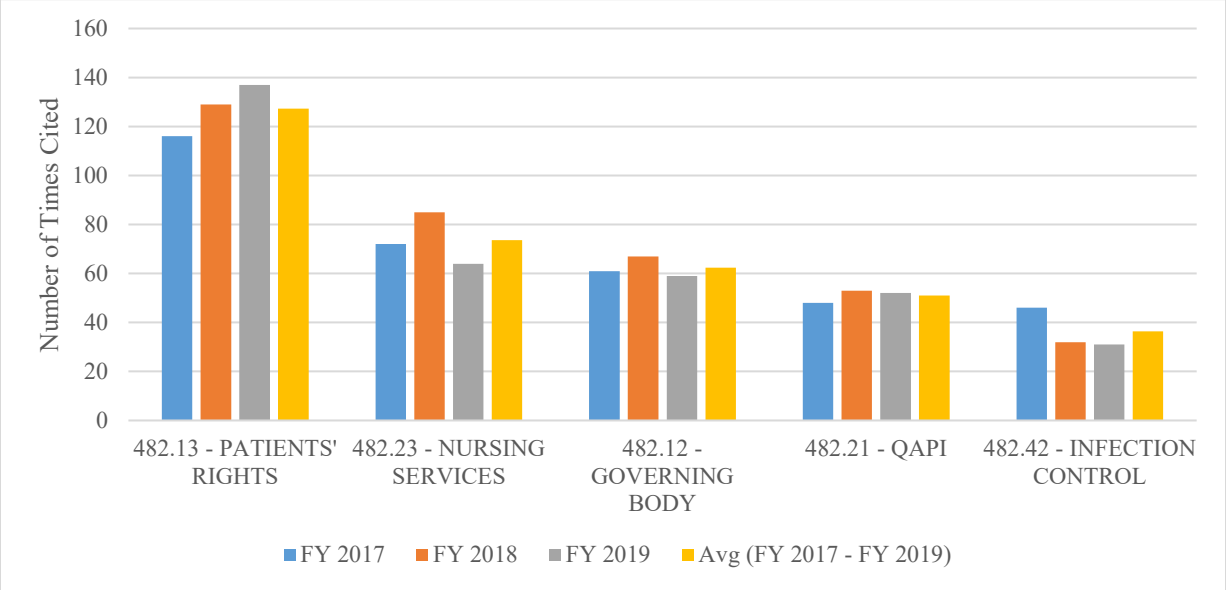
Graph 22
Top Five Hospital and LTCH
LSC Category Disparity Rates
FYs 2017–2019



In FYs 2017-2019, 301 hospital and LTCH validation surveys were performed and 1,967 LSC categories were cited by the SAs. The top two most frequently cited LSC categories during that time were Fire/Smoke Barrier and Sprinkler. The SA cited the Fire/Smoke Barrier category 301 times. The AOs missed 28 comparable citations resulting in a disparity rate of 7 percent. The SA cited the Sprinkler category 132 times. The AOs missed each comparable citation resulting in a 7 percent disparity rate. In FY 2019, the most frequently cited LSC category was Fire/Smoke Barrier, cited 109 times by the SA and missed 49 times by the AOs resulting in a disparity rate of 9 percent. The FY 2019 Fire/Smoke Barrier disparity rate is 1 percentage point higher than the FY 2017 Fire/Smoke Barrier disparity rate.

The top five disparate LSC categories found during LSC surveys for hospitals and LTCHs account for 69 percent of all the LSC category disparities cited in FYs 2017-2019.

Graph 23
Top 5 Hospital and LTCH Condition-Level Deficiencies Cited During Complaint Surveys
FYs 2017-2019

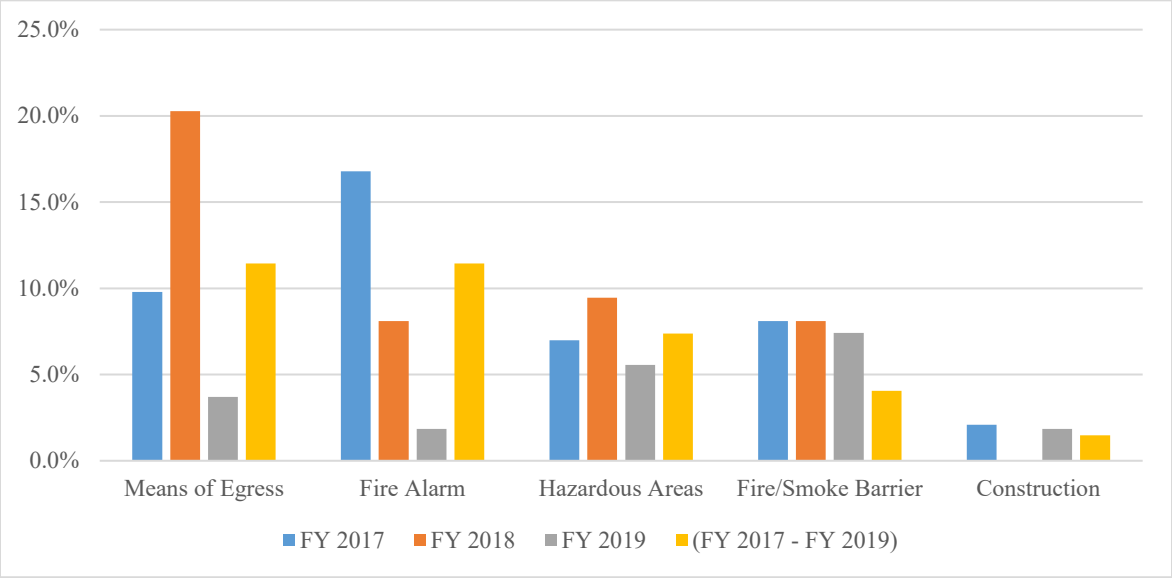


In FYs 2017-2019, there were 1,455 condition-level deficiencies cited for AO accredited hospital and LTCH facilities during complaint surveys. During that time, the most frequently cited condition was Patients' Rights, cited 382 times. The next most frequently cited conditions were Nursing Services, cited 221 times; and Governing Body, cited 187 times. In FY 2019, the most frequently cited condition was Patients' Rights, cited 137 times. In FY 2017 and FY 2018, the Patients' Rights requirement was cited at the condition level 116 times and 129 times respectively.

The top five condition-level deficiencies found during complaint surveys for hospitals and LTCHs account for 72 percent of all the conditions cited in FYs 2017-2019.

Psychiatric Hospital

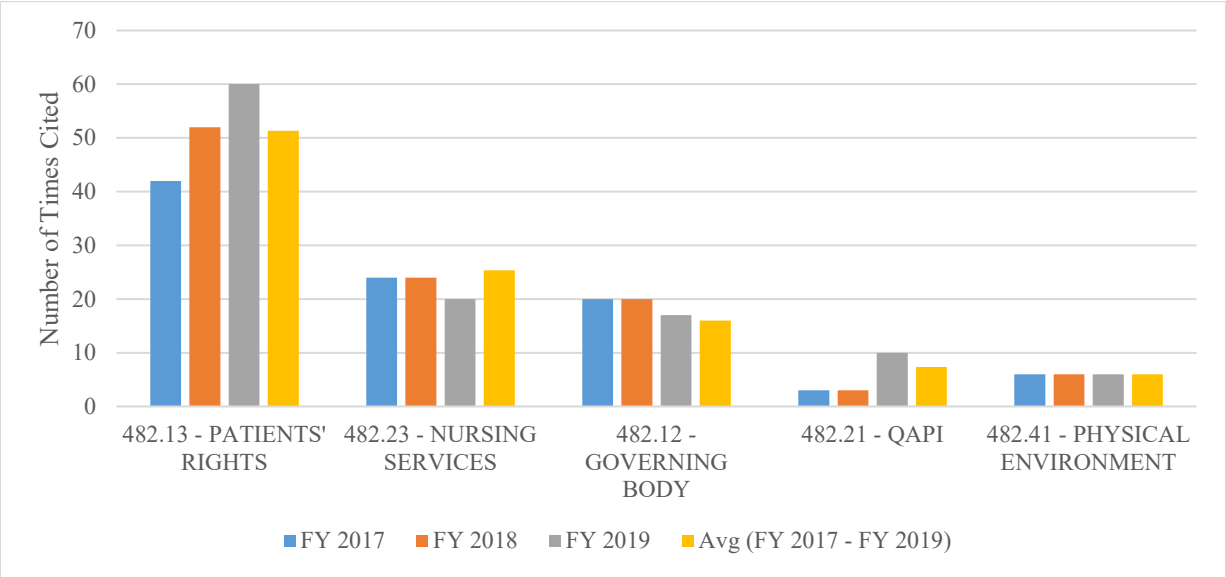
Graph 24
Top Five Psychiatric Hospital
LSC Category Disparity Rates
FYs 2017–2019



In FYs 2017-2019, 62 psychiatric validation surveys were performed and 271 LSC category citations were cited by the SAs. The top two most frequently cited LSC categories during that time were Means of Egress, cited 43 times by the SAs, and Fire Alarm, cited 41 times by the SAs. In both instances, TJC missed 31 comparable citations resulting in an 11 percent disparity rate. In FY 2019, the most frequently cited LSC category was Fire/Smoke Barrier, cited 15 times by the SA. TJC missed four comparable citations resulting in a disparity rate of seven percent. The FY 2019 Fire/Smoke Barrier disparity rate is 6 percentage points higher than the FY 2017 Fire/Smoke Barrier disparity rate.

The top five disparate LSC categories found during LSC surveys for psychiatric hospitals accounts for 94 percent of all the LSC category disparities cited in FYs 2017-2019.

Graph 25
Top 5 Psychiatric Hospital Condition-Level Deficiencies Cited During Complaint Surveys
FYs 2017–2019

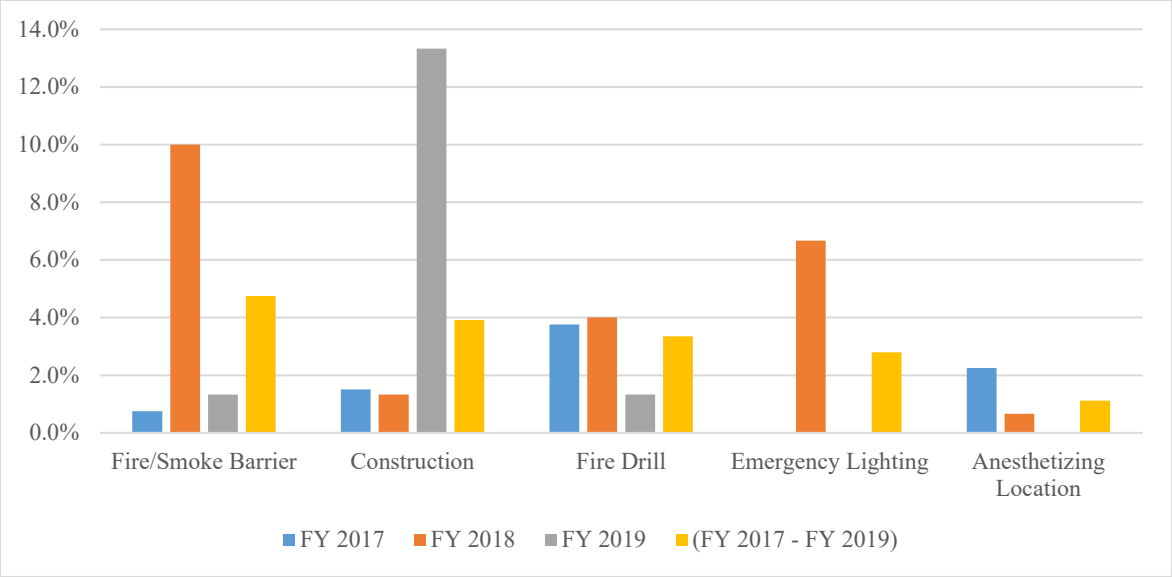


In FYs 2017-2019, there were 379 condition-level deficiencies cited for AO accredited psychiatric hospital facilities during complaint surveys. During that time, the most frequently cited condition was Patients' Rights, cited 154 times. The next most frequently cited conditions were Nursing Services, cited 76 times; and Governing Body, cited 48 times. In FY 2019, the most frequently cited condition was Patients' Rights, cited 60 times. In FY 2017 and FY 2018, the Patients' Rights requirement was cited at the condition level 42 times and 52 times respectively.

The top five condition-level deficiencies found during complaint surveys for psychiatric hospitals accounts for 84 percent of all the conditions cited in FYs 2017-2019.

Ambulatory Surgery Center

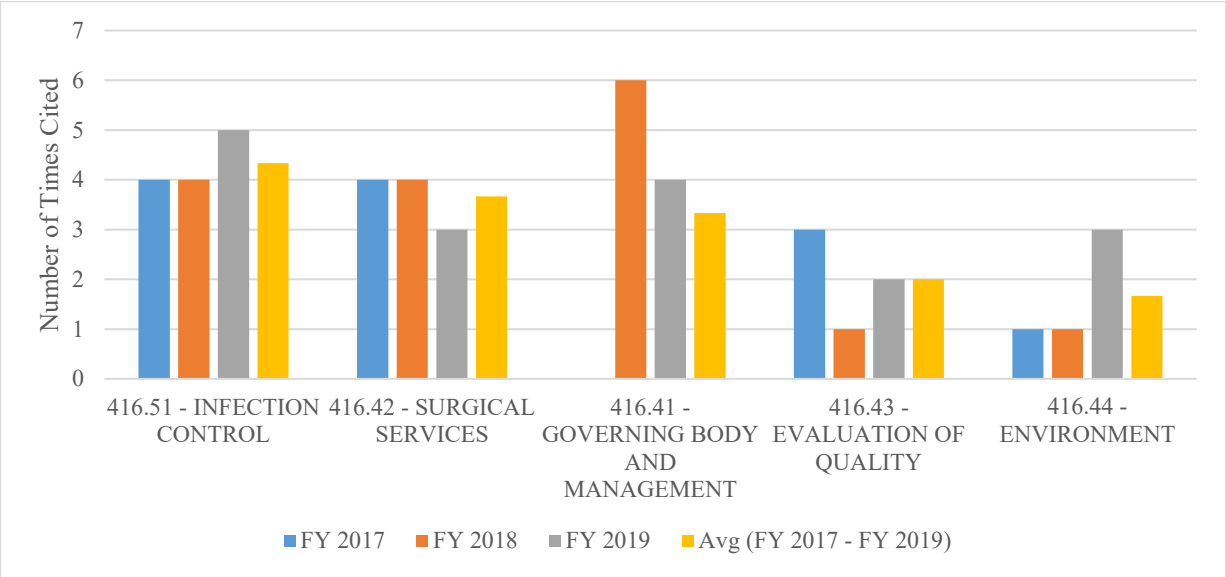
Graph 26
Top Five ASC
LSC Category Disparity Rates
FYs 2017–2019



In FYs 2017-2019, 197 ASC validation surveys were performed and 358 LSC categories were cited by the SAs. The top two most frequently cited LSC categories during that time were Fire/Smoke Barrier and Construction. The SA cited the Fire/Smoke Barrier category 66 times. The AOs missed 17 comparable citations resulting in a disparity rate of 5 percent. The SA cited the Construction category 16 times. The AOs missed 14 comparable citations resulting in a disparity rate of 4 percent. In FY 2019, the most frequently cited LSC category was Construction, cited 11 times by the SA and missed 10 times by the AOs resulting in a disparity rate of 13 percent. The FY 2019 Fire/Smoke Barrier disparity rate is 11 percentage points higher than the FY 2017 Construction disparity rate.

The top five disparate LSC categories found during LSC surveys for ASCs accounts for 92 percent of all the LSC category disparities cited in FYs 2017-2019.

Graph 27
Top 5 ASC Condition-Level Deficiencies Cited
During Complaint Surveys
FYs 2017-2019

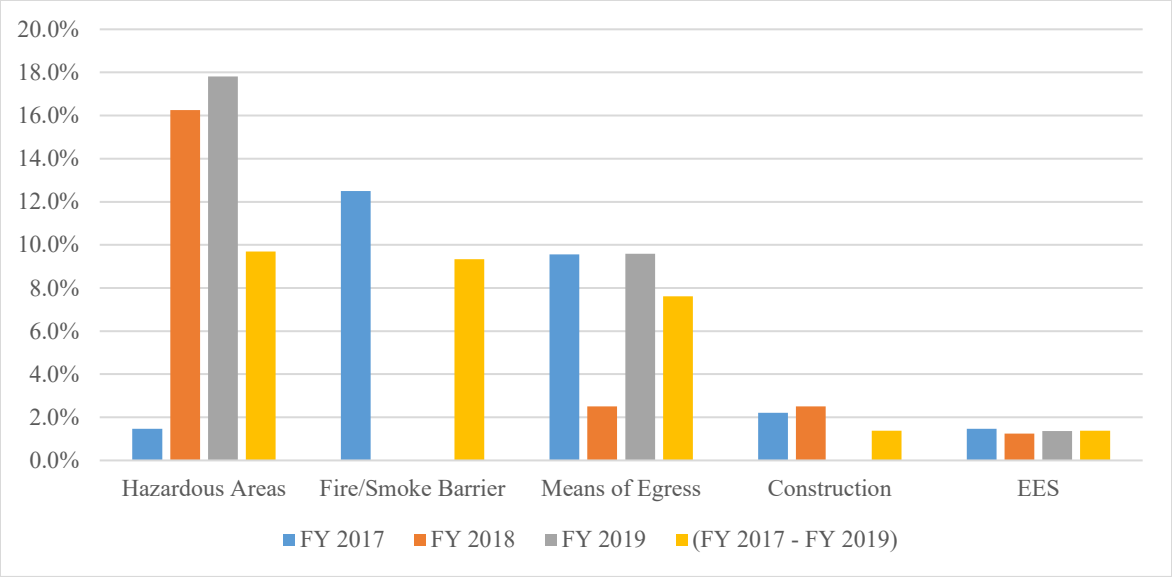


In FYs 2017-2019, there were 45 condition-level deficiencies cited for AO accredited ASCs during complaint surveys. During that time, the most frequently cited condition was Infection Control, cited 13 times. The next most frequently cited condition was Surgical Services, cited 11 times. In FY 2019, the most frequently cited condition-level deficiency was Infection Control, cited five times. In FY 2017 and FY 2018, the Infection Control requirement was cited at the condition level four times.

The top five condition-level deficiencies found during complaint surveys for ASCs accounts for 68 percent of all the conditions cited in FYs 2017-2019.

Critical Access Hospital

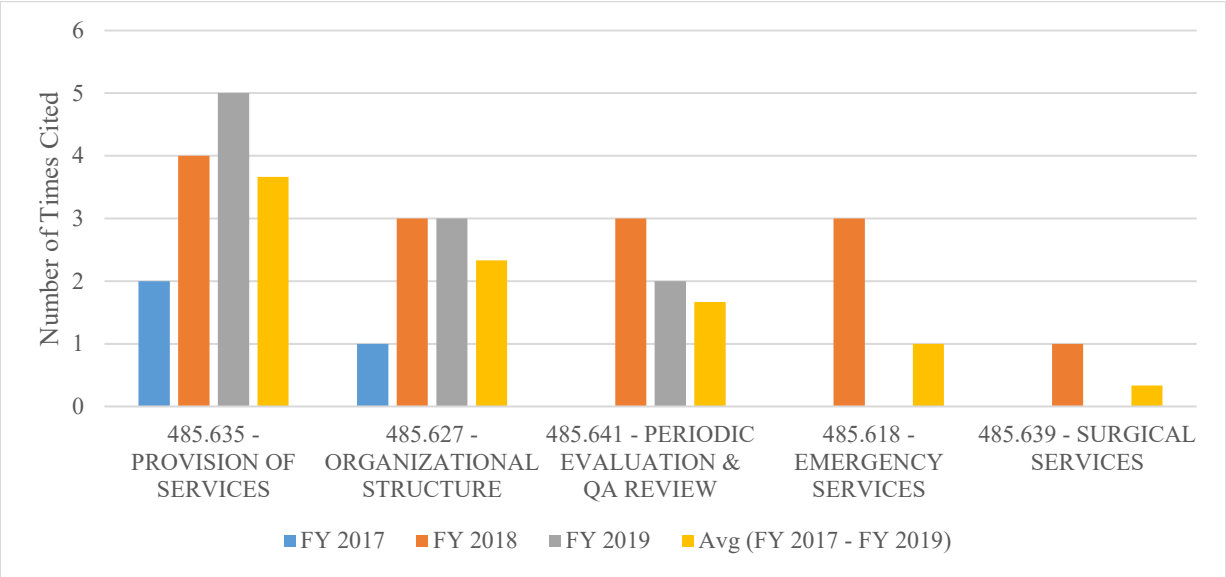
Graph 28
Top Five CAH
LSC Category Disparity Rates
FYs 2017–2019



In FYs 2017-2019, 62 CAH validation surveys were performed and 289 LSC categories were cited by the SAs. The top two most frequently cited LSC categories were Hazardous Areas and Fire/Smoke Barrier. The SA cited the Hazardous Areas category 36 times. The AOs missed 28 comparable citations resulting in a disparity rate of 10 percent. The SA cited the Fire/Smoke Barrier category 56 times. The AOs missed 27 comparable citations resulting in a disparity rate of 9 percent. In FY 2019, the most frequently cited LSC category was Hazardous Areas, cited 13 times by the SAs and missed 13 times by the AOs resulting in an 18 percent disparity rate. The FY 2019 Hazardous Areas category disparity rate is 16 percentage points higher than the FY 2017 Hazardous Areas category disparity rate.

The top five disparate LSC categories found during LSC surveys for CAHs accounts for 89 percent of all the LSC category disparities cited in FYs 2017-2019.

Graph 29
Top 5 CAH Condition-Level Deficiencies Cited
During Complaint Surveys
FYs 2017–2019

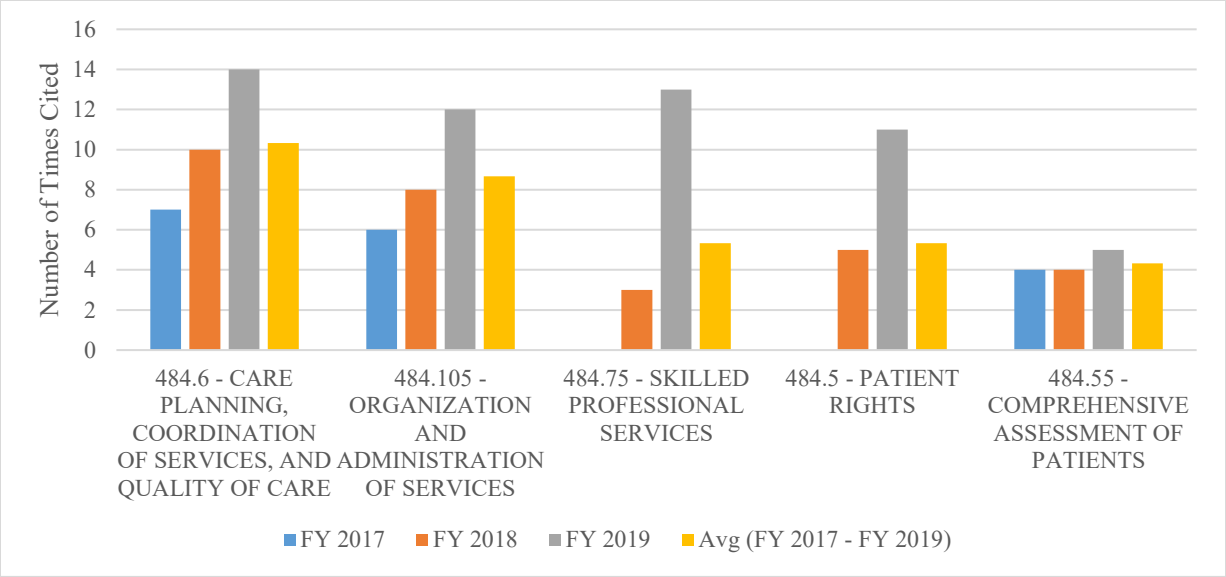


In FYs 2017-2019, there were 29 condition-level deficiencies cited for AO accredited CAHs during complaint surveys. During that time, the most frequently cited condition was Provision of Services, cited 11 times. The next most frequently cited conditions were Organizational Structure, cited seven times; and Periodic Evaluation and QA Review, cited five times. Although the graph depicts the total number of top five condition-level deficiencies cited in FYs 2017-2019, only the top two of the five conditions had citations for all three years.

The top five condition-level deficiencies found during complaint surveys for CAHs accounts for 93 percent of all the conditions cited in FYs 2017-2019.

Home Health Agency

Graph 30
Top 5 HHA Condition-Level Deficiencies Cited
During Complaint Surveys
FYs 2017–2019

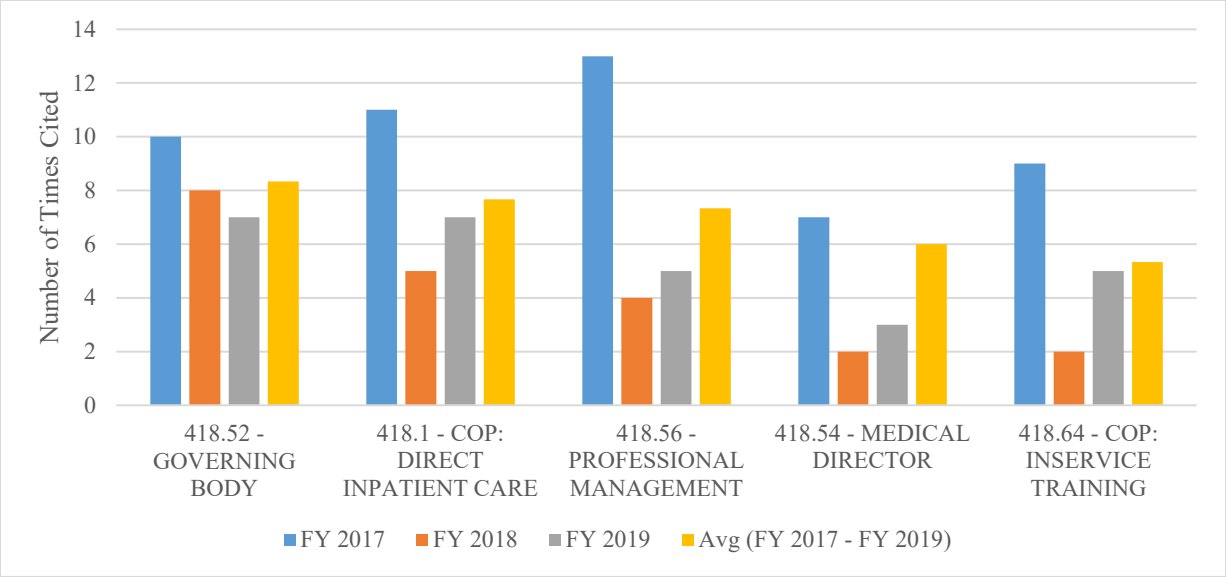


In FYs 2017-2019, there were 144 condition-level deficiencies cited for AO accredited HHAs during complaint surveys. During that time, the most frequently cited condition was Care Planning, Coordination of Services, and Quality of Care, cited 31 times. The next most frequently cited condition was Organization and Administration of Services, cited 26 times. The number of Care Planning, Coordination of Services, and Quality of Care requirement citations has increased each year since FY 2017.

The top five condition-level deficiencies found during complaint surveys for HHAs accounts for 71 percent of all the conditions cited in FYs 2017-2019.

Hospice

Graph 31
Top 5 Hospice Condition-Level Deficiencies Cited
During Complaint Surveys
FYs 2017–2019



In FYs 2017-2019, there were 168 condition-level deficiencies cited for AO accredited hospice facilities during complaint surveys. During that time, the most frequently cited condition was Governing Body, cited 25 times. The next most frequently cited conditions were COP: Direct Inpatient Care, cited 23 times; and Professional Management, cited 22 times. In FY 2019, the most frequently cited condition was COP: Direct Inpatient Care, cited seven times.

The top five condition-level deficiencies found during complaint surveys for hospice facilities accounts for 62 percent of all the conditions cited in FYs 2017-2019.

Conclusion

CMS has identified the top conditions and LSC categories driving the disparity rate. The PE/Environment requirement is one of the leading disparate conditions, accounting for 21 to 31 percent of all disparate surveys from FY 2017 to FY 2019 throughout all the program types except for HHAs and hospices. The largest portion of the PE/Environment condition-level findings are LSC related. The SA and AO LSC survey validation findings are divided into various categories for analysis and comparison, yielding the top five disparate LSC categories. In FYs 2017-2019, Fire/Smoke Barrier remains the top disparate LSC category which accounts for nearly 22% of all the missed LSC category citations for the three years. Hazardous Areas is the second highest top disparate LSC category in FYs 2017-2019 and accounts for nearly 18 percent of the missed LSC category citations during that time. Fire/Smoke Barrier, Hazardous Areas, Sprinkler, Means of Egress, and Fire Alarm are the top five missed LSC citations for the PE/Environment conditions. These top five disparities account for 72 percent of all the missed LSC category citations. In FYs 2017-2019, among the AOs with a CMS-approved hospital

accreditation program and LTCHs, AAHHS/HFAP has the highest average health and safety disparity rate, 32 percent, and AAHHS/HFAP also has the highest average PE disparity rate, 70 percent. In FYs 2017-2019, among the AOs with a CMS-approved ASC accreditation program, AAASF has the highest average health and safety disparity rate, 47 percent, and the highest average PE disparity rate, 32 percent. In FYs 2017-2019, among the AOs with a CMS-approved CAH accreditation program, TJC is the only AO with a valid sample size. TJC's average health and safety and PE disparity rates for FYs 2017-2019 are 16 percent and 39 percent respectively.

Recommendations

Accrediting Organizations Need to Focus Their Interventions on Their Top Disparate Conditions.

Each AO needs to develop interventions focusing on their high-volume disparate conditions. If the AOs were to focus on their top disparate conditions, they would have an opportunity to positively impact their disparity rate. For example, for FY 2019, if the AOs would address the top five disparate conditions for hospitals, they could potentially eliminate 78 percent of the disparate citations.

CMS will monitor the disparate findings on a quarterly basis concurrent with the FY in which the validation surveys are conducted. Trending of the conditions involved as well as identification of the problem facilities will be discussed on the individual monthly AO liaison calls. Action plans to address identified trends and disparity rates will be required of each AO.

Detailed information for each program type and AO for this section can be found in Appendix B of this report.

SECTION 6: Centers for Medicare & Medicaid Services Improvements

The volume of facilities that participate in the Medicare programs through accreditation from a CMS-approved accreditation program continued to grow in FY 2019. Currently, 32 percent (13,608 facilities) of all Medicare-participating facilities that have an approved accreditation program option demonstrate compliance with the Medicare requirements and participate in the Medicare program via their deemed status. There are currently 11 CMS-recognized AOs and 24 approved accreditation programs.

CMS has worked to enhance systems and processes to ensure a robust and consistent approach to its monitoring and oversight of CMS-recognized AO performance and activities of their approved accreditation programs. In FY 2019, CMS focused on the following key areas in order to continue to refine and maintain an effective oversight infrastructure:

- CMS/AO Communication and Relationship Building
- AO Education
- Standards Update in Response to Changes in CMS Requirements
- Deemed Facility Data (See Section 2 for more information)
- AO Performance Measures (See Section 3 for more information)

Validation Redesign Project (VRP) Centers for Medicare & Medicaid Services/Accrediting Organization Communication and Relationship Building

Communication

CMS embarked upon the implementation of a new model in FY 2017 for supporting the vital work that the national AOs provide. This model, which was began in March 2017, included a dedicated CMS central office AO liaison team that interacts with the Medicare AOs on a monthly basis addressing key issues as they arise. CMS believes this new model will support and strengthen the relationship between CMS and the AOs. CMS will continue its periodic meetings with the AOs, including quarterly teleconferences. These meetings serve to foster communication between the AOs and CMS and serve as a forum to: discuss any issues as they arise, communicate and discuss regulatory changes, assure ongoing deemed facility compliance with Medicare conditions, and provide information and education for AO staff. CMS CO, RO staff, and individual AOs communicate on a weekly, if not daily, basis either by email or telephone to address a wide variety of issues, including, but not limited to: specific deemed facility deficiencies, certification issues, program operations, surveys, requirements, interpretation of regulations, and data.

Consultation

CMS increased opportunities for AOs as well as other stakeholders to provide input into the development of sub-regulatory guidance concerning Medicare standards and survey processes. AOs and other key stakeholders are provided the opportunity to review and provide comment on guidance prior to release. CMS has committed to ongoing consultation with the AOs and the stakeholders in an effort to improve the resulting guidance.

Accrediting Organization Education

CMS affords AO staff many opportunities for education. CMS provides detailed written and verbal feedback to the AOs as part of the deeming application and data review processes. This feedback includes specific references to Medicare regulatory requirements as well as the SOM references and attachments. Formal education is provided periodically at the request of individual AOs. AOs are also provided the opportunity to participate in face-to-face as well as online SA surveyor training which can be accessed at https://qsep.cms.gov/welcome.aspx. In FY 2019, CMS provided updates to the AO resource manual. This manual contains a wide variety of information on CMS requirements and expectations of AO performance.

Standards Update in Response to Changes in Centers for Medicare & Medicaid Services Requirements

Burden Reduction & Discharge Planning

On September 30, 2019, CMS published two Final Rules in the *Federal Register* which revised the CoPs and CfCs*:*

1) Medicare and Medicaid Programs; Regulatory Provisions to Promote Program Efficiency, Transparency, and Burden Reduction; Fire Safety Requirements for Certain Dialysis Facilities; Hospital and Critical Access Hospital (CAH) Changes to Promote Innovation, Flexibility, and Improvement in Patient Care(CMS 3346-F, CMS-3334-F and CMS-3295-F). This final rule revised requirements for Ambulatory Surgical Centers (ASCs) at 42 C.F.R. Part 416; Hospices at 42 C.F.R. Part 418; Hospitals at 42 C.F.R. Part 482; Home Health Agencies (HHA) at 42 C.F.R. Part 484; Critical Access Hospitals at 42 C.F.R. Part 485; Rural Health Clinics (RHCs) at 42 C.F.R. Part 491; and End Stage Renal Disease (ESRD) Facilities at 42 C.F.R. Part 494, as well as changes to all providers and suppliers for Emergency Preparedness. This final rule can be accessed at https://www.federalregister.gov/documents/2019/09/30/2019-20736/medicare-and-medicaid-programs-regulatory-provisions-to-promote-program-efficiency-transparency-and-burden-reduction.

2) Medicare and Medicaid Programs; Revisions to Requirements for Discharge Planning for Hospitals, Critical Access Hospitals, and Home Health Agencies, and Hospital and Critical Access Hospital Changes to Promote Innovation, Flexibility, and Improvement in Patient Care (CMS 3317-F and CMS-3295-F). This final rule revised requirements for Hospitals at 42 C.F.R. Part 482; HHAs at 42 C.F.R. Part 484 and CAHs at 42 C.F.R. Part 485. This final rule can be accessed at https://www.federalregister.gov/documents/2019/09/30/2019-20732/medicare-and-medicaid-programs-revisions-to-requirements-for-discharge-planning-for-hospitals.

While these Final Rules were published within FY 2019, CMS did not begin review of AO standards in response to these changes until FY 2020, therefore the number of reviews is not reflected in Table 1 (CMS Review of AO Medicare Accreditation Programs). CMS will provide further detail on standards reviews in the next annual RTC.

Swing Beds requirements for Hospitals and CAHs

The final rule entitled, "Medicare and Medicaid Programs; Reform of Requirements for Long Term Care Facilities," was published in the *Federal Register* on October 4, 2016, revising the requirements that Long-Term Care facilities must meet to participate in the Medicare and Medicaid programs, including provisions of the special requirements for hospitals and CAHs with swing beds. The effective date of the final rule was November 28, 2016. The final rule can be accessed at https://www.gpo.gov/fdsys/pkg/FR-2016-10-04/pdf/2016-23503.pdf. On July 13, 2017, CMS published revisions to that final rule correcting technical and typographical errors identified in the October 4, 2016 final rule. The published revisions can be accessed at https://www.gpo.gov/fdsys/pkg/FR-2017-07-13/pdf/2017-14646.pdf.

Home Health Agency Regulations

CMS published a final rule on July 10, 2017 delaying the effective date for the final rule entitled "Medicare and Medicaid Programs: Conditions of Participation for Home Health Agencies" published in the Federal Register on January 13, 2017 (82 FR 4504). The published effective date for the final rule was July 13, 2017, and this rule delays the effective date for an additional 6 months until January 13, 2018. This final rule also includes two conforming changes to dates that are included in the regulations text. The CoPs include several major changes for home health care agencies, including Quality Assurance Performance Improvement (QAPI). Performance improvement projects will be phased in slower than other QAPI requirements, with a phase-in date of July 13, 2018. The published delay can be accessed at https://www.gpo.gov/fdsys/pkg/FR-2017-07-10/pdf/2017-14347.pdf.

Life Safety Code Regulations

The final rule entitled, "Medicare and Medicaid Programs; Fire Safety Requirements for Certain Health Care Facilities," was published in the *Federal Register* on May 4, 2016, which provides updates to health care facilities' fire protection guidelines to improve protections from fire for all Medicare beneficiaries in facilities. The effective date of the final rule was July 5, 2016. The final rule can be accessed at https://www.gpo.gov/fdsys/pkg/FR-2016-05-04/pdf/2016-10043.pdf. The final rule amended the fire safety standards for Medicare and Medicaid participating hospitals, CAHs, long-term care facilities, intermediate care facilities for individuals with intellectual disabilities (ICF-IID), ASCs, hospices which provide inpatient services, religious non-medical health care institutions (RNHCIs), and programs of all-inclusive care for the elderly (PACE) facilities. Further, this final rule adopted the 2012 edition of the LSC and eliminated references in regulations to all earlier editions of the LSC. It also adopted the 2012 edition of the Health Care Facilities Code (HCFC), with some exceptions.

CMS began surveying facilities for compliance with the 2012 edition of the LSC and HCFC on November 1, 2016. In addition, this allowed CMS the opportunity to train existing surveyors, revise fire safety survey forms, and update the ASPEN program.

CMS reviewed and approved 11 AO programs that have requirements containing LSC Standards to ensure consistency with CMS regulatory adoption of the 2012 edition of the LSC.

CMS developed a 2000 to 2012 edition LSC transition course. All AOs were provided access to this training course to ensure existing surveyors had the opportunity to receive training in support of CMS regulatory adoption of the 2012 edition of the LSC. In addition, the CMS in-person Basic LSC Course required by all new state LSC surveyors was converted to a web-based platform in 2018. This course has been made available to all AOs and stakeholders as an additional source of LSC training in an effort to further reduce LSC disparity through education.

In reference to the LSC SharePoint site, improvements and system upgrades to the functionality of the site have been performed. These upgrades allow for more robust reporting, additional system notifications, and workflow notifications making the system more user friendly.

Meetings with ROs and AOs have been held to identify issues and opportunities for improvement. The LSC SharePoint site continues to be modified to increase functionality and usability.

Validation Redesign Project

In March 2018, CMS appointed a workgroup to redesign the validation survey process. The overall goal of the validation redesign pilot (VRP) is to redesign the validation program where the SAs evaluate the ability of the AO surveyors to survey for compliance to CMS CoPs versus conducting a second survey of the facility, as is the current practice. Facilities will be surveyed simultaneously by the AO and SA, using the same Medicare certification full survey process (e.g., surveying for compliance with the Medicare CoPs or CfCs. Using the CMS/AO Observation Worksheet and Rating Guide developed by CMS, the SA surveyor team evaluates the skill, knowledge, and performance of the AO's survey process and score the AO accordingly. There will be no separate SA validation survey conducted. SA surveyors/observers will complete an AO Observation worksheet and abbreviated 2567 upon completion of the AO survey. The AO will provide the survey report with the POCs going to the RO. The data from the CMS/AO Observation worksheet will be used for the disparity data report. During the FY 2019 reporting period, there were a total of 24 VRP direct observation validation surveys conducted. In August 2019, CMS placed the VRP pilot on hold to assess the data and lessons learned to make enhancements to the process as needed. The VRP pilot is tentatively scheduled to restart in FY 2022.

SECTION 7: Clinical Laboratory Improvement Amendments Validation Program

Introduction

CLIA of 1988 expanded survey and certification of clinical laboratories from interstate commerce laboratories to most facilities testing and reporting out human specimens, regardless of location. CMS regulates laboratory testing by these laboratories whether the testing is provided to beneficiaries of CMS programs or to others, including certain testing performed in physicians' offices, for a total of 263,705 CLIA certified facilities at the beginning of calendar year (CY) 2019. The CLIA standards are based on the complexity of testing; thus, the more complex the test is to perform, the more stringent the requirements. There are three categories of tests: waived, moderate, and high complexity. Laboratories that perform only waived tests are not subject to the quality standards under CLIA or routine oversight. Laboratories which perform moderate and high complexity testing are subject to routine on-site surveys. These laboratories have a choice of the agency they wish to survey their laboratory. They can select CMS via the SAs or a CMS-approved AO. CMS partners with the states to certify and inspect approximately 17,655 laboratories every 2 years. CMS-approved AOs conduct on-site surveys of an additional 15,212 laboratories every 2 years as well. Data from these inspections reflect significant improvements in the quality of testing over time. The CLIA program is 100 percent user-fee financed, and is jointly administered by three HHS components: (1) CMS manages the financial aspects, contracts and trains state surveyors to inspect labs, and oversees program administration including enrollment, fee assessment, regulation and policy development, approval of AOs, exempt states and proficiency testing providers, certificate generation, enforcement and data system design; (2) the Centers for Disease Control and Prevention (CDC) conducts research, provides scientific and technical support, jointly develops regulations with CMS , develops and disseminates educational materials, and coordinates the Secretary's Clinical Laboratory Improvement Advisory Committee (CLIAC); and (3) the Food and Drug Administration (FDA) performs test categorization, including waiver approvals.

This report on the Clinical Laboratory Improvement Validation Program covers the evaluations of FY 2019 performance by the seven AOs approved by CMS under CLIA. The seven organizations are:

- AABB
- American Association for Laboratory Accreditation (A2LA)
- AAHHS/HFAP
- American Society for Histocompatibility and Immunogenetics (ASHI)
- COLA
- College of American Pathologists (CAP)
- TJC

CMS appreciates the cooperation of all the organizations in providing their inspection schedules and results. While an annual performance evaluation of each approved AO is required by law, this is an opportunity to present information about, and dialogue with, each organization as part

of a mutual interest in improving the quality of testing performed by clinical laboratories across the nation.

Legislative Authority and Mandate

Section 353 of the Public Health Service Act and the implementing regulations in 42 CFR part 493 require any laboratory that performs testing or assessment of human specimens for the diagnosis, prevention or treatment of a disease or impairment of, or the assessment of the health of, human beings to meet the requirements established by the CLIA statute and regulations including maintenance of an appropriate certificate. The CLIA certificate requirements include the option to meet the standards of an approved AO, in which case they would be issued a CLIA Certificate of Accreditation. Under the CLIA Certificate of Accreditation provisions, the laboratory is not routinely subject to direct Federal oversight by CMS. Instead, the laboratory receives an inspection by the AO in the course of maintaining its accreditation, and by virtue of this accreditation, is "deemed" to meet the CLIA requirements. The CLIA requirements pertain to QA and quality control programs, records, equipment, personnel, proficiency testing, and other areas to assure accurate and reliable laboratory examinations and procedures, and the AO's requirements must meet or exceed those CLIA requirements.

In Section 353(e)(2)(D), the Secretary is required to evaluate each approved AO by inspecting a sample of the laboratories they accredit and by "such other means as the Secretary determines appropriate." In addition, Section 353(e)(3) requires the Secretary to submit to Congress an annual report on the results of the evaluation. This section of this report is submitted to satisfy that requirement.

Regulations implementing Section 353 are contained in 42 CFR Part 493 "Laboratory Requirements." Subpart E of Part 493 contains the requirements for validation inspections, which are conducted by CMS or its agent to ascertain whether an accredited laboratory is in compliance with the applicable CLIA requirements. Validation inspections for clinical laboratories are conducted no more than 90 days after the AO's inspection, on a representative sample basis or in response to a complaint. The results of these validation inspections provide:

- On a laboratory-specific basis, insight into the effectiveness of the AO's standards and accreditation process; and
- In the aggregate, an indication of the organization's capability to assure laboratory performance equal to or more stringent than that required by CLIA.

The CLIA regulations, at 42 CFR § 493.575, provide that if the validation inspection results over a 1-year period indicate a rate of disparity[14] of 20 percent or more between the findings in the AO's results and the findings of the CLIA validation surveys, CMS will re-evaluate whether the AO continues to meet the criteria for an approved AO (also called "deeming authority"). Section 493.575 further provides that CMS has the discretion to conduct a review of an AO program if validation review findings, irrespective of the rate of disparity, indicate such widespread or

[14] The methodology for the CLIA Rate of Disparity is calculated the same as in Figure 2 of this report. The only difference is that CLIA validation surveys are performed up to 90 days after an AO inspection instead of 60 days.

systematic problems in the organization's accreditation process that the AO's requirements are no longer equivalent to CLIA requirements.

Validation Reviews

The validation review methodology focuses on the actual implementation of an organization's accreditation program, which is described in its request for approval as an AO. Those standards are reviewed as a whole, and, if appropriate, are approved by CMS as being equivalent to or more stringent than the CLIA condition-level requirements.[15] This equivalency is the basis for CMS granting the AO its deeming authority.

In evaluating an organization's performance during a validation review, it is important to examine whether the organization's inspection findings are similar to the CLIA validation survey findings. It is also important to examine whether the organization's inspection process sufficiently identifies, brings about correction, and monitors for sustained correction, of laboratory practices and outcomes that do not meet their accreditation standards, so that those accredited by the programs continue to meet or exceed the CLIA program requirements.

The organization's inspection findings are compared, case-by-case for each laboratory in the sample, to the CLIA validation survey findings at the condition level. If it is reasonable to conclude that one or more of those condition-level deficiencies were present in the laboratory's operations at the time of the organization's inspection, yet the inspection results did not note them, the case is a disparity. When all the cases in each sample have been reviewed, the rate of disparity for each organization is calculated by dividing the number of disparate cases by the total number of validation surveys, in the manner prescribed by Section 493.2 of the CLIA regulations.

Number of Validation Surveys Performed

As directed by the CLIA statute, Section 353(e)(2)(D)(i), the number of validation surveys should be sufficient to "allow a reasonable estimate of the performance" of each AO. A representative sample of more than 15,000 accredited laboratories received a validation survey in 2019. Laboratories seek and relinquish accreditation on an ongoing basis, so the number of laboratories accredited by an organization during any given year fluctuates. Moreover, many laboratories are accredited by more than one organization. Each laboratory holding a Certificate of Accreditation, however, is subject to only one validation survey for the AO it designates for CLIA compliance, irrespective of the number of accreditations it attains.

Nationwide, fewer than 500 of the accredited laboratories used AABB, A2LA, AAHHS/HFAP, or ASHI accreditation for CLIA purposes. Given these proportions, very few validation surveys were performed in laboratories accredited by those organizations. The overwhelming majority of accredited laboratories in the CLIA program used their accreditation by COLA, CAP, or TJC, thus the sample sizes for these organizations were larger. The sample sizes are roughly

[15] A condition-level requirement pertains to the significant, comprehensive requirements of CLIA, as opposed to a standard-level requirement, which is more detailed and more specific. A condition-level deficiency is an inadequacy in the laboratory's quality of services that adversely affects, or has the potential to adversely affect, the accuracy and reliability of patient test results.

proportionate to each organization's representation in the universe of accredited laboratories; however, true proportionality is not always possible due to the complexities of scheduling.

The number of validation surveys performed for each organization is specified below in the summary findings for the organization.

Results of the Validation Reviews of Each Accrediting Organization

AABB

Rate of disparity: N/A

In FY 2019, approximately 187 laboratories used their AABB accreditation for CLIA program purposes. No validation surveys were conducted during this survey cycle. (See Table 32.)

American Association for Laboratory Accreditation

Rate of disparity: N/A

On March 25, 2014, A2LA was the seventh AO to receive deeming authority by CMS. The organization has a total of five deemed facilities. No CLIA validation surveys were conducted during the FY 2019 survey cycle. (See Table 32.)

Accreditation Association for Hospitals and Health Systems/Healthcare Facilities Accreditation Program

Rate of disparity: None

For CLIA purposes, approximately 132 laboratories used their AAHHS/HFAP accreditation. Validation surveys were conducted in ten AAHHS/HFAP-accredited laboratories. No condition-level deficiencies were cited in any survey therefore, there is no disparity rate to report. (See Table 32.)

American Society for Histocompatibility and Immunogenetics

Rate of disparity: N/A

Approximately 113 laboratories used their ASHI accreditation for CLIA purposes. A total of three validation surveys were conducted in ASHI-accredited laboratories. Due to the low number of validation surveys conducted, no additional data is reported. (See Table 32.)

COLA

Rate of disparity: 9.7 percent

In FY 2019, 6,375 laboratories used their COLA accreditation for CLIA program purposes. A total of 145 validation surveys were conducted in COLA-accredited laboratories. Eighteen laboratories were cited with condition-level deficiencies. In 14 laboratories, however, COLA

noted comparable findings for only some or none of the CLIA condition-level deficiencies cited; thus, there were 14 disparate cases yielding a disparity rate of 9.7 percent. (See Table 32)

College of American Pathologists

Rate of disparity: 9.7 percent

In FY 2019, 6,341 laboratories used their CAP accreditation for CLIA program purposes. A total of 124 validation surveys were conducted in CAP-accredited laboratories. Thirteen laboratories were cited with CLIA condition-level deficiencies. In 12 laboratories, CAP findings weren't comparable to the CLIA condition-level deficiencies cited; thus, there were 12 disparate cases for a disparity rate of 9.7 percent. (See Table 32.)

The Joint Commission

Rate of disparity: 18.6 percent

In FY 2019, 2,059 laboratories used their TJC accreditation for CLIA program purposes. During this validation period, a total of 43 validation surveys were conducted in TJC-accredited laboratories. Eight laboratories were cited with CLIA condition-level deficiencies. TJC findings were not comparable to the CLIA condition-level deficiencies cited; thus, there were eight disparate cases yielding a disparity rate of 18.6 percent. (See Table 32.)

Table 32
Validation Survey Results for Clinical Laboratories
FY 2019

Number of—	AABB	A2LA	AAHHS/HFAP	ASHI	CAP	COLA	TJC	Total
Accredited Laboratories	187	5	132	113	6,341	6,375	2,059	15,212
Validation Surveys	0	0	10	3	124	145	43	325
Surveys with Condition-Level Deficiencies	*N/A	*N/A	0	*N/A	13	18	8	39
Surveys with One or More Condition-Level Deficiencies Missed by AO	*N/A	*N/A	0	*N/A	12	14	8	34
Disparity Rate	***N/A**	***N/A**	**None**	***N/A**	**9.7%**	**9.7%**	**18.6%**	**10.5%**

*N/A: When a minimum sample size of five is not achieved for an AO, no data is reported given the lack of statistical significance.

Conclusion

CMS has performed this statutorily mandated validation review in order to evaluate and report to Congress on the performance of the seven laboratory AOs approved under CLIA. This endeavor is two-fold: to verify each organization's capability to assure laboratory performance equal to, or more stringent than, that required by CLIA ("equivalency"); and to gain insight into the effectiveness of the AO's standards and accreditation process on a laboratory-specific basis.

CMS recognizes that similarity of AO findings to CLIA validation survey findings is an important measure of the organization's capability to ensure and sustain equivalency and effectiveness of oversight. When an accredited laboratory's practices and outcomes fail to conform fully to the accreditation standards, it is important that the AO's inspection protocol sufficiently identifies the deficiencies, brings about correction, and monitors for sustained compliance, so that the laboratory is again in full conformance with the accreditation standards and equivalency is sustained.

In the interest of furthering the mutual goal of promoting quality testing in clinical laboratories and furthering the goal of sustained equivalency, CMS hosts an annual meeting of all CMS-approved AOs for CLIA. The group meets to discuss and resolve issues of mutual interest and to share best practices. The group endeavors to improve their overall consistency in application of laboratory standards, coordination, collaboration, and communication in both routine and emergent situations. Through these efforts, CLIA hopes to further improve the level of laboratory oversight and ultimately, patient care.

APPENDIX A: Performance Measures

Appendix A Table 1
Performance Measure Results (Percentage) by AO
for FYs 2018-2019

	AAAASF		AAAHC		ACHC		AAHHS/HFAP		CHAP		CIHQ		DNV GL		IMQ		NDAC		TCT		TJC	
	FY18	FY19	FY18	FY19	FY18	FY19	FY18	FY19	FY18	FY19	FY18	FY19	FY18	FY19	FY18	FY19	FY18	FY19	FY18	FY19	FY18	FY19
ASSURE Database																						
Denied initial survey with condition-level findings	95	100	100	100	100	100	100	**NA	100	100	**NA	92	75	100	**NA	**NA	*NA	**NA	100	100	83	100
Timeliness of facility notification of survey results	95	95	93	92	100	100	97	99	93	95	100	99	96	100	88	76	*NA	82	97	96	100	100
CMS notified timely of withdrawals	98	96	83	93	100	86	100	88	89	83	**NA	**NA	100	100	*NA	*NA	*NA	**NA	63	97	100	100
Facility Notification Letters																						
Notification letters contain all required information	100	98	90	90	100	100	99	100	99	100	93	97	100	97	47	58	*NA	73	94	98	99	99
ASSURE is updated consistent with letters	93	98	86	88	98	100	95	100	86	98	66	89	97	99	84	67	*NA	86	80	85	69	91

	AAAASF		AAAHC		ACHC		AAHHS/HFAP		CHAP		CIHQ		DNV GL		IMQ		NDAC		TCT		TJC	
	FY18	FY19	FY18	FY19	FY18	FY19	FY18	FY19	FY18	FY19	FY18	FY19	FY18	FY19	FY18	FY19	FY18	FY19	FY18	FY19	FY18	FY19
Survey Schedule																						
Number of surveys performed matches number reported in ASSURE	98	99	93	99	100	100	100	98	99	100	100	96	99	100	100	60	*NA	100	97	93	99	100

*NA: No information available for calculation.
**NA: Not applicable due to sample size less than five.

APPENDIX B: Fiscal Year 2019 Life Safety Code and Health & Safety Disparity Rates

Accrediting Organizations

American Association for Accreditation of Ambulatory Surgery Facilities, Inc.

Ambulatory Surgery Centers

AAAASF (FY 2019 ASC Surveys)	All CfCs	PE	Health & Safety
Number of 60-Day Validation Surveys	6	6	6
Number of Surveys with Conditions Missed by AO	3	2	2
Disparity Rate	50.00%	33.33%	33.33%

Appendix B Table 1: AAAASF
ASC Disparity Rate
FY 2019

CfCs	Facilities with CfC(s)	Matching Surveys	Disparate Surveys	Disparity Rate
Environment	3	1	2	33%
Infection Control	3	1	2	33%
Governing Body and Management	2	0	2	33%
Quality Assessment & Performance Improvement	2	0	2	33%
Basic Requirements	1	0	1	17%

Appendix B Table 2: AAAASF
Top Five Disparate CfCs for ASCs
90 Percent of all Disparate Findings

Category	Total Cited by SA	Missed by AO	Disparity Rate
Fire/Smoke Barrier	5	5	23.81%
Medical Gas	4	4	19.05%
Hazardous Areas	3	3	14.29%
Construction	2	2	9.52%
Fire Alarm	2	2	9.52%

Appendix B Table 3: AAAASF
Top Five Missed LSC Citations for ASCs
76 Percent of all Missed Citations

Accreditation Association for Ambulatory Health Care, Inc

Ambulatory Surgery Centers

AAAHC (FY 2019 ASC Surveys)	All CfCs	PE	Health & Safety
Number of 60-Day Validation Surveys	39	39	39
Number of Surveys with Conditions Missed by AO	15	5	12
Disparity Rate	38.46%	12.82%	30.77%

Appendix B Table 4: AAAHC
ASC Disparity Rate
FY 2019

CfCs	Facilities with CfC(s)	Matching Surveys	Disparate Surveys	Disparity Rate
Infection Control	12	4	8	20.51%
Environment	11	6	5	12.82%
Governing Body and Management	7	2	5	12.82%
Quality Assessment & Performance Improvement	3	1	2	5.13%

Appendix B Table 5: AAAHC
Top Disparate CfCs for ASCs
88 Percent of all Disparate Surveys

Category	Total Cited by SA	Missed by AO	Disparity Rate
Construction	8	7	18.92%
Fire Drill	3	1	2.70%
Means of Egress	3	1	2.70%
Fire Extinguisher	1	1	2.70%

Appendix B Table 6: AAAHC
Top Four Missed LSC Citations for ASCs
100 Percent of all Missed Citations

Accreditation Commission for Health Care

Hospice

ACHC (FY 2019 Hospice Surveys)	All CoPs	Health & Safety
Number of 60-Day Validation Surveys	8	8
Number of Surveys with Conditions Missed by AO	2	2
Disparity Rate	25.0%	25.0%

Appendix B Table 7: ACHC
Hospice Disparity Rate
FY 2019

Category	Total Cited by SA	Missed by AO	Disparity Rate
Clinical Records	2	1	1
IDG, Care Planning, Coordination of Services	4	2	2
Quality Assessment & Performance Improvement	2	1	1

Appendix B Table 8: ACHC
Top Disparate CoPs for Hospice
100 Percent of all Disparate Surveys

Accreditation Association for Hospitals and Health Systems/Healthcare Facilities Accreditation Program

Hospitals

AAHHS/HFAP (FY 2019 Hospital Surveys)	All CoPs	PE	Health & Safety
Number of 60-Day Validation Surveys	3	3	3
Number of Surveys with Conditions Missed by AO	2	2	N/A
Disparity Rate	66.67%	66.67%	N/A

Appendix B Table 9: AAHHS/HFAP
Hospital Disparity Rate
FY 2019

CoP	Facilities with CoP	Matching Surveys	Disparate Surveys	Disparity Rate
Physical Environment	4	2	2	66.67%

Appendix B Table 10: AAHHS/HFAP
Disparate CoP for Hospitals
100 Percent of all Disparate Surveys

Category	Total Cited by SA	Missed by AO	Disparity Rate
Sprinkler	12	11	23.40%
Fire/Smoke Barrier	18	6	12.77%
Medical Gas	3	3	6.38%
Construction	3	2	4.26%
Emergency Lighting	2	2	4.26%
Cooking Facility	1	1	2.13%
Hazardous Areas	1	1	2.13%

Appendix B Table 11: AAHHS/HFAP
Top 7 Missed LSC Citations for Hospitals
100 Percent of all Missed Citations

Ambulatory Surgery Center

AAHHS/HFAP (FY 2019 ASC Surveys)	All CfCs	PE	Health & Safety
Number of 60 Day Validation Surveys	1	1	1
Number of Surveys with Conditions Missed by AO	1	1	N/A
Disparity Rate	100.00%	100.00%	N/A

Appendix B Table 92: AAHHS/HFAP
ASC Disparity Rate
FY 2019

CfC	Facilities with CfC	Matching Surveys	Disparate Surveys	Disparity Rate
Environment	1	0	1	100.00%

Appendix B Table 103: AAHHS/HFAP
Top Disparate CfC for ASCs
100 Percent of all Disparate Surveys

Category	Total Cited by SA	Missed by AO	Disparity Rate
Hazardous Areas	1	1	100.00%

Appendix B Table 114: AAHHS/HFAP
Missed LSC Citation for ASCs
100 Percent of all Missed Citations

Community Health Accreditation Partner

Home Health Agency

CHAP (FY 2019 HHA Surveys)	All CoPs	Health & Safety
Number of 60-Day Validation Surveys	36	36
Number of Surveys with Conditions Missed by AO	5	5
Disparity Rate	13.89%	13.89%

Appendix B Table 125: CHAP
HHA Disparity Rate
FY 2019

CoPs	Facilities with CoP(s)	Matching Surveys	Disparate Surveys	Disparity Rate
Comprehensive Assessment of Patients	3	1	2	5.56%
Skilled Professional Services	3	1	2	5.56%
Establishment of the Emergency Program	3	2	1	2.78%
Establishment of Emergency Program	1	0	1	2.78%
Care Planning, Coordination, and Quality of Care	3	2	1	2.78%

Appendix B Table 136: CHAP
Top Five Disparate CoPs for HHAs
88 Percent of all Disparate Surveys

Hospice

CHAP (FY 2019 Hospice Surveys)	All CoPs	Health & Safety
Number of 60-Day Validation Surveys	11	11
Number of Surveys with Conditions Missed by AO	1	1
Disparity Rate	9.09%	9.09%

Appendix B Table 147: CHAP
Hospice Disparity Rate
FY 2019

CoPs	Facilities with CoP(s)	Matching Surveys	Disparate Surveys	Disparity Rate
Organizational Environment	1	0	1	9.09%
IDG, Care Planning, Coordination of Services	2	1	1	9.09%

Appendix B Table 18: CHAP
Top Two Disparate CoPs for Hospice
100 Percent of all Disparate Surveys

DNV GL-Healthcare

Hospitals

DNV GL (FY 2019 Hospital Surveys)	All CoPs	PE	Health & Safety
Number of 60-Day Validation Surveys	7	7	7
Number of Surveys with Conditions Missed by AO	3	2	3
Disparity Rate	42.86%	28.57%	42.86%

Appendix B Table 19: DNV GL-Healthcare
Hospital Disparity Rate
FY 2019

CoPs	Facilities with CoP(s)	Matching Surveys	Disparate Surveys	Disparity Rate
Physical Environment	4	2	2	28.57%
Infection Control	2	1	1	14.29%
Governing Body	1	0	1	14.29%
Food and Dietetic Services	1	0	1	14.29%
Organ, Tissue, and Eye Procurement	1	0	1	14.29%

Appendix B Table 150: DNV GL-Healthcare
Top Five Disparate CoPs for Hospitals
100 Percent of all Disparate Surveys

Category	Total Cited by SA	Missed by AO	Disparity Rate
Fire/Smoke Barrier	4	2	33.33%
Doors	2	2	33.33%

Appendix B Table 21: DNV GL-Healthcare
Top Two Missed LSC Citations for Hospitals
100 Percent of all Missed Citations

The Joint Commission

Hospitals

TJC (FY 2019 Hospital and LTCH Surveys)	All CoPs	PE	Health & Safety
Number of 60-Day Validation Surveys	99	99	99
Number of Surveys with Conditions Missed by AO	44	26	27
Disparity Rate	44.44%	26.26%	27.27%

Appendix B Table 162: TJC
Hospital and LTCH Disparity Rate
FY 2019

CoPs	Facilities with CoPs	Matching Surveys	Disparate Surveys	Disparity Rate
Physical Environment	55	29	26	26.26%
Infection Control	17	6	11	11.11%
Patient Rights	16	6	10	10.10%
Governing Body	13	6	7	7.07%
QAPI	8	2	6	6.06%

Appendix B Table 23: TJC
Top Five Disparate CoPs for Hospitals and LTCHs
81 Percent of all Disparate Surveys

Category	Total Cited by SA	Missed by AO	Disparity Rate
Fire/Smoke Barrier	87	41	8.28%
Fire Alarm	38	16	3.23%
Hazardous Areas	31	15	3.03%
Flammable & Combustible Storage	12	9	1.82%
Cooking Facility	10	9	1.82%
Emergency Lighting	11	7	1.41%
Sprinkler	83	6	1.21%
Electrical	56	5	1.01%
Construction	9	3	0.61%
EES	4	1	0.20%

Appendix B Table 2417: TJC
Top 10 Missed LSC Citations for Hospital
98 Percent of all Missed Citations

Psychiatric Hospitals

TJC (FY 2019 Psychiatric Hospital Surveys)	All CoPs	PE	Health & Safety
Number of 60-Day Validation Surveys	20	20	20
Number of Surveys with Conditions Missed by AO	9	4	6
Disparity Rate	38.10%	28.57%	33.33%

Appendix B Table 25: TJC
Psychiatric Hospital Disparity Rate
FY 2019

CoPs	Facilities with CoPs	Matching Surveys	Disparate Surveys	Disparity Rate
Physical Environment	8	4	4	20.00%
Infection Control	3	0	3	15.00%
Special Medical Record Reqs for Psych Hospitals	7	5	2	10.00%
Governing Body	3	1	2	10.00%
Food and Dietetic Services	2	0	2	10.00%

Appendix B Table 26: TJC
Top Six Disparate CoPs for Psychiatric Hospitals
76 Percent of all Disparate Surveys

Category	Total Cited by SA	Missed by AO	Disparity Rate
Fire/Smoke Barrier	15	4	7.41%
Hazardous Areas	3	3	5.56%
Electrical	8	2	3.70%
Means of Egress	4	2	3.70%
Elevators	2	2	3.70%
Sprinkler	7	1	1.85%
Fire Alarm	4	1	1.85%
Construction	1	1	1.85%
EES	1	1	1.85%

Appendix B Table 27: TJC
Missed LSC Citations for Psychiatric Hospitals
100 Percent of all Missed Citations

Ambulatory Surgery Center

TJC (FY 2019 ASC Surveys)	All CfCs	PE	Health & Safety
Number of 60-Day Validation Surveys	21	21	21
Number of Surveys with Conditions Missed by AO	4	3	3
Disparity Rate	42.86%	33.33%	14.29%

Appendix B Table 28: TJC
ASC Disparity Rate
FY 2018

CfCs	Facilities with CfC(s)	Matching Surveys	Disparate Surveys	Disparity Rate
Environment	5	2	3	14.29%
Governing Body and Management	4	2	2	9.52%
Surgical Services	3	2	1	4.76%
Infection Control	2	1	1	4.76%
Establishment of the Emergency Program	1	0	1	4.76%

Appendix B Table 29: TJC
Top Five Disparate CfCs for ASCs
100 Percent of all Disparate Surveys

Category	Total Cited by SA	Missed by AO	Disparity Rate
Medical Gas	4	4	26.67%
Construction	1	1	6.67%
HVAC	1	1	6.67%
Means of Egress	1	1	6.67%

Appendix B Table 180: TJC
Top Four Missed LSC Citations for ASCs
100 Percent of all Missed Citations

Home Health Agency

TJC (FY 2019 HHA Surveys)	All CoPs	Health & Safety
Number of 60-Day Validation Surveys	31	31
Number of Surveys with Conditions Missed by AO	2	2
Disparity Rate	6.45%	6.45%

Appendix B Table 191: TJC
HHA Disparity Rate
FY 2019

CoPs	Facilities with CoP(s)	Matching Surveys	Disparate Surveys	Disparity Rate
Care Planning, Coordination, and Quality of Care	3	2	1	3.23%
Clinical Records	2	1	1	3.23%
Compliance with Federal, State, Local Law	1	0	1	3.23%
Comprehensive Assessment of Patients	1	0	1	3.23%

Appendix B Table 202: TJC
Top Disparate CoPs for HHAs
100 Percent of all Disparate Surveys

Hospice

TJC (FY 2019 Hospice Surveys)	All CoPs	Health & Safety
Number of 60-Day Validation Surveys	13	13
Number of Surveys with Conditions Missed by AO	3	3
Disparity Rate	23.08%	23.08%

Appendix B Table 33: TJC
Hospice Disparity Rate
FY 2019

CoPs	Facilities with CoP(s)	Matching Surveys	Disparate Surveys	Disparity Rate
IDG, Care Planning, Coordination of Services	4	2	2	15.38%
Quality Assessment & Performance Improvement	2	0	2	15.38%
Organizational Environment	2	1	1	7.69%
Clinical Records	1	0	1	7.69%
Establishment of the Emergency Program	1	0	1	7.69%

Appendix B Table 34: TJC
Top Five Disparate CoPs for Hospice
78 Percent of all Disparate Surveys

Critical Access Hospital

TJC (FY 2019 CAH Surveys)	All CoPs	PE	Health & Safety
Number of 60-Day Validation Surveys	9	9	9
Number of Surveys with Conditions Missed by AO	6	5	2
Disparity Rate	66.67%	55.56%	22.22%

Appendix B Table 35: TJC
CAH Disparity Rate
FY 2019

CoPs	Facilities with CoP(s)	Matching Surveys	Disparate Surveys	Disparity Rate
Physical Plant and Environment	10	5	5	55.56%
Provision of Services	3	2	1	11.11%
Surgical Services	2	1	1	11.11%
Organizational Structure	1	0	1	11.11%
Special Reqs for CAH Providers of LTC Srvcs	1	0	1	11.11%

Appendix B Table 36: TJC
Disparate CoPs for CAHs
100 Percent of all Disparate Surveys

Category	Total Cited by SA	Missed by AO	Disparity Rate
Hazardous Areas	13	13	17.81%
Means of Egress	12	7	9.59%
Sprinkler	14	4	5.48%
Fire Drill	3	3	4.11%
EES	2	1	1.37%
HVAC	1	1	1.37%

Appendix B Table 37: TJC
Top Six Missed LSC Citations for CAHs
100 Percent of all Missed Citations

Program Types

Hospital

ALL AOs (FY 2019 Hospital and LTCH Surveys)	All CoPs	PE	Health & Safety
Number of 60-Day Validation Surveys	99	99	99
Number of Surveys with Conditions Missed by AO	44	26	30
Disparity Rate	44.44%	26.26%	30.30%

Appendix B Table 38: Hospital Disparities FY 2019

CoPs	Facilities with CoPs	Matching Surveys	Disparate Surveys	Disparity Rate
Physical Environment	55	29	26	26%
Infection Control	17	6	11	11%
Patient Rights	16	6	10	10%
Governing Body	13	6	7	7%
QAPI	8	2	6	6%

Appendix B Table 39: Top Five Disparate CoPs for Hospitals
81 Percent of all Disparate Surveys

Category	Total Cited by SA	Missed by AO	Disparity Rate
Fire/Smoke Barrier	109	49	8.94%
Sprinkler	95	17	3.10%
Hazardous Areas	32	16	2.92%
Fire Alarm	39	13	2.37%
Cooking Facility	11	10	1.82%
Flammable & Combustible Storage	12	9	1.64%
Emergency Lighting	13	8	1.46%
Construction	12	5	0.91%
Electrical	58	4	0.73%
EES	4	1	0.18%

Appendix B Table 210: Top 10 Missed LSC Citations for Hospitals
99 Percent of all Missed Citations

Psychiatric Hospital

ALL AOs (FY 2019 Psychiatric Hospital Surveys)	All CoPs	PE	Health & Safety
Number of 60-Day Validation Surveys	20	20	20
Number of Surveys with Conditions Missed by AO	9	4	6
Disparity Rate	45.00%	20.00%	30.00%

Appendix B Table 221: Psychiatric Hospital Disparities FY 2019

CoPs	Facilities with CoPs	Matching Surveys	Disparate Surveys	Disparity Rate
Physical Environment	8	4	4	20.00%
Infection Control	3	0	3	15.00%
Special Medical Record Reqs for Psych Hospitals	7	5	2	10.00%
Governing Body	3	1	2	10.00%
Food and Dietetic Services	2	0	2	10.00%

Appendix B Table 42: Top Five Disparate CoPs for Psychiatric Hospitals
76 Percent of all Disparate Surveys

Category	Total Cited by SA	Missed by AO	Disparity Rate
Fire/Smoke Barrier	15	4	7.41%
Hazardous Areas	3	3	5.56%
Electrical	8	2	3.70%
Means of Egress	4	2	3.70%
Elevators	2	2	3.70%
Sprinkler	7	1	1.85%
Fire Alarm	4	1	1.85%
Construction	1	1	1.85%

Appendix B Table 43: Top Nine Missed LSC Citations for Psychiatric Hospitals
100 Percent of all Missed Citations

Ambulatory Surgery Center

ALL AOs (FY 2019 ASC Surveys)	All CfCs	PE	Health & Safety
Number of 60-Day Validation Surveys	67	67	67
Number of Surveys with Conditions Missed by AO	23	17	11
Disparity Rate	34.33%	25.37%	16.42%

Appendix B Table 44: ASC Disparities FY 2019

CfCs	Facilities with CfCs	Matching Surveys	Disparate Surveys	Disparity Rate
Environment	20	9	11	16.42%
Infection Control	17	6	11	16.42%
Governing Body and Management	13	4	9	13.43%
Quality Assessment & Performance Improvement	6	2	4	5.97%
Surgical Services	4	2	2	2.99%
Environment	20	9	11	16.42%

Appendix B Table 45: Top Six Disparate CfCs for ASCs
84 Percent of all Disparate Surveys

Category	Total Cited by SA	Missed by AO	Disparity Rate
Construction	11	10	13.33%
Hazardous Areas	6	4	5.33%
Medical Gas	9	3	4.00%
HVAC	4	2	2.67%
Fire/Smoke Barrier	14	1	1.33%
Means of Egress	4	1	1.33%
Fire Drill	3	1	1.33%
Interior Finish	1	1	1.33%

Appendix B Table 46: Top Nine Missed LSC Citations for ASCs
100 Percent of all Missed Citations

Critical Access Hospital

ALL AOs (FY 2019 CAH Surveys)	All CoPs	PE	Health & Safety
Number of 60-Day Validation Surveys	13	13	13
Number of Surveys with Conditions Missed by AO	6	5	2
Disparity Rate	46.15%	38.46%	15.38%

Appendix B Table 47: CAH Disparities FY 2019

CoPs	Facilities with CoP(s)	Matching Surveys	Disparate Surveys	Disparity Rate
Physical Plant and Environment	10	5	5	38.46%
Provision of Services	3	2	1	7.69%
Surgical Services	2	1	1	7.69%
Organizational Structure	1	0	1	7.69%
Special Reqs for CAH Providers of LTC Srvcs	1	0	1	7.69%

Appendix B Table 48: Top Five Disparate CoPs for CAHs
100 Percent of all Disparate Surveys

Category	Total Cited by SA	Missed by AO	Disparity Rate
Hazardous Areas	13	13	17.81%
Means of Egress	12	7	9.59%
Sprinkler	14	4	5.48%
Fire Drill	3	3	4.11%
EES	2	1	1.37%
HVAC	1	1	1.37%

Appendix B Table 49: Top Six Missed LSC Citations for CAHs
100 Percent of all Missed Citations

Hospice

ALL AOs (FY 2019 Hospice Surveys)	All CoPs	Health & Safety
Number of 60-Day Validation Surveys	32	32
Number of Surveys with Conditions Missed by AO	6	6
Disparity Rate	18.75%	18.75%

Appendix B Table 50: Hospice Disparities FY 2019

CoPs	Facilities with CoP(s)	Matching Surveys	Disparate Surveys	Disparity Rate
IDG, Care Planning, Coordination of Services	10	5	5	15.63%
Quality Assessment & Performance Improvement	4	1	3	9.38%
Organizational Environment	3	1	2	6.25%
Clinical Records	3	1	2	6.25%
Establishment of the Emergency Program	1	0	1	3.13%
Patient Rights	1	0	1	3.13%
Infection Control	1	0	1	3.13%

Appendix B Table 51: Top Seven Disparate CoPs for Hospice Facilities
100 Percent of all Disparate Surveys

Home Health Agency

ALL AOs (FY 2019 HHA Surveys)	All CoPs	Health & Safety
Number of 60-Day Validation Surveys	84	84
Number of Surveys with Conditions Missed by AO	7	7
Disparity Rate	8.33%	8.33%

Appendix B Table 52: HHA Disparities FY 2019

CoPs	Facilities with CoP(s)	Matching Surveys	Disparate Surveys	Disparity Rate
Comprehensive Assessment of Patients	4	1	3	3.57%
Care Planning, Coordination, and Quality of Care	6	4	2	2.38%
Skilled Professional Services	3	1	2	2.38%
Quality Assessment/Performance Improvement	4	3	1	1.19%
Establishment of the Emergency Program	3	2	1	1.19%
Clinical Records	2	1	1	1.19%
Compliance with Federal, State, Local Law	1	0	1	1.19%
Establishment of Emergency Program	1	0	1	1.19%

Appendix B Table 53: Top Eight Disparate CoPs for HHAs
100 Percent of all Disparate Surveys

APPENDIX C: Life Safety Code Category Definitions

Anesthetizing Location: Location where inhalation agents are used to produce sedation, analgesia, or general anesthesia.

Construction: Buildings should be classified to their type of construction based on the five different construction types: Type I, Type II, Type III, Type IV, and Type V with fire-resistive ratings.

Cooking Facility: An area for food preparation and commercial cooking operations requiring protection for exhaust and automatic extinguishing system.

Doors: The door assembly including any combination of a door, frame, hardware, and other accessories that is placed in an opening in a wall that is intended primarily for access or for human entrance or exit.

Electrical: Electrically connected energized with a source of voltage and general term of equipment, including fitting, devices, appliances, luminaires, apparatus, machinery and the like used as part of electrical installation.

Elevator: A machine used for carrying people and things to different levels in a building and components, machinery, and shaft.

Fire Plan: A fire or emergency management program that is documented and shall include four phases: mitigation, preparedness, response, and recovery.

Emergency Lighting: Emergency illumination provided for means of egress in designated areas and the performance of the system in relation to length of operation and testing.

Essential Electrical System (EES): A system comprised of alternate sources of power and all connected distribution systems and ancillary equipment, designed to ensure continuity of electrical power to designated areas and functions of a health care facility during interruption of normal power sources, and to minimize disruption within the internal wiring system.

Eye Wash: An apparatus for irrigating the eyes after exposure to dust or other debris or chemical contamination. The shower directs one or two streams of water so that they flush over the eyes and lids and must be inspected and maintained.

Fire Alarm: A system or portion of a combination system that consist of components and circuits arranged to monitor and annunciate the status of fire alarm or supervisory signal initiating device to initiate the proper response to those signals.

Fire Drill: Practice of the fire plan to evacuate or relocate persons in the event of a fire, to be conducted quarterly for each shift.

Fire Extinguisher: A portable device, carried or on wheels and operated by hand, containing an extinguishing agent that can be expelled under pressure for the purpose of suppressing or extinguishing a fire.

Fire/Smoke Barrier: Fire compartment or Smoke compartment within a building enclosed by either a fire or smoke barrier on all sides including the top and bottom.

Flammable & Combustible Storage: Storage area for combustible materials that have a flash point at or above a 100° F and flammable materials that have a flash point at or below 100° F.

Furnishings and Decorations: Draperies, curtains, and other loosely hanging fabrics and films servicing as furnishings or decorations in health care occupancies.

Generator: A complete emergency power system coupled to a system of conductors, disconnecting means and overcurrent protective devices, transfer switches, and all control, supervisory, and support devices up to and including the load terminals of the transfer equipment needed for the system to operate as a safe and reliable source of electrical power.

Hazardous Areas: An area of a structure or building that poses a degree of hazard greater than that normal to the general occupancy of the building or structure.

Heating Venting Air Conditioning (HVAC): System components and air distribution; integration of ventilation of air conditioning system with building construction, including air handling rooms, protection of openings, and fire, smoke, and ceiling dampers; and automatic controls and acceptance testing.

Interior Finish: The exposed surfaces of walls, ceilings, and floors in a building.

Means of Egress: A continuous and unobstructed way of travel from any point in a building or structure to a public way consisting of three separate and distinct parts: (1) the exit access, (2) the exit, and (3) the exit discharge.

Medical Gas: A patient medical gas or support gas. An assembly of equipment and piping for the distribution of nonflammable medical gases such as oxygen, nitrous oxide, compressed air, carbon dioxide, and helium.

Smoking Regulations: Regulations adopted pertaining to locations prohibited, signs, and containers permitted for disposal.

Sprinkler: A system that consists of an integrated network of piping designed in accordance with fire protection engineering standards that includes a water supply source, a water control valve, a water flow alarm, and a drain. The system is normally activated from a fire and discharges water over the fire area through sprinkler heads.