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

Ref: QSO-21-12-AO/CLIA

DATE: **January 19, 2021**

TO: State Survey Agency Directors

FROM: Director
Quality, Safety & Oversight Group

SUBJECT: FY 2019 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 2019 annual RTC details the review, validation, and oversight of the FY 2018 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 HHS and have in effect an applicable certificate. The CMS annual Report to Congress (RTC) details the review, validation, and oversight of the AOs Medicare accreditation programs as well as those under CLIA.

State Agency surveyors conduct the validation surveys that are the basis for the analysis in the RTC. 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.

There are ten 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)

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

Posting AO Performance Data & Complaint Surveys:

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 currently out of compliance that also references the provider's AO, and select performance data for the AOs themselves. The list will include only hospitals at this time, however CMS anticipates publishing the similar information for other providers and suppliers at a future time.

https://qcor.cms.gov/main.jsp

The Validation Program:

CMS is piloting a new way to assess AOs' ability to ensure that facilities and suppliers comply with CMS requirements.

CMS evaluates the ability of AOs to accurately assess providers' and suppliers' compliance with health and safety standards through a validation survey process. Historically, CMS has measured the effectiveness of AOs by choosing a sample of facilities and suppliers, performing a state-conducted assessment survey within 60 days following an AO survey, and comparing results. In a pilot test, CMS is eliminating the second state-conducted validation survey and instead using direct observation during the original AO-run survey to evaluate the AO's program in assessing compliance with CMS Conditions of Participation.

Direct observation will provide CMS another way to evaluate AO performance and enable a process to suggest improvements and address concerns with AOs immediately. This approach will relieve some providers from having to undergo the traditional 60-day follow up assessment. The approach is another example of the wide-ranging effort at CMS to eliminate duplication and relieve burden, reducing the amount of time that healthcare facilities must spend on compliance activities.

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

/s/
David Wright

Attachment: FY2019 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 2019

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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.

[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; 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 "Medicare conditions" and is used to cover CoPs, CfCs, 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), facilities providing 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) – CMS has developed a pilot program that allows the SAs to 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.

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) 2018 (October 1, 2017 – September 30, 2018), 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 2018, 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 2018 AO performance measures; and comparison of FYs 2017 and 2018 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 2016–2018 are presented by facility type for each AO. The FY 2018 AO and State Agency (SA) condition-level citations for each facility type are presented and compared. For hospital accreditation programs, validation performance results provide separate comparisons for short-term acute care and long-term care hospitals (LTCHs).

(MPD) tier system. The State standard survey frequencies are resource driven and depend on CMS' 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.

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 2018.

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 2017–2018 measures.

Appendix B – Fiscal Year 2018 Life Safety Code and Health & Safety Disparity Rates
Detailed FY 2018 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 2011–2018

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

From FY 2011 through FY 2018, CMS completed 50 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 423 focused reviews. In total, 473 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, 2018, there were 10 national AOs with 22 approved Medicare accreditation programs. (See Tables 2 and 3.)

Table 2
AOs with Approved Medicare Accreditation Programs
FY 2018

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
TCT	The Compliance Team
TJC	The Joint Commission

*Formerly, Accreditation Association for Hospitals and Health Systems/Healthcare Facilities Accreditation Program (AAHHS/HFAP)

Table 3
Approved Medicare Accreditation Programs by AO
FY 2018

AO	Hospital	Psych Hospital	CAH	HHA	Hospice	ASC	OPT	RHC	Total
AAAASF						X	X	X	3
AAAHC						X			1
ACHC				X	X				2
AAHHS/HFAP	X		X			X			3
CHAP				X	X				2
CIHQ	X								1
DNV GL	X		X						2
IMQ						X			1
TCT								X	1
TJC	X	X	X	X	X	X			6
Total	4	1	3	3	3	5	1	2	22

Note: AOs weren't approved for the ESRD program in FY 2018; therefore, the ESRD program isn't included in this table.

The number of CMS-approved Medicare accreditation programs has grown steadily over the past several years resulting in 22 approved programs in FY 2018.

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

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, 2013 through November 27, 2019. The final notice announcing this decision was published in the *Federal Register* (78 FR 66364) (November 5, 2013), and can be accessed at https://www.govinfo.gov/content/pkg/FR-2013-11-05/pdf/2013-26374.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, 2013 through December 27, 2019. The final notice announcing this decision was published in the *Federal Register* (78 FR 71619) (November 29, 2013), and can be accessed at https://www.govinfo.gov/content/pkg/FR-2013-11-29/pdf/2013-28521.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.

Performance Review:

CMS had significant concerns that IMQ no longer met the definition of a national accrediting organization according to § 488.1. Due to lack of implementation, a 180-day accreditation program performance review was opened for IMQ's CMS-approved ASC accreditation program on February 28, 2017. The AO was required to provide CMS with evidence that they continued to meet the requirements for national accrediting organizations in accordance with CMS regulation at § 488.1 and § 488.5(a). At a minimum, this plan had to address: strategies for fully implementing and maintaining implementation of the ASC accreditation program on a national level; quarterly targets for numbers of Medicare surveys to be completed for the purposes of deemed status; ongoing marketing plans; and monthly progress toward meeting the agreed-upon evaluation criteria.

The 180-day accreditation program performance review ended September 29, 2017. CMS found that IMQ had made progress during the 180-day period, had satisfactorily implemented its CMS-approved ASC accreditation program, and therefore met the regulatory definition of a national AO. However, once IMQ began conducting Medicare surveys for the purposes of awarding deemed status, CMS identified significant issues with IMQ's survey process and required IMQ to provide additional documentation. While IMQ had begun to initiate revisions to these processes, full implementation had not yet been achieved.

On October 19, 2017, CMS placed IMQ's ASC accreditation program on probation for 180 calendar days to implement corrective actions. On June 8, 2018, CMS determined that IMQ implemented a program that has demonstrated significant improvement towards meeting CMS standards and use of a survey process comparable to that of CMS during its 180-day probationary period. In accordance with the provision at 42 CFR 488.8(c)(3)(i), the IMQ ASC accreditation program was removed from probationary status.

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, 2014 through July 15, 2020. The final notice announcing this decision was published in the *Federal Register* (79 FR 36524) (June 27, 2014), and can be accessed at https://www.govinfo.gov/content/pkg/FR-2014-06-27/pdf/2014-15103.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, 2014 through March 31, 2020. The final notice announcing this decision was published in the *Federal Register* (79 FR 14049) (March 12, 2014), and can be accessed at https://www.govinfo.gov/content/pkg/FR-2014-03-12/pdf/2014-05328.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:

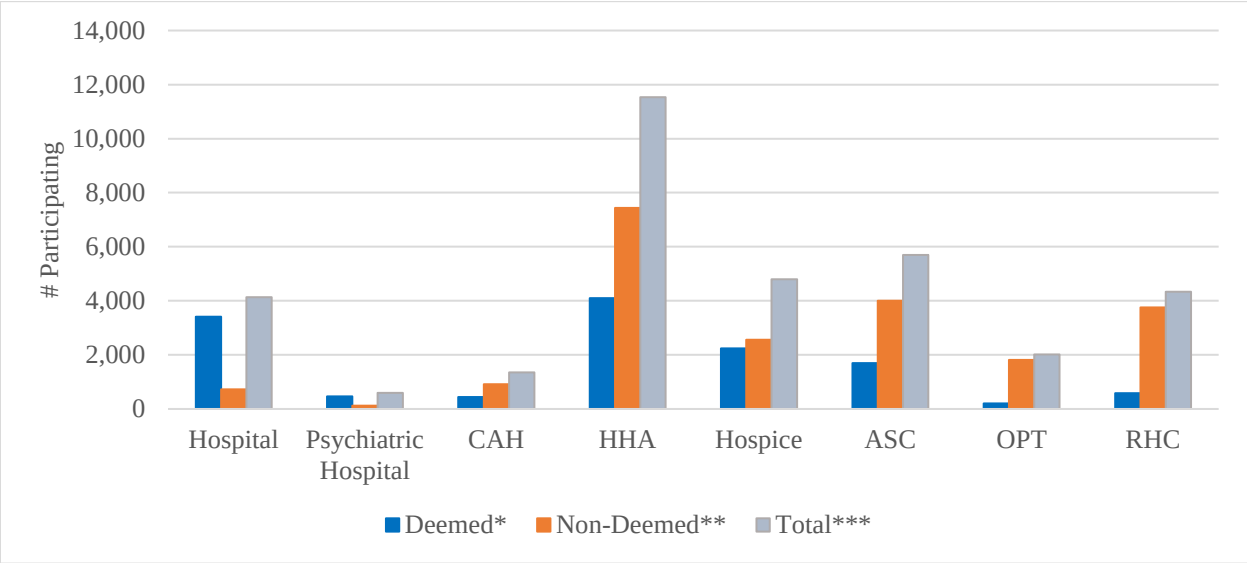
In FY 2018, AOs were responsible for assuring compliance with Medicare conditions for 38 percent (13,137) of all Medicare-participating facilities in the eight program types for which there was a CMS-approved AO Medicare accreditation program. (See Table 4 and Graph 1.)

Table 4
Deemed & Non-Deemed Medicare-Participating Facilities
Program Types with a Medicare Accreditation Program Option
FY 2018

Program Type	Deemed* (percentage)	Non-Deemed** (percentage)	Total***
Hospital	3,409 (82)	731 (18)	4,140
Psychiatric Hospital	469 (79)	127 (21)	596
CAH	438 (32)	915 (68)	1,353
HHA	4,095 (36)	7,439 (64)	11,534
Hospice	2,238 (47)	2,560 (53)	4,798
ASC	1,699 (30)	3,999 (70)	5,698
OPT	204 (10)	1,810 (90)	2,014
RHC	585 (13)	3,753 (87)	4,338
Total	13,137 (38)	21,334 (62)	34,471

*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 5/29/2019.

Graph 1
Deemed & Non-Deemed Medicare-Participating Facilities
Program Types with a Medicare Accreditation Program Option
FY 2018



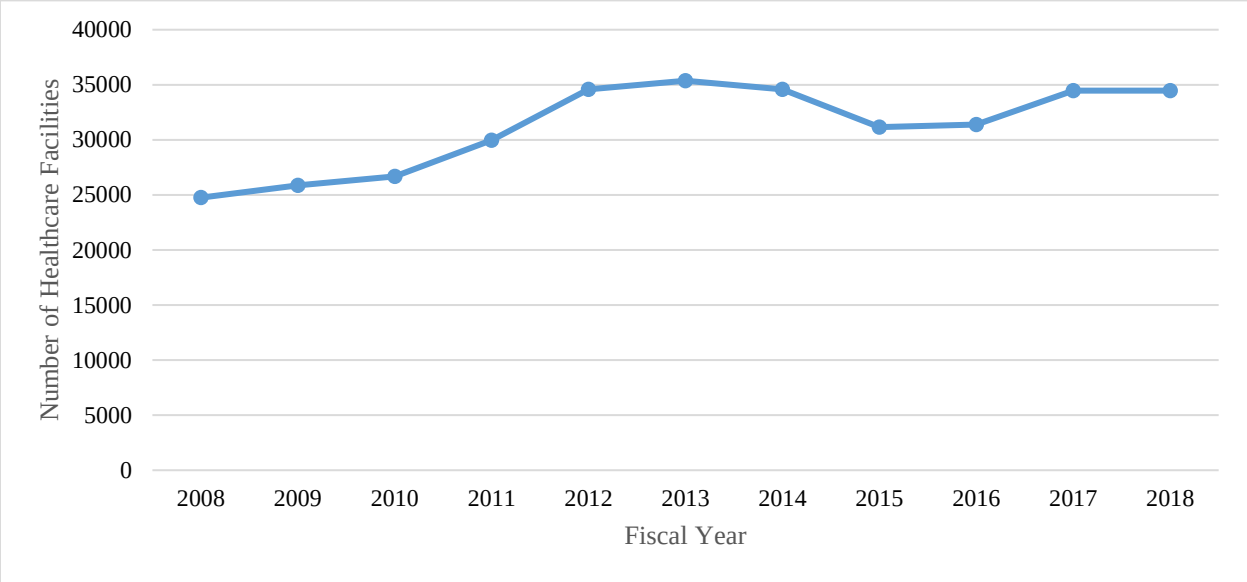
*As reported by AOs in ASSURE.
**Surveyed by an SA for compliance with Medicare conditions.
***As reported in QIES/CASPER and QIES/ASSURE 5/29/2019.

In FY 2018, 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 10 percent for OPTs. 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 across all program types has increased 39 percent from 24,752 in FY 2008 to 34,471 in FY 2018. (See Graph 2.) 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 84 percent from 7,128 in FY 2008 to 13,137 in FY 2018.

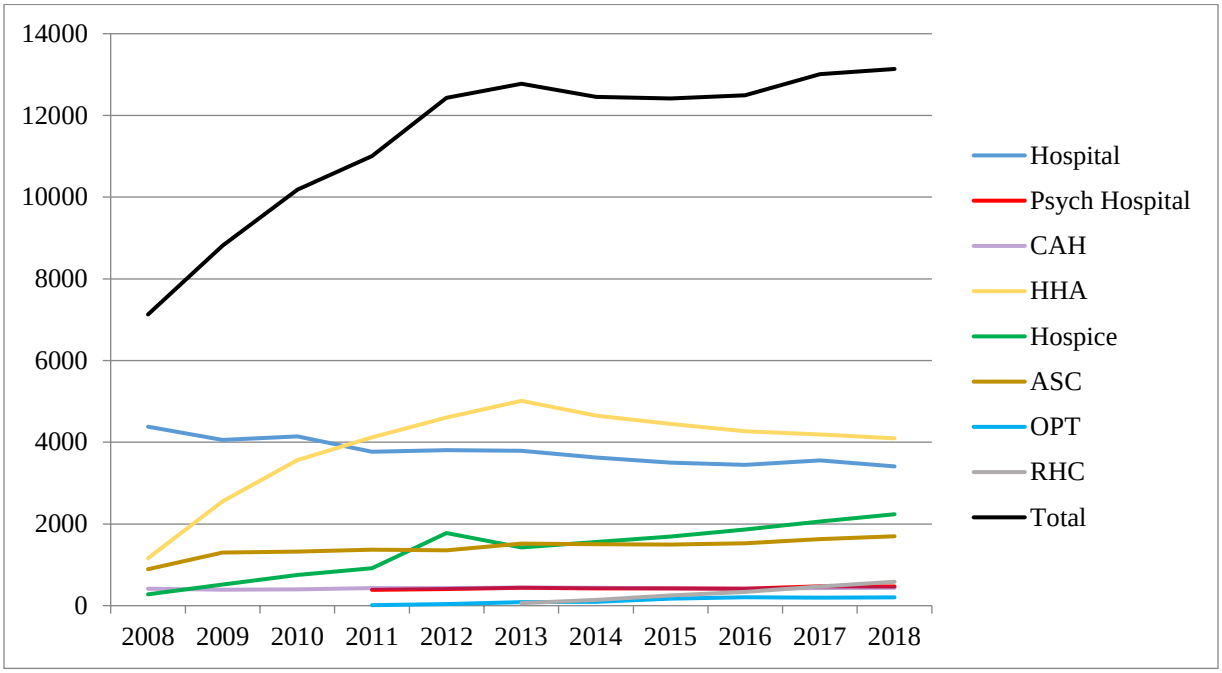
Graph 2
Medicare-Participating Health Care Facilities
FYs 2008–2018



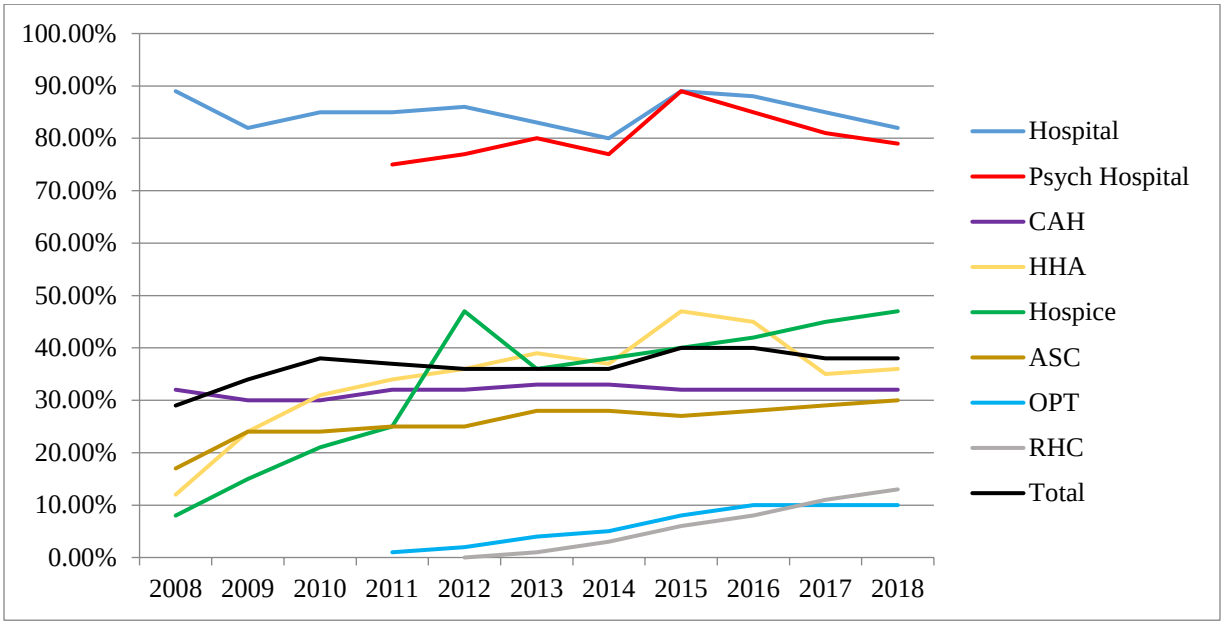
The growth in the number of deemed facilities is likely attributable, in part, to CMS' workload priorities for SAs. The long-standing CMS policy for SAs has been that initial surveys for newly enrolling facilities with an approved accreditation option have a lower priority as compared to statutorily 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 eight program types for which there is currently more than 1 year of data.

Graph 3
Number of Deemed Facilities by Program Type
FYs 2008–2018



Graph 4
Deemed Facilities as Percentage of Medicare-Participating Facilities by Program Type
FYs 2008-2018



- **Total:** Since the introduction of the original AO Medicare accreditation programs (hospitals, CAHs, HHAs, hospices, and ASCs), three 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. Although the number of Medicare-participating facilities increased 39 percent, the growth in deemed facilities during that same period was much larger.
  - From FY 2008 to FY 2017, the number of facilities participating in Medicare via deemed status increased from 7,128 to 13,013, an 83-percent increase.
  - From FY 2017 to FY 2018, the number of facilities participating in Medicare via deemed status increased slightly from 13,013 to 13,137, a 1-percent increase.
  - The SAs continue to survey and monitor the majority of Medicare-participating facilities. However, the proportion of facilities participating in Medicare via their accreditation from a CMS-approved Medicare accreditation program and deemed status has grown from 29 percent to 38 percent.

- **Hospital:** The number of Medicare-participating hospitals was largely unchanged between FYs 2008 and 2018. 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 2017, the number of deemed hospitals decreased from 4,381 to 3,557, a decrease of 19 percent.
  - From FY 2017 to FY 2018, the number of deemed hospitals decreased from 3,557 to 3,409, a 4-percent decrease.
  - The proportion of all Medicare-participating hospitals that were deemed decreased by 3 percent from FY 2017 to FY 2018.

- **Psychiatric Hospital:** The number of Medicare-certified psychiatric hospitals increased from 516 in FY 2011 to 596 in FY 2018, a 16-percent increase.
  - From FY 2011 to FY 2017, the number of deemed psychiatric hospitals increased from 388 to 474, a 22-percent increase.
  - From FY 2017 to FY 2018, the number of deemed psychiatric hospitals decreased from 474 to 469, a 1-percent decrease.
  - The proportion of all Medicare- participating psychiatric hospitals which were deemed increased from 75 percent in FY 2011 to 79 percent in FY 2018.

- **CAH:** The number of Medicare-certified CAHs was increased slightly from 1,310 in FY 2008 to 1,353 in FY 2018, a 3-percent increase.
  - From FY 2008 to FY 2017, the number of deemed CAHs increased slightly from 415 to 432, a 4-percent increase.
  - From FY 2017 to FY 2018, the number of deemed CAHs increased slightly from 432 to 438, a 1-percent increase.
  - The proportion of all Medicare-certified deemed CAHs remained at 32 percent in FY 2018.

[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.

- **HHA:** The number of Medicare-certified HHAs increased from 9,893 in FY 2008 to 11,534 in FY 2018, a 17-percent increase.
  - From FY 2008 to FY 2017, the number of deemed HHAs increased from 1,161 to 4,191, a 268-percent increase.
  - From FY 2017 to FY 2018, the number of deemed HHAs decreased from 4,191 to 4,095, a 2-percent decrease.
  - The proportion of all Medicare-certified HHAs which were deemed tripled from 12 percent in FY 2008 to 36 percent in FY 2018.

- **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 4,798 in FY 2018, a 42-percent increase. There has also been corresponding significant growth in the number and proportion of deemed hospices.
  - From FY 2008 to FY 2017, the number of deemed hospices increased from 278 to 2,058, a 640-percent increase.
  - From FY 2017 to FY 2018, the number of deemed hospices increased from 2,058 to 2,238, a 9-percent increase.
  - The proportion of all Medicare-certified hospices which were deemed increased five-fold from 8 percent in FY 2008 to 47 percent in FY 2018.

- **ASC:** The number of Medicare-certified ASCs increased from 5,217 in FY 2008 to 5,698 in FY 2018, a 9-percent increase.
  - From FY 2008 to FY 2017, the number of deemed ASCs increased significantly from 893 to 1,631, an 83-percent increase.
  - From FY 2017 to FY 2018, the number of deemed ASCs increased slightly from 1,631 to 1,699, a 4-percent increase.
  - The proportion of all Medicare-certified ASCs which were deemed increased from 17 percent in FY 2008 to 30 percent in FY 2018.

- **OPT:** The number of Medicare-certified OPTs decreased from 2,471 in FY 2011 to 2,014 in FY 2018, an 18-percent decrease.
  - From FY 2011 to FY 2017, the number of deemed OPTs increased from 13 to 197, a 1,415-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 2017 to FY 2018, the number of deemed OPTs increased slightly from 197 to 204, a 4-percent increase.
  - The proportion of all Medicare-certified OPTs which were deemed increased from 1 percent in FY 2011 to 10 percent in FY 2018.

- **RHC:** The number of Medicare-certified RHCs increased from 4,108 in FY 2012 to 4,338 in FY 2018, a 6-percent increase.
  - From FY 2012 to FY 2017, the number of deemed RHCs increased from 3 to 473, a 15,667-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 2017 to FY 2018, the number of deemed RHCs increased from 473 to 585, a 24-percent increase.
  - The proportion of all Medicare-certified RHCs which were deemed increased from less than 1 percent in FY 2012 to 13 percent in FY 2018.

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; 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. A "standard-level" deficiency means that the provider 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) 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 2018, the AOs reported having performed 1,699 initial surveys and 4,328 renewal surveys. The total number of deemed status facilities in FY 2018 was 13,164. The total number of facilities denied was 309. (See Table 5.)

Table 5
Total Number of Deemed Facilities
Initial Surveys and Renewal Surveys and
Denials by AO Accreditation Program
FY 2018

Program Type/ AOs	Total Deemed Facilities	Initial Surveys	Renewal Surveys	Denials
Hospital				
AAHHS/HFAP	107	3	29	2
CIHQ	48	11	16	1
DNV GL	292	33	100	5
TJC	2,974	32	1,134	7
Hospital Total	**3,421**	**79**	**1,279**	**15**
Psychiatric Hospital				
TJC	469	23	153	4
Psychiatric Hospital Total	**469**	**23**	**153**	**4**
CAH				
AAHHS/HFAP	22	2	9	2
DNV GL	95	29	20	7
TJC	324	9	133	2
CAH Total	**441**	**40**	**162**	**11**
HHA				
ACHC	897	237	174	44
CHAP	1,672	155	529	43
TJC	1,536	130	741	27
HHA Total	**4,105**	**522**	**1,444**	**114**
Hospice				
ACHC	418	171	43	24
CHAP	746	118	224	30
TJC	1,074	193	376	28
Hospice Total	**2,238**	**482**	**643**	**82**
ASC				
AAAASF	192	29	54	8
AAAHC	840	134	219	33
AAHHS/HFAP	24	4	10	1
IMQ	25	21	0	3

Program Type/ AOs	Total Deemed Facilities	Initial Surveys	Renewal Surveys	Denials
TJC	620	117	165	14
ASC Total	**1,701**	**305**	**448**	**59**
OPT				
AAAASF	204	48	93	13
OPT Total	**204**	**48**	**93**	**13**
RHC				
AAAASF	257	73	75	3
TCT	328	127	31	8
RHC Total	**585**	**200**	**106**	**11**
Total	**13,164**	**1,699**	**4,328**	**309**

Source: As reported by the AOs in ASSURE.

Note: The total number of deemed facilities in this table includes 27 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 Quality Improvement Evaluation System (QIES) infrastructure for network access; ensures that data conforms to the national data structures framework; and allows for Certification and Survey Provider Enhanced Reports (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 2018 Accrediting Organization Performance Measures

In FY 2018, AOs were scored on their performance on 7 measures in 3 key performance focus areas: ASSURE Database, Facility Notification Letters, and Survey Schedule. In FY 2018, no measures were retired, and no new measures were implemented. (See Table 6.)

Table 6
AO Performance Measures
FY 2018

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 • The number of surveys with final survey decisions > 5 months
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 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 2017 and FY 2018 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 2017–2018

Performance Measure Results (Percentage) for All Accrediting Organizations Comparable Measures FY 2018 ganizations Comparable 2016	FY 2017	FY 2018
Denied initial survey with condition-level findings	98	95
Timeliness of facility notification of survey results	97	96
Timeliness of notifying CMS of withdrawals	91	93
No pending survey > 5 months	100	100
Notification letters contain all required information	97	92
ASSURE is updated consistent with the letters	89	85
Number of surveys performed matches number reported in ASSURE	98	99

Note: IMQ's Medicare accreditation program was initially approved April 29, 2016, and IMQ didn't have data to calculate in FY 2017. In FY 2018, IMQ didn't have data to calculate the measure "Timeliness of notifying CMS of withdrawals."

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 2017, three of the AOs excelled on the measure "Denied initial survey with condition-level findings." Two of the AOs performed well scoring 95 percent and 99 percent respectively. One AO showed opportunity for improvement, scoring 91 percent. One AO didn't have any data to calculate. Three of the AOs had sample sizes less than five; therefore, couldn't calculate a score for this measure. In FY 2018, five of the AOs scored 100 percent on the same measure. One AO performed well scoring 95 percent. Two of the AOs demonstrated opportunity for improvement scoring 75 percent and 83 percent respectively. (See Table 8.)

Table 8
"Denied Initial Surveys with Condition-Level Findings"
Performance Measure Results for All AOs by Scoring Definition
FYs 2017–2018

Scoring Definitions	FY 2017 AOs	FY 2018 AOs
Excelled	• AAAHC • ACHC • TCT	• AAAHC • AAHHS/HFAP • ACHC • CHAP • TCT
Performed Well	• AAAASF • TJC	• AAAASF
Opportunity for Improvement	• CHAP	• DNV GL • TJC
No Data or Sample Size <5	• IMQ • AAHHS/HFAP • CIHQ • DNV GL	• CIHQ • IMQ

2. Timely Facility Notification of Survey Results

In FY 2017, four AOs scored 100 percent for the measure "Timeliness of facility notification of survey results." Two of the AOs performed well scoring 97 percent and 99 percent respectively. However, three of the AOs demonstrated opportunity for improvement with two AOs scoring 93 percent and the third AO scoring 92 percent. One AO didn't have any data to calculate this measure. In FY 2018, three of the AOs excelled, scoring 100 percent for the same measure. 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. (See Table 9.)

Table 9
"Timely Facility Notification of Survey Results"
Performance Measure Results for All AOs by Scoring Definition
FYs 2017–2018

Scoring Definitions	FY 2017 AOs	FY 2018 AOs
Excelled	• AAAASF • ACHC • AAHHS/HFAP • TJC	• ACHC • CIHQ • TJC
Performed Well	• CHAP • TCT	• AAAASF • AAHHS/HFAP • DNV GL • TCT
Opportunity for Improvement	• AAAHC • CIHQ • DNV GL	• AAAHC • CHAP • IMQ
No Data or Sample Size <5	• IMQ	*NA

*NA: In FY 2018, 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 2017, one of the AOs excelled on the measure "CMS notified timely of withdrawals." Two of the AOs performed well, scoring 96 percent and 97 percent respectively. Four of the AOs demonstrated opportunity for improvement with scores ranging from 81 percent to 93 percent. Two of the AOs did not have sufficient samples sizes to calculate this measure. One of the AOs did not have data available to complete the calculation. In FY 2018, four of the AOs scored 100 percent on the same measure. 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. One AO 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. (See Table 10.)

Table 10
"CMS Notified Timely of Withdrawals"
Performance Measure Results for All AOs by Scoring Definition
FYs 2017–2018

Scoring Definitions	FY 2017 AOs	FY 2018 AOs
Excelled	• AAHHS/HFAP	• ACHC • AAHHS/HFAP • DNV GL • TJC
Performed Well	• AAAASF • ACHC	• AAAASF
Opportunity for Improvement	• AAAHC • CHAP • DNV GL • TJC	• AAAHC • CHAP • TCT
No Data or Sample Size <5	• CIHQ • IMQ • TCT	• CIHQ • IMQ

4. No Pending Survey > 5 Months

In FY 2017, nine of the AOs excelled on the measure, "No pending survey > 5 months." One of the AOs didn't have any data to calculate. In FY 2018, all ten AOs scored 100 percent on the same measure. (See Table 11.)

Table 11
"No Pending Survey > 5 Months"
Performance Measure Results for All AOs by Scoring Definition
FYs 2017–2018

Scoring Definitions	FY 2017 AOs	FY 2018 AOs
Excelled	• AAAASF • AAAHC • AAHHS/HFAP • ACHC • CHAP • CIHQ • DNV GL • TCT • TJC	• AAAASF • AAAHC • AAHHS/HFAP • ACHC • CHAP • CIHQ • DNV GL • IMQ • TCT • TJC
Performed Well	**NA	**NA
Opportunity for Improvement	***NA	***NA
No Data or Sample Size <5	• IMQ	*NA

*NA: In FY 2018, each of the AOs had data and met the required sample size (<5) to calculate the measure.
**NA: In FYs 2017-2018, none of the AOs performed well for the measure.
***NA: In FYs 2017-2018, none of the AOs showed opportunity for improvement for the measure.

Facility Notification Letters

1. Notification Letters Contain all Required Information

In FY 2017, three of the AOs excelled, scoring 100 percent for the measure "Letters contain all required information." Four of the AOs performed well with scores ranging from 96 percent to 99 percent. Two of the AOs showed opportunity for improvement with scores of 91 percent and 94 percent respectively. One AO didn't have any data to calculate this measure. In FY 2018, three of the AOs excelled for the same measure. 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. (See Table 12.)

Table 12
"Notification Letters Contain all Required Information"
Performance Measure Results for All AOs by Scoring Definition
FYs 2017–2018

Scoring Definitions	FY 2017 AOs	FY 2018 AOs
Excelled	• AAHHS/HFAP • ACHC • CHAP	• AAAASF • ACHC • DNV GL
Performed Well	• AAAASF • DNV GL • TCT • TJC	• AAHHS/HFAP • CHAP • TJC
Opportunity for Improvement	• AAAHC • CIHQ	• AAAHC • CIHQ • IMQ • TCT
No Data or Sample Size <5	• IMQ	*NA

*NA: In FY 2018, 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 2017, three of the AOs performed well for the measure "ASSURE is updated consistent with letters," with scores ranging from 95 percent to 98 percent. Six of the AOs showed opportunity for improvement with scores ranging from 63 percent to 94 percent. One AO didn't have any data to calculate this measure. In FY 2018, three of the AOs performed well for the same measure with scores again ranging from 95 percent to 98 percent. Seven of the AOs showed opportunity for improvement with scores ranging from 66 percent to 93 percent. (See Table 13.)

Table 13
"ASSURE is Updated Consistent with Letters"
Performance Measure Results for All AOs by Scoring Definition
FYs 2017–2018

Scoring Definitions	FY 2017 AOs	FY 2018 AOs
Excelled	**NA	**NA
Performed Well	• AAHHS/HFAP • ACHC • TCT	• AAHHS/HFAP • ACHC • DNV GL
Opportunity for Improvement	• AAAASF • AAAHC • CHAP • CIHQ • DNV GL • TJC	• AAAASF • AAAHC • CHAP • CIHQ • IMQ • TCT • TJC
No Data or Sample Size <5	• IMQ	*NA

*NA: In FY 2018, each of the AOs had data and met the required sample size (<5) to calculate the measure.

**NA: In FYs 2017-2018, none of the AOs excelled on the measure.

Survey Schedule

1. Number of Surveys Performed Matches Number Reported in ASSURE

In FY 2017, two of the AOs excelled, scoring 100 percent for the measure "Number of surveys performed matches number reported in ASSURE." Six of the AOs performed well with scores ranging from 95 percent to 99 percent. One of the AOs showed opportunity for improvement with a score of 94 percent. One AO didn't have any data to calculate this measure. In FY 2018, four of the AOs excelled for the same measure. 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. (See Table 14.)

Table 14
"Number of Surveys Performed Matches Number Reported in ASSURE"
Performance Measure Results for All AOs by Scoring Definition
FYs 2017–2018

Scoring Definitions	FY 2017 AOs	FY 2018 AOs
Excelled	• AAHHS/HFAP • DNV GL	• AAHHS/HFAP • ACHC • CIHQ • IMQ
Performed Well	• AAAASF • AAAHC • ACHC • CHAP • TCT • TJC	• AAAASF • CHAP • DNV GL • TCT • TJC
Opportunity for Improvement	• CIHQ	• AAAHC
No Data or Sample Size <5	• IMQ	*NA

*NA: In FY 2018, 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 2017 and FY 2018 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

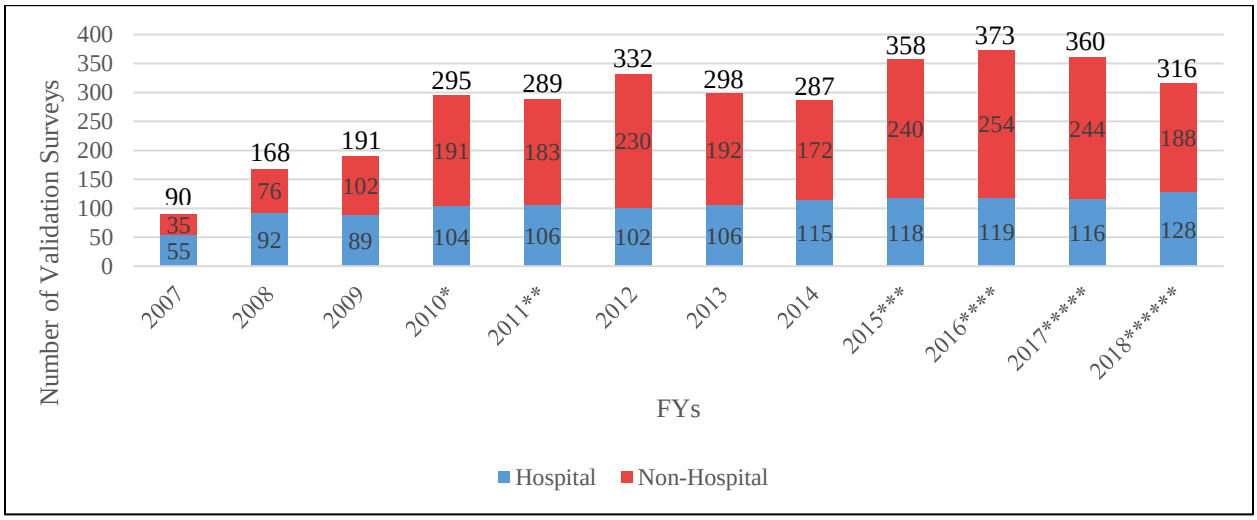
- Representative sample validation surveys – full surveys which are routinely performed for a representative sample of deemed facilities as part of the annual CMS-AO representative sample validation survey program. These surveys must be completed by the SA within 60 days of an AO full accreditation survey 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 2018, CMS conducted a total of 316 representative sample 60-day validation surveys for 6 facility types across AOs.[10] This total comprised 128 hospital surveys (including 21 psychiatric hospitals) and 188 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 2007-2018



*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.

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.

These numbers represent a 251-percent increase in the overall number of validation surveys conducted, from 90 in FY 2007 to 316 in FY 2018. During the same time period, the number of non-hospital validation surveys conducted increased by 437 percent, from 35 surveys in FY 2007 to 188 surveys in FY 2018. The number of hospital validation surveys conducted increased by 133 percent, from 55 surveys in FY 2007 to 128 surveys in FY 2018.

60-Day Validation Surveys

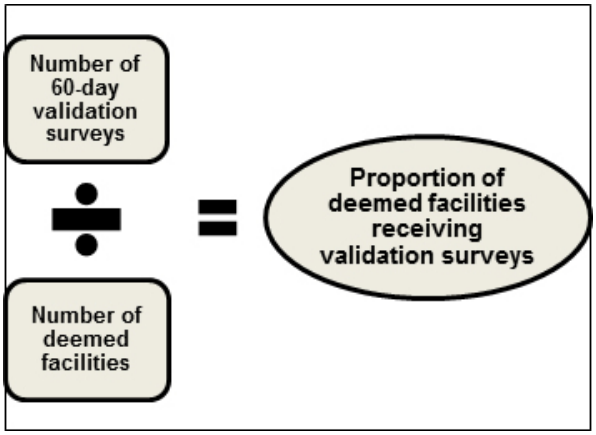
The purpose of 60-day validation surveys is to assess the AO's ability to ensure compliance with Medicare conditions. These validation surveys are on-site full surveys completed by SA surveyors no later than 60 days after the end date of an AO's Medicare accreditation program full survey. The SA performs 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

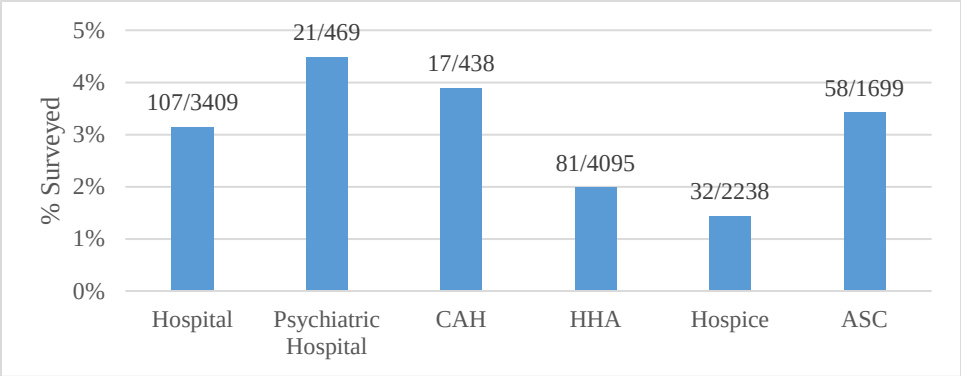


The proportion of deemed facilities that received a 60-day validation survey in FY 2018 is as follows:

- **Hospitals:** Three percent of deemed hospitals received a validation survey in FY 2018 (107 validation surveys conducted out of 3,409 deemed facilities).
- **Psychiatric Hospitals:** Four percent of deemed psychiatric hospitals received a validation survey in FY 2018 (21 validation surveys conducted out of 469 deemed facilities).
- **CAHs:** Four percent of deemed CAHs received a validation survey in FY 2018 (17 validation surveys conducted out of 438 deemed facilities).
- **HHAs:** Two percent of deemed HHAs received a validation survey in FY 2018 (81 validation surveys conducted out of 4,095 deemed facilities).
- **Hospices:** One percent of deemed hospices received a validation survey in FY 2018 (32 validation surveys conducted out of 2,238 deemed facilities).
- **ASCs:** Three percent of deemed ASCs received a validation survey in FY 2018 (58 validation surveys conducted out of 1,699 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 2018



Validation Analysis

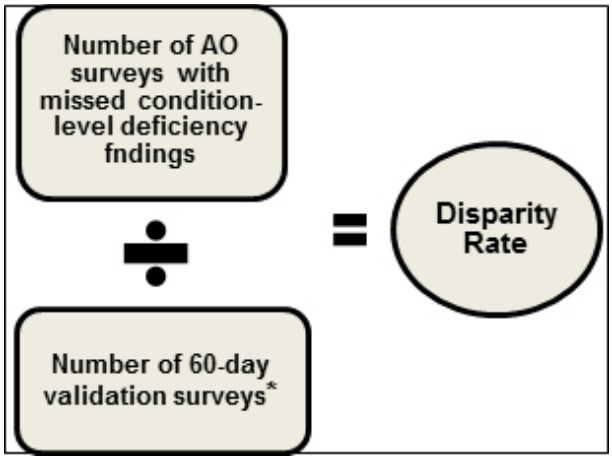
Condition-Level Deficiencies and Disparity Rate

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.

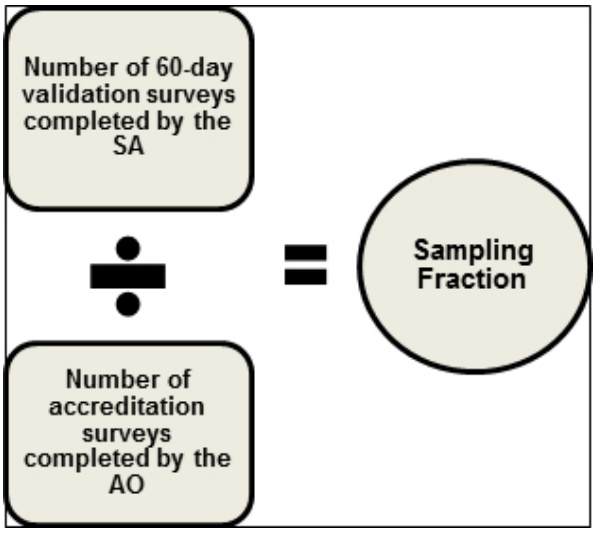
The methodology for the disparity rate is set by regulation at 42 CFR § 488.1. The numerator is the number of surveys where the AO did not cite a comparable serious (condition-level) deficiency as cited by the SA. The denominator is the total number of surveys in the 60-day representative validation 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 2016 through FY 2018 by facility type. (See Table 15.)

Table 15
60-Day Validation Survey Results for Each Facility Type
FYs 2016–2018

	FY 2016	FY 2017	FY 2018
HOSPITAL			
60-Day Validation Sample Surveys	98	95	107
SA Surveys with Condition-Level Deficiencies	50	47	57
AO Surveys with Missed Comparable Deficiencies	45	43	50
Disparity Rate	**46%**	**45%**	**47%**
Sampling Fraction	.07	.07	.08
PSYCHIATRIC HOSPITAL			
60-Day Validation Sample Surveys	21	21	21
SA Surveys with Condition-Level Deficiencies	12	14	13
AO Surveys with Missed Comparable Deficiencies	12	12	8
Disparity Rate	**57%**	**57%**	**38%**
Sampling Fraction	.11	.11	.12
CRITICAL ACCESS HOSPITAL			
60-Day Validation Sample Surveys	34	32	17
SA Surveys with Condition-Level Deficiencies	16	12	7
AO Surveys with Missed Comparable Deficiencies	15	11	7
Disparity Rate	**44%**	**34%**	**41%**
Sampling Fraction	.24	.19	.08

	FY 2016	FY 2017	FY 2018
HOME HEALTH AGENCY			
60-Day Validation Sample Surveys	110	106	81
SA Surveys with Condition-Level Deficiencies	23	16	17
AO Surveys with Missed Comparable Deficiencies	20	13	15
Disparity Rate	**18%**	**12%**	**19%**
Sampling Fraction	.06	.07	.04
HOSPICE			
60-Day Validation Sample Surveys	34	34	32
SA Surveys with Condition-Level Deficiencies	6	4	6
AO Surveys with Missed Comparable Deficiencies	6	4	5
Disparity Rate	**18%**	**12%**	**16%**
Sampling Fraction	.04	.04	.03
AMBULATORY SURGERY CENTER			
60-Day Validation Sample Surveys	75	72	58
SA Surveys with Condition-Level Deficiencies	28	33	28
AO Surveys with Missed Comparable Deficiencies	26	26	24
Disparity Rate	**35%**	**36%**	**41%**
Sampling Fraction	.11	.10	.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 2016–2018. 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 2017 to FY 2018, psychiatric hospitals had the only decrease in the disparity rate of all the program types, with a 19-percent decrease. The disparity rates for hospitals increased by 2 percent from FYs 2017 to 2018. The disparity rates for HHAs and hospices increased by 7 percent and 4 percent respectively from FY 2017 to FY 2018. The disparity rate for ASCs increased 5 percent from FY 2017 to FY 2018.

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 2016 to 2018. (See Tables 16-21.)

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 2016–2018 60-day validation surveys for individual AOs are outlined in the tables below by program type.

Hospital

The AOs with hospital programs in FY 2018 were AAHHS/HFAP, CIHQ, DNV GL, and TJC. (See Table 16.)

Table 16
Hospital 60-Day Validation Survey Results by AO
FYs 2016–2018

Emp	AAHHS/HFAP			CIHQ			DNV GL			TJC			Total
	FY 2016	FY 2017	FY 2018	FY 2016	FY 2017	FY 2018	FY 2016	FY 2017	FY 2018	FY 2016	FY 2017	FY 2018	FYs 2016–2018
60-Day Validation Sample Surveys	14	5	9	1	4	0	15	15	19	68	71	78	300
SA Surveys with Condition-Level Deficiencies	10	5	9	*N/A	*N/A	*N/A	5	4	6	34	34	42	149
AO Surveys with Missed Comparable Deficiencies	9	5	9	*N/A	*N/A	*N/A	5	4	5	30	30	36	133
Overall Disparity Rate	**64%**	**100%**	**100%**	***N/A**	***N/A**	***N/A**	**33%**	**27%**	**26%**	**44%**	**42%**	**46%**	**44%**
Health and Safety Disparity Rate	**14%**	**40%**	**56%**	***N/A**	***N/A**	***N/A**	**26%**	**13%**	**5%**	**25%**	**23%**	**27%**	**26%**
Physical Environment Disparity Rate	**64%**	**100%**	**44%**	***N/A**	***N/A**	***N/A**	**20%**	**13%**	**26%**	**25%**	**31%**	**26%**	**39%**
Sampling Fraction	.34	.10	.28	*N/A	*N/A	*N/A	.16	.15	.14	.06	.06	.07	.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 2018, the overall disparity rate was 100 percent based on the completion of nine validation surveys. The number of validation surveys conducted represents a 28-percent sample of the surveys conducted by AAHHS/HFAP. The FY 2018 overall disparity rate is 36 percentage points higher than the overall disparity rate from FY 2016. The FY 2018 sample size was slightly smaller compared to the FY 2016 sample size. The overall disparity rate for FY 2016 was based on a 34-percent sample of the surveys conducted during that period. In FY 2018, AAHHS/HFAP's health and safety disparity rate was 12 percentage points higher than the PE disparity rate. In FY 2018, the primary driver of AAHHS/HFAP's health and safety disparity rate was the Infection Control condition. The SAs cited the Infection Control requirement at the condition level four times. AAHHS/HFAP missed four comparable deficiencies resulting in a 44-percent disparity rate. The FY 2018 health and safety disparity rate is 42 percentage points higher than the FY 2016 health and safety disparity rate.

- **CIHQ:** In FY 2018, the State Agency did not conduct any validation surveys for CIHQ hospitals. Therefore, no additional data is reported.

- **DNV GL:** In FY 2018, the overall disparity rate was 26 percent based on the completion of 19 validation surveys. The number of validation surveys conducted represents a 14-percent sample of the surveys conducted by DNV GL. The FY 2018 overall disparity rate is 7 percentage points lower than the overall disparity rate for FY 2016. The FY 2016 overall disparity rate was based on a 16-percent sample of the surveys conducted during that period. In FY 2018, DNV GL's PE disparity rate was 21 percentage points higher than the health and safety disparity rate. In FY 2018, the SA cited PE at the condition level seven times. DNV GL missed five comparable deficiencies resulting in a 26-percent disparity rate. The FY 2018 PE disparity rate is 6 percentage points higher than the FY 2016 PE disparity rate.

- **TJC:** In FY 2018, the overall disparity rate was 46 percent based on the completion of 78 validation surveys. The number of validation surveys conducted represents a 7-percent sample of surveys conducted by TJC. The FY 2018 overall disparity rate is 2 percentage points higher than the overall disparity rate for FY 2016. The overall disparity rate in FY 2016 was based on a 6-percent sample of surveys conducted during that period. In FY 2018, TJC's health and safety disparity rate was 1 percentage point higher than the PE disparity rate. In FY 2018, 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 24 times. TJC missed 12 comparable deficiencies resulting in a 15-percent disparity rate. The FY 2018 health and safety disparity rate is 2 percentage points higher than the FY 2016 health and safety disparity rate.

Psychiatric Hospital

TJC was the only AO with a CMS-approved psychiatric hospital Medicare accreditation program in FY 2018. The psychiatric hospital program was initially approved by CMS in FY 2011. (See Table 17.)

Table 17
Psychiatric Hospital 60-Day Validation Survey Results by AO
FYs 2016–2018

				Total
	FY 2016	FY 2017	FY 2018	FYs 2016–2018
60-Day Validation Sample Surveys	21	21	21	63
SA Surveys with Condition-Level Deficiencies	12	14	13	39
AO Surveys with Missed Comparable Deficiencies	12	12	8	32
Overall Disparity Rate	**57%**	**57%**	**38%**	**51%**
Health and Safety Disparity Rate	**48%**	**43%**	**33%**	**41%**
Physical Environment Disparity Rate	**19%**	**38%**	**29%**	**29%**
Sampling Fraction	.11	.11	.12	.11

- **TJC:** In FY 2018, the overall disparity rate was 38 percent based on the completion of 21 validation surveys. The number of validation surveys completed represents a 12-percent sample of the surveys conducted by the TJC. The FY 2018 overall disparity rate is 19 percentage points lower than the overall disparity rate for FY 2016. The FY 2016 overall disparity rate was based on an 11-percent sample of the surveys conducted during that period. In FY 2018, 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 the Governing Body condition. The SAs cited the Governing Body requirement at the condition level six times. TJC missed five comparable deficiencies resulting in a 24-percent disparity rate. The FY 2018 health and safety disparity rate is 15 percentage points lower than the FY 2016 health and safety disparity rate.

Critical Access Hospital

The AOs with CAH accreditation programs in FY 2018 were AAHHS/HFAP, DNV GL, and TJC. (See Table 18.)

Table 18
CAH 60-Day Validation Survey Results
by AO
FYs 2016–2018

	AOA / HFAP			DNV GL			TJC			Total
	FY 2016	FY 2017	FY 2018	FY 2016	FY 2017	FY 2018	FY 2016	FY 2017	FY 2018	FYs 2016–2018
60-Day Validation Sample Surveys	2	3	1	2	6	5	30	23	11	83
SA Surveys with Condition-Level Deficiencies	*N/A	*N/A	*N/A	*N/A	1	2	13	10	4	30
AO Surveys with Missed Comparable Deficiencies	*N/A	*N/A	*N/A	*N/A	1	2	12	9	4	28
Overall Disparity Rate	***N/A**	***N/A**	***N/A**	***N/A**	**17%**	**40%**	**40%**	**39%**	**36%**	**34%**
Health and Safety Disparity Rate	***N/A**	***N/A**	***N/A**	***N/A**	**17%**	**40%**	**23%**	**9%**	**18%**	**21%**
Physical Environment Disparity Rate	***N/A**	***N/A**	***N/A**	***N/A**	**N/A**	**20%**	**33%**	**35%**	**27%**	**29%**
Sampling Fraction	*N/A	*N/A	*N/A	*N/A	.17	.10	.25	.19	.08	.16

*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 2018, due to the low number of deemed CAHs due for resurvey, only one validation survey was conducted. Therefore, no additional data is reported.

- **DNV GL:** In FY 2018, the overall disparity rate was 40 percent based on the completion of five validation surveys. The number of validation surveys conducted represents a 10-percent sample of the surveys conducted by DNV GL. The FY 2018 overall disparity rate is 23 percentage points higher than the overall disparity rate for FY 2017. The FY 2017 overall disparity rate was based on a 17-percent sample of surveys conducted during that period. In FY 2018, DNV GL's health and safety disparity rate was 20 percentage points higher than the PE disparity rate. In FY 2018, the primary drivers of DNV GL's health and safety disparity rate were as follows: Provision of Services; and Surgical Services. The SA cited the Provision of Services requirement at the condition level one time. DNV GL missed one comparable deficiency. The SA cited the Surgical Services requirement at the condition level two times. DNV GL missed one comparable deficiency. Both conditions yielded a 20-percent disparity rate. The FY 2018 health and safety disparity rate is 23 percentage points higher than the FY 2017 health and safety disparity rate. FY 2016 data wasn't comparable due to the small sample size.

- **TJC:** In FY 2018, the overall disparity rate was 36 percent based on the completion of 11 validation surveys. The number of validation surveys conducted represents an 8-percent sample of the surveys conducted by TJC. The FY 2018 overall disparity rate is 4 percentage points lower than the FY 2016 overall disparity rate. The FY 2016 overall disparity rate was based on a 25-percent sample of surveys conducted during that period. In FY 2018, the PE disparity rate was 9 percentage points higher than the health and safety disparity rate. The SA cited PE at the condition level six times. TJC missed three comparable deficiencies resulting in a 27-percent disparity rate. The FY 2018 PE disparity rate is 6 percentage points lower than the FY 2016 PE disparity rate.

Home Health Agency

The AOs with HHA accreditation programs in FY 2018 were ACHC, CHAP, and TJC. (See Table 19.)

Table 19
HHA 60-Day
Validation Survey Results by AO
FYs 2016–2018

	ACHC			CHAP			TJC			Total
	FY 2016	FY 2017	FY 2018	FY 2016	FY 2017	FY 2018	FY 2016	FY 2017	FY 2018	FYs 2016–2018
60-Day Validation Sample Surveys	14	22	12	55	45	36	41	39	33	297
SA Surveys with Condition-Level Deficiencies	6	4	2	12	7	6	5	5	9	56
AO Surveys with Missed Comparable Deficiencies	3	3	2	12	6	6	5	4	7	48
Overall Disparity Rate	**21%**	**14%**	**17%**	**22%**	**13%**	**17%**	**12%**	**10%**	**21%**	**16%**
Sampling Fraction	.06	.08	.03	.07	.08	.05	.06	.06	.04	.06

- **ACHC:** In FY 2018, the overall disparity rate was 17 percent based on the completion of 12 validation surveys. The number of validation surveys completed represents a 3-percent sample of surveys conducted by ACHC. The FY 2018 overall disparity rate is 4 percentage point lower than the overall disparity rate of FY 2016. The FY 2016 overall disparity rate was based on a 6-percent sample of surveys conducted during that period. In FY 2018, the primary driver of ACHC's overall disparity rate was the Skilled Professional Services condition. The SA cited this requirement at the condition level three times. ACHC missed two comparable deficiencies resulting in a disparity rate of 17 percent.

- **CHAP:** In FY 2018, the overall disparity rate was 17 percent based on the completion of 36 validation surveys. The number of validation surveys completed represents a 5-percent sample of the surveys conducted by CHAP. The FY 2018 overall disparity rate is 5 percentage points lower than the overall disparity rate for FY 2016. The overall disparity rate for FY 2016 was based on a 7-percent sample of surveys conducted during that period. In FY 2018, each condition cited by the SA yielded a 3-percent disparity rate.

- **TJC:** In FY 2018, the overall disparity rate was 21 percent based on the completion of 33 validation surveys. The number of validation surveys completed represents a 4-percent sample of the surveys conducted by TJC. The FY 2018 overall disparity rate is 9 percentage points higher than the overall disparity rate for FY 2016. The overall disparity rate for FY 2016 was based on a 6-percent sample of surveys conducted during that period. In FY 2018, the primary drivers of TJC's overall disparity rate were Patient Rights; Care Planning, Coordination, and Quality of Care; and Home Health Aide Services. The SA cited the Patient Rights requirement at the condition level four times. TJC missed two comparable deficiencies. The SA cited the Care Planning, Coordination, and Quality of Care requirement at the condition level five times. TJC missed two comparable deficiencies. The SA cited the Home Health Aide Services requirement at the condition level two times. TJC missed both comparable deficiencies. Each of the conditions yielded a 6-percent disparity rate

Hospice

The AOs with hospice accreditation programs in FY 2018 were ACHC, CHAP and TJC. (See Table 20.)

Table 20
Hospice 60-Day Validation Survey Results
by AO
FYs 2016–2018

	ACHC			CHAP			TJC			Total
	FY 2016	FY 2017	FY 2018	FY 2016	FY 2017	FY 2018	FY 2016	FY 2017	FY 2018	FYs 2016-2018
60-Day Validation Sample Surveys	3	3	8	19	17	17	12	14	7	100
SA Surveys with Condition-Level Deficiencies	*N/A	*N/A	1	3	2	4	2	2	1	15
AO Surveys with Missed Comparable Deficiencies	*N/A	*N/A	0	3	2	4	2	2	1	14
Overall Disparity Rate	***N/A**	***N/A**	**0%**	**16%**	**12%**	**24%**	**17%**	**14%**	**14%**	**14%**
Sampling Fraction	*N/A	*N/A	.04	.06	.06	.05	.03	.04	.01	.06

*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 2018, the overall disparity rate was 0 percent based on the completion of eight validation surveys. The number of validation surveys completed represents a 4-percent sample of the surveys conducted by ACHC. Due to the low number of deemed hospices due for resurvey in FYs 2016 and 2017, only three validation surveys were conducted during each of those times. Therefore, no additional data is reported.

- **CHAP:** In FY 2018, the overall disparity rate was 24 percent based on the completion of 17 validation surveys. The number of validation surveys completed represents a 5-percent sample of the surveys conducted by CHAP. The FY 2018 overall disparity rate is 8 percentage points higher than the overall disparity rate for FY 2016. The overall disparity rate for FY 2016 was based on a 6-percent sample of surveys conducted during that period. In FY 2018, the primary drivers of CHAP's overall disparity rate were Quality Assessment & Performance Improvement; IDG, Care Planning, Coordination of Service; and Hospice Aide and Homemaker Services. The SA cited the Quality Assessment & Performance Improvement and IDG, Care Planning, Coordination of Service requirements at the condition level two times. CHAP missed both comparable deficiencies for each of the requirements resulting in a disparity rate of 12 percent. The SA cited the Hospice Aide and Homemaker Services requirement at the condition level three times. CHAP missed two comparable deficiencies yielding a 12-percent disparity rate.

- **TJC:** In FY 2018, the overall disparity rate was 14 percent based on the completion of seven validation surveys. The number of validation surveys completed represents a 1-percent sample of the surveys performed by TJC. The FY 2018 overall disparity rate is 3 percentage points lower than the overall disparity rate for FY 2016. The overall disparity rate for FY 2016 was based on a 3-percent sample of the surveys conducted during that period. In FY 2018, one condition was cited by the SAs at the condition level. The Infection Control requirement was cited by the SAs two times. TJC missed one comparable deficiency resulting in a 14-percent disparity rate.

Ambulatory Surgery Center

The AOs with ASC accreditation programs in FY 2018 were AAAASF, AAAHC, AAHHS/HFAP, IMQ and TJC. (See Table 21.)

Table 21
ASC 60-Day
Validation Survey Results by AO
FYs 2016–2018

	AAAASF			AAAHC			AAHHS/HFAP**			TJC			Total
	FY 2016	FY 2017	FY 2018	FY 2016	FY 2017	FY 2018	FY 2016	FY 2017	FY 2018	FY 2016	FY 2017	FY 2018	FYs 2016–2018
60-Day Validation Sample Surveys	6	6	7	35	35	30	0	0	0	34	31	21	205
SA Surveys with Condition-Level Deficiencies	2	4	4	15	12	12	*N/A	*N/A	*N/A	11	17	12	89
AO Surveys with Missed Comparable Deficiencies	2	4	4	14	8	11	*N/A	*N/A	*N/A	10	14	9	76
Overall Disparity Rate	**33%**	**67%**	**57%**	**40%**	**23%**	**37%**	***N/A**	***N/A**	***N/A**	**29%**	**45%**	**43%**	**37%**
Health and Safety Disparity Rate	**17%**	**50%**	**57%**	**26%**	**11%**	**30%**	***N/A**	***N/A**	***N/A**	**24%**	**35%**	**14%**	**23%**
Physical Environment Disparity Rate	**33%**	**33%**	**29%**	**17%**	**14%**	**20%**	***N/A**	***N/A**	***N/A**	**18%**	**26%**	**33%**	**25%**
Sampling Fraction	.06	.08	.08	.10	.10	.08	*N/A	*N/A	*N/A	.15	.13	.07	.10

*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 FY 2018.

- **AAAASF:** In FY 2018, the overall disparity rate was 57 percent based on the completion of seven validation surveys. The number of validation surveys completed represents an 8-percent sample of the surveys performed by AAAASF. The FY 2018 overall disparity rate is 24 percentage points higher than the overall disparity rate for FY 2016. The overall disparity rate for FY 2016 was based on a 6-percent sample of the surveys conducted during that period. In FY 2018, AAAASF's health and safety disparity rate was 28 percentage points higher than the PE disparity rate. The primary drivers for AAAASF's health and safety disparity rate were Infection Control; Governing Body and Management; Quality Assessment and Performance Improvement; and Medical Staff. The SA cited each of the requirements at the condition level three times. In each instance, AAAASF missed three comparable deficiencies resulting in a disparity rate of 43 percent. The FY 2018 health and safety disparity rate is 40 percentage points higher than the FY 2016 health and safety disparity rate.

- **AAAHC:** In FY 2018, the overall disparity rate was 37 percent based on the completion of 30 validation surveys. The number of validation surveys completed represents an 8-percent sample of the surveys performed by AAAHC. The FY 2018 overall disparity rate is 3 percentage points lower than the overall disparity rate for FY 2016. The overall disparity rate for FY 2016 was based on a 10-percent sample of the surveys conducted during that period. In FY 2018, AAAHC's health and safety disparity rate was 10 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 nine times. AAAHC missed five comparable deficiencies resulting in a disparity rate of 17 percent. The FY 2018 health and safety disparity rate is 4 percentage points higher than the FY 2016 health and safety disparity rate.

- **AAHHS/HFAP:** Due to the consistently low number of deemed AAHHS/HFAP ASCs, no validation surveys were conducted in FY 2018. Therefore, no additional data is reported.

- **TJC:** In FY 2018, the overall disparity rate was 43 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 2018 overall disparity rate is 14 percentage points higher than the overall disparity rate for FY 2016. The disparity rate for FY 2016 was based on a 15-percent sample of surveys conducted during that period. In FY 2018, TJC's PE disparity rate was 19 percentage points higher than the health and safety disparity rate. The SA cited PE at the condition level 14 times. TJC missed seven comparable deficiencies resulting in a disparity rate of 33 percent. The FY 2018 PE disparity rate is 15 percentage points higher than the FY 2016 PE 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.

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 22-27 and Graphs 7-14.)

Table 22
Number and Type of Condition-Level Deficiencies
Cited on 60-Day Validation Surveys
Hospitals
FY 2018

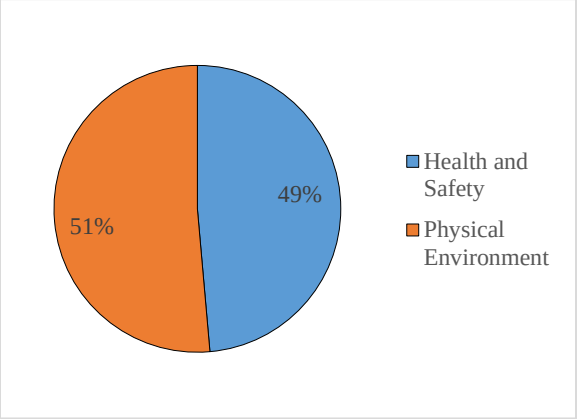
Medicare Conditions* Sample Size - 107	Cited by SA	Missed by AO
Physical Environment*	**55**	**28**
Infection Control	29	17
Governing Body	17	10
QAPI	6	5
Food and Dietetic Services	6	5
Pharmaceutical Services	5	4
Patient Rights	5	3
Surgical Services	5	3
Nursing Services	4	2
Organ, Tissue, and Eye Procurement	2	2
Anesthesia Services	2	2
Compliance with Laws	1	1
Establishment of the Emergency Program	1	1
Emergency Services	1	1
TOTAL	139	84

*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.

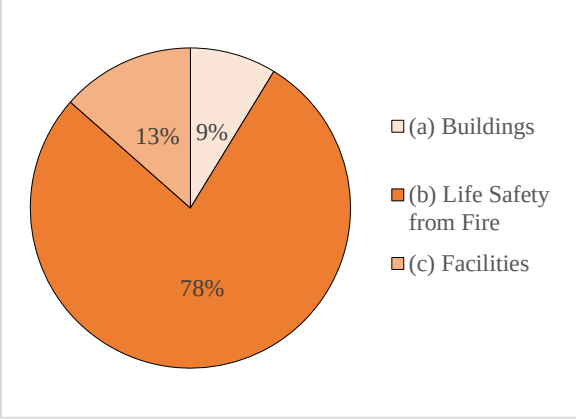
In FY 2018, the hospital sample consisted of 107 validation surveys. In this sample, the SAs cited condition-level deficiencies in 57 facilities. The PE CoP was the primary driver of the hospital disparity rate. The SAs cited PE at the condition level 55 times. The AOs missed 28 comparable deficiencies for PE. The findings were similar in FYs 2012–2017.

In FY 2018, the next most frequently SA-cited conditions were as follows: Infection Control, cited 29 times by the SAs, and missed 17 times by the AOs; and Governing Body, cited 17 times by the SAs, and missed 10 times by the AOs.

Graph 7
Percentage of Health and Safety vs PE Condition-Level Deficiencies Cited on 60-Day Validation Surveys
Hospitals
FYs 2016–2018



Graph 8
Percentage of PE Standards Cited on 60-Day
Validation Surveys
Hospitals
FYs 2016–2018



From FY 2016 to FY 2018, there were 154 validation surveys cited with condition-level deficiencies for hospitals. Of the 154 surveys, 87 of the surveys had health and safety citations, 92 of the surveys had PE citations, and 25 of the surveys were cited with both. For hospitals, the PE condition consists of three standards: (a) Buildings, (b) Life Safety from Fire, and (c) Facilities. There were 126 standards cited for the PE condition and 98 of these standards were related to Life Safety from Fire.

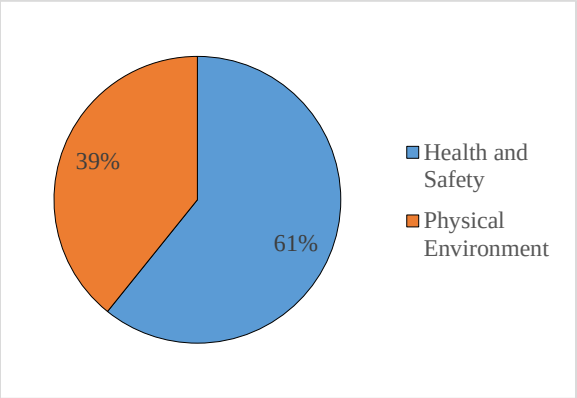
Table 23
Number and Type of Condition-Level Deficiencies
Cited on 60-Day Validation Surveys
Psychiatric Hospitals
FY 2018

Medicare Conditions Sample Size – 21	Cited by SA	Missed by AO
Physical Environment	11	6
Special Medical Record Reqs for Psych Hospitals	11	3
Infection Control	7	4
Governing Body	6	5
Food and Dietetic Services	5	3
Nursing Services	3	2
Patient Rights	1	1
QAPI	1	1
Radiologic Services	1	1
TOTAL	46	26

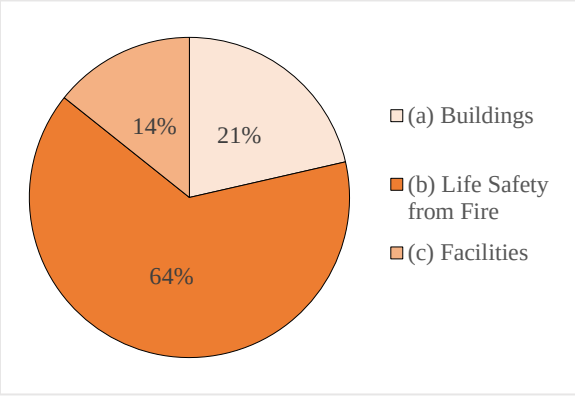
In FY 2018, the psychiatric hospital sample consisted of 21 validation surveys. In this sample, the SAs cited 13 facilities at the condition level. The primary drivers of the psychiatric hospital disparity rate were the following conditions: Physical Environment, cited 11 times by the SAs, and missed six times by the AOs; and Special Medical Record Requirements for Psychiatric Hospitals, cited 11 times by the SAs, and missed three times by the AOs. The Physical Environment condition was the primary driver for the psychiatric hospital disparity rate in FY 2017. In FY 2016, Special Medical Record Requirements for Psychiatric Hospitals was the primary driver of the disparity rate.

In FY 2018, the next most frequently SA-cited condition for psychiatric hospitals was Infection Control, cited seven times by the SAs, and missed four 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 2016–2018



Graph 10
Percentage of PE Standards Cited on 60-Day
Validation Surveys
Psychiatric Hospitals
FYs 2016–2018



From FY 2016 to FY 2018, there were 39 validation surveys cited with condition-level deficiencies for psychiatric hospitals. Of the 39 surveys, 32 of the surveys had health and safety citations, 20 of the surveys had PE citations, and 13 of the surveys were 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 24
Number and Type of Condition-Level Deficiencies
Cited on 60-Day Validation Surveys
CAHs
FY 2018

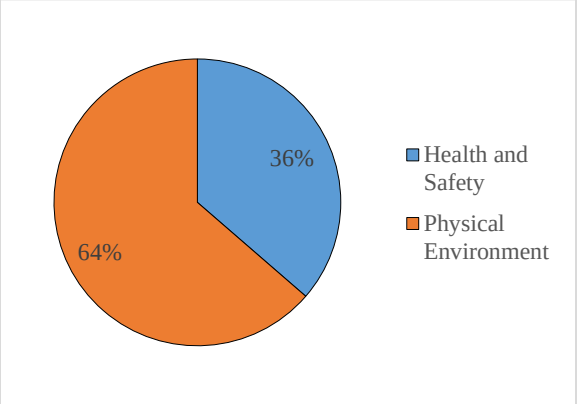
Medicare Conditions Sample Size – 17	Cited by SA	Missed by AO
Physical Plant and Environment*	**9**	**5**
Provision of Services	3	2
Emergency Services	1	1
Establishment of the Emergency Program	1	1
Surgical Services	2	1
TOTAL	16	10

*Most frequently cited deficiency

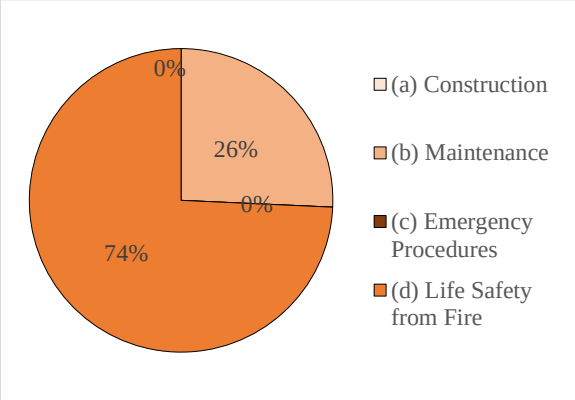
In FY 2018, the CAH sample consisted of 17 validation surveys. In this sample, seven facilities were cited at the condition level by the SAs. Physical Plant and Environment was the primary driver of the disparity rate. The SAs cited this requirement at the condition level nine times. The AOs missed five comparable deficiencies for PE, which was also the most frequently cited condition in FYs 2012–2017.

In FY 2018, the next most frequently SA-cited condition for CAHs was Provision of Services, cited three times by the SAs, and missed two times by the AOs.

Graph 11
Percentage of Health and Safety vs PE Condition-Level Deficiencies Cited on 60-Day Validation Surveys
CAHs
FYs 2016–2018



Graph 12
Percentage of PE Standards Cited on 60-Day
Validation Surveys
CAHs
FYs 2016–2018



From FY 2016 to FY 2018, there were 35 validation surveys cited with condition-level deficiencies for CAHs. Of the 35 surveys, 16 of the surveys had health and safety citations, 28 of the surveys had PE citations, and 9 of the surveys were 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. Thirty-five standards were cited for the PE condition and 26 of these standards were related to Life Safety from Fire.

Table 25
Number and Type of Condition-Level Deficiencies
Cited on 60-Day Validation Surveys
HHAs
FY 2018

Medicare Conditions Sample Size – 81	Cited by SA	Missed by AO
Care Planning, Coordination, and Quality of Care*	**9**	**4**
Skilled Professional Services	6	4
Clinical Records	4	3
Home Health Aide Services	4	3
Acceptance of Patients, POC, Med Super	4	2
Skilled Nursing Service	2	2
Patient Rights	4	2
Comprehensive Assessment of Patients	3	2
Organization and Administration of Services	1	1
Organization, Services & Administration	1	1
Establishment of Emergency Program	3	1
Home Health Aide Services	2	1
Quality Assessment/Performance Improvement	1	1
Clinical Records	1	0
TOTAL	45	27

*Most frequently cited deficiency

In FY 2018, the HHA sample consisted of 81 validation surveys. In this sample, the SAs cited condition-level deficiencies in 17 agencies. The primary driver of the HHA disparity rate was the Care Planning, Coordination, and Quality of Care condition, cited nine times by the SAs, and missed four times by the AOs. In FY 2017, the primary driver of the HHA disparity rate was the Skilled Nursing Services condition. Acceptance of Patients, Plan of Care & Medical Supervision was the primary driver of the HHA disparity rate in FY 2016.

In FY 2018, the next most frequently SA-cited condition was Skilled Professional Services, cited six times by the SAs at the condition level, and missed four times by the AOs.

Table 26
Number and Type of Condition-Level Deficiencies
Cited on 60-Day Validation Surveys
Hospices
FY 2018

Medicare Conditions Sample Size – 32	Cited by SA	Missed by AO
IDG, Care Planning, Coordination of Services	3	2
Quality Assessment & Performance Improvement	3	2
Infection Control	3	2
Hospice Aide and Homemaker Services	3	2
Establishment of the Emergency Program	2	1
Volunteers	1	1
Organizational Environment	1	1
Medical Director	1	1
Core Services	1	1
TOTAL	18	13

In FY 2018, the Hospice sample consisted of 32 validation surveys. In this sample, the SAs cited condition-level deficiencies in six agencies. The primary drivers of the hospice disparity rate were the following conditions: 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 primary driver of the hospice disparity rate was the IDG, Care Planning, Coordination of Services condition. In FY 2016, the Quality Assessment & Performance Improvement condition was the primary driver of the hospice disparity rate.

In FY 2018, the next most frequently SA-cited condition was Establishment of the Emergency Program, cited two times by the SAs, and missed one time by the AOs.

Table 27
Number and Type of Condition-Level Deficiencies
Cited on 60-Day Validation Surveys
ASCs
FY 2018

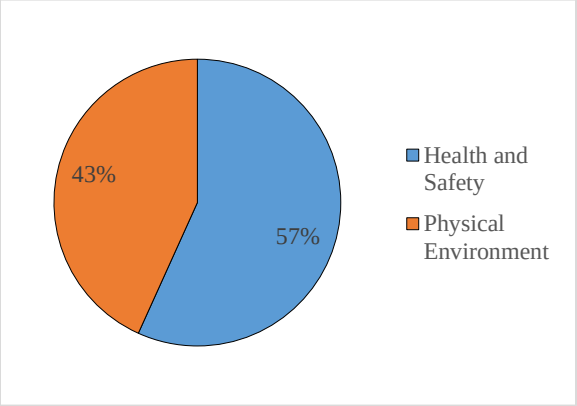
Medicare Conditions Sample Size – 58	Cited by SA	Missed by AO
Environment*	**29**	**16**
Infection Control	16	8
Governing Body and Management	12	8
Quality Assessment & Performance Improvement	11	7
Medical Staff	8	4
Surgical Services	5	4
Nursing Services	3	3
Pharmaceutical Services	2	1
Patient Rights	2	1
Basic Requirements	1	1
Laboratory and Radiologic services	1	1
Compliance with State Licensure Law	1	1
Patient Admission, Assessment and Discharge	1	1
TOTAL	92	56

*Most frequently cited deficiency

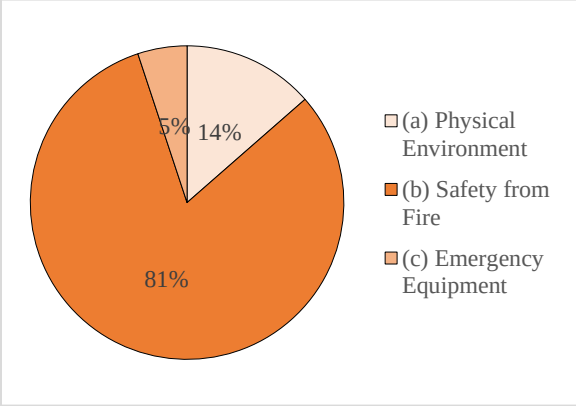
In FY 2018, the ASC sample consisted of 58 validation surveys. In this sample, the SAs cited condition-level deficiencies in 28 facilities. The primary driver of the disparity rate was the PE condition. The SAs cited PE at the condition level 29 times. The AOs missed 16 comparable deficiencies for PE, which was also the most frequently cited condition in FYs 2016 and 2017.

In FY 2018, the next most frequently SA-cited conditions were as follows: Infection Control, cited 16 times by the SAs, and missed eight times by the AOs; Governing Body and Management, cited 12 times by the SAs, and missed eight times by the AOs; and Quality Assessment & Performance Improvement, cited 11 times by the SAs, and missed seven times by the AOs.

Graph 13
Percentage of Health and Safety vs PE Condition-Level Deficiencies Cited on 60-Day Validation Surveys
ASCs
FYs 2016–2018



Graph 14
Percentage of PE Standards Cited on 60-Day
Validation Surveys
ASCs
FYs 2016–2018



From FY 2016 to FY 2018, there were 89 validation surveys cited with condition-level deficiencies for ASCs. Of the 89 surveys, 63 of the surveys had health and safety citations, 48 of the surveys had PE citations, and 22 of the surveys were cited with both. For ASCs, the PE condition consists of three standards: (a) PE, (b) Safety from Fire, and (c) Emergency equipment. Fifty-nine standards were cited for the PE condition and 48 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 28-29 and Graph 15.)

Table 28
Number of 60-Day Validation Surveys for Facility Types with LSC Requirements
FY 2018

Validation Survey Analysis	Hospital*	Psych Hospital	CAH	ASC
60-Day Validation Sample Surveys	107	21	17	58

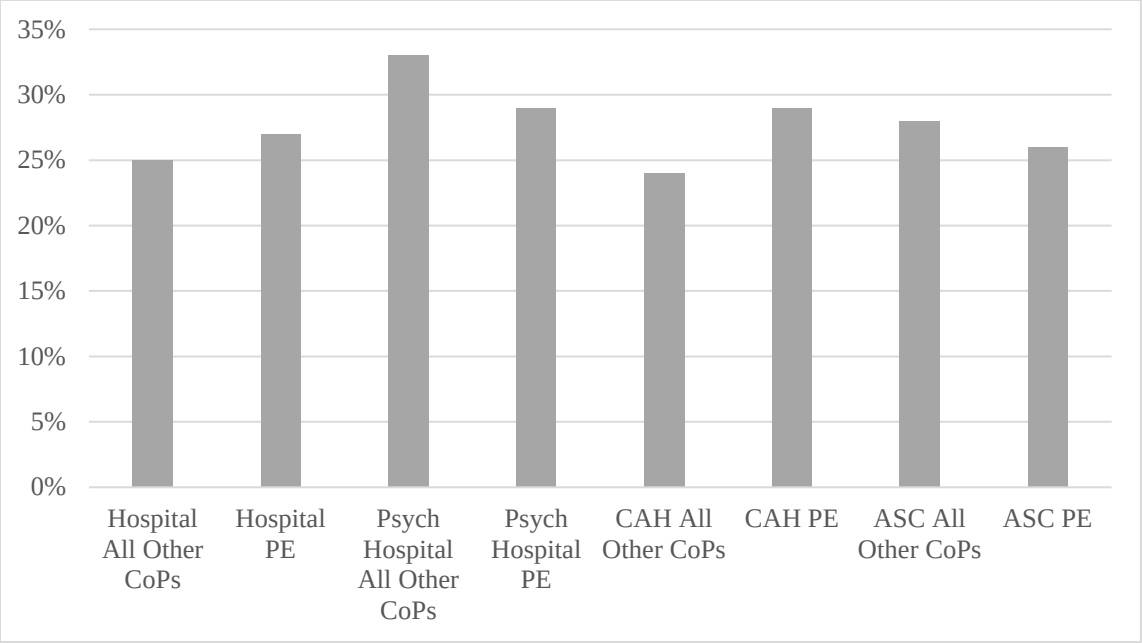
*Acute Care and LTCHs

Table 29
60-Day Validation Survey Results
Comparison between All Other CoPs Cited and
PE for Facility Types with LSC Requirements
FY 2018

	Hospital All Other CoPs	Hospital PE	Psych Hospital All Other CoPs	Psych Hospital PE	CAH All Other CoPs	CAH PE	ASC All Other CoPs	ASC PE
SA Surveys with Condition-Level Deficiencies	31	32	12	6	4	5	20	15
AO Surveys with Missed Comparable Deficiencies	27	29	7	6	5	5	16	15
Disparity Rate	**25%**	**27%**	**33%**	**29%**	**24%**	**29%**	**28%**	**26%**

In FY 2018, the PE CoP impacted the overall disparity rate for both hospitals and CAHs. The disparity rate based on the PE condition for hospitals is 2 percentage points higher than the disparity rate based on other health and safety conditions; this is down from FY 2017, where the differences in disparity rates were 5 percentage points. For FY 2018, the disparity rate based on the PE condition for CAHs is 5 percentage points higher than the disparity rate based on other health and safety conditions; this is down from FY 2017, where the differences in disparity rates were 19 percentage points. The PE disparity rate for ASCs was 2 percentage points lower than the disparity rate for other health and safety conditions compared to 4 percentage points in FY 2017. In FY 2018, the PE disparity rate for psychiatric hospitals was 4 percentage points lower than the disparity rate for other health and safety conditions. In FY 2017, the PE and health and safety disparity rates equally impacted psychiatric hospitals. (See Graph 15.)

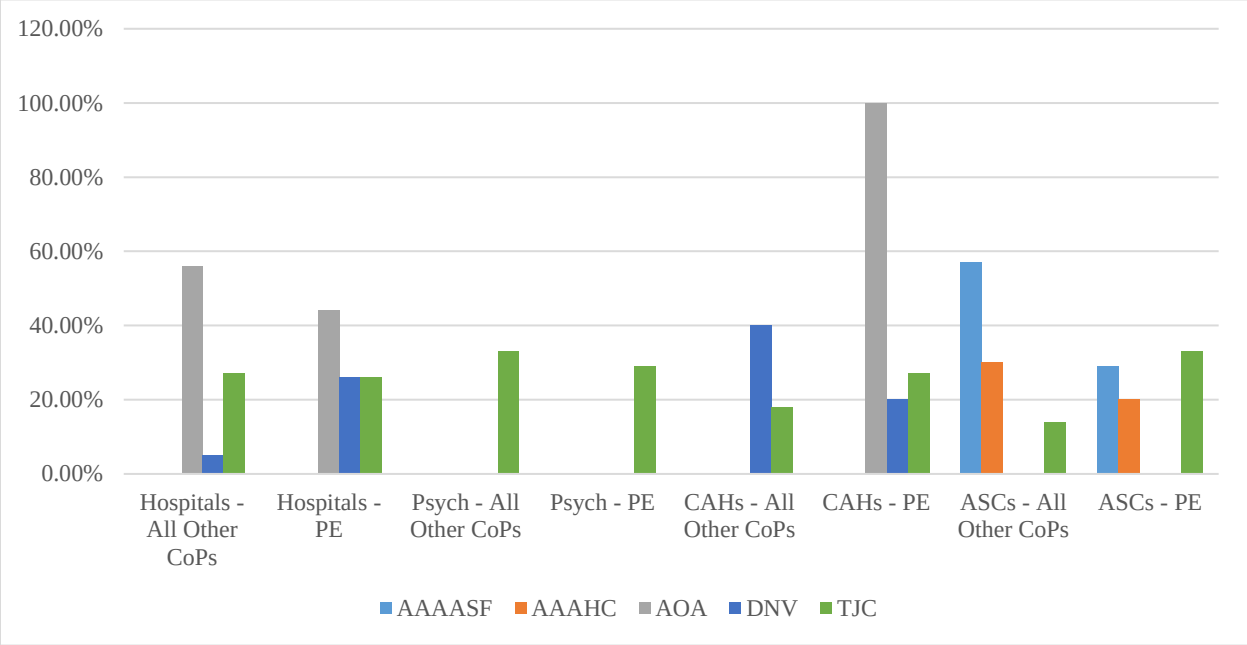
Graph 15
60-Day Validation Survey Disparity Rate Results
Comparison between All Other CoPs Cited and
PE for Facility Types with LSC Requirements
FY 2018



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 2018. 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.

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. CMS has been working with all 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. CMS has engaged in rulemaking to update the Federal regulations to the 2012 edition of the LSC. While CMS does not believe that the difference in LSC editions accounts for AOs' problems in identifying LSC deficiencies, this is an issue that AOs and the healthcare industry have raised and could affect the survey process. (See Graph 16.)

Graph 16
60-Day Validation Survey Results
Comparison between All Other CoPs Cited and
PE for Facility Types with LSC Requirements
by AO
FY 2018



Comparison of Deficiencies and Disparity Rates for Long-Term Care Hospitals and All Other Hospital Subtypes[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 30-32 and Graphs 17-20.) In FY 2018, CMS increased the LTCH sample size for 60-day representative sample surveys. In FY 2018, the total number of Medicare-participating LTCHs was 388 and the total number of Medicare-participating hospitals minus the LTCHs was 3,752.

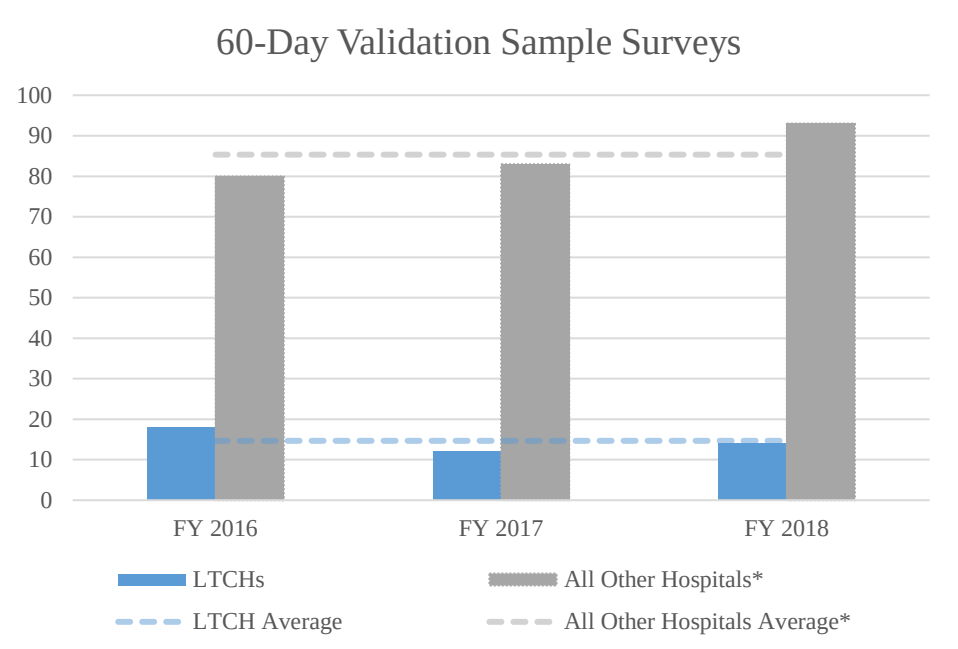
[11] LTCHs differ from other acute care hospitals in that they furnish extended medical and rehabilitative care to individuals with clinically complex problems, such as multiple acute or chronic conditions, who need hospital-level care for relatively extended periods. Other hospital subtypes are specific to acute care hospitals and 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 30
Number of 60-Day Validation Surveys and Overall Disparity Rate
LTCHs and All Other Hospital Subtypes
FYs 2016–2018

	LTCHs			All Other Hospitals*			Average LTCHs	Average All Other Hospitals*
	FY 2016	FY 2017	FY 2018	FY 2016	FY 2017	FY 2018	FYs 2016–2018	FYs 2016–2018
60-Day Validation Sample Surveys	18	12	14	80	83	93	14.67	85.33
Overall Disparity Rate	**39%**	**75%**	**57%**	**48%**	**41%**	**45%**	**57%**	**45%**

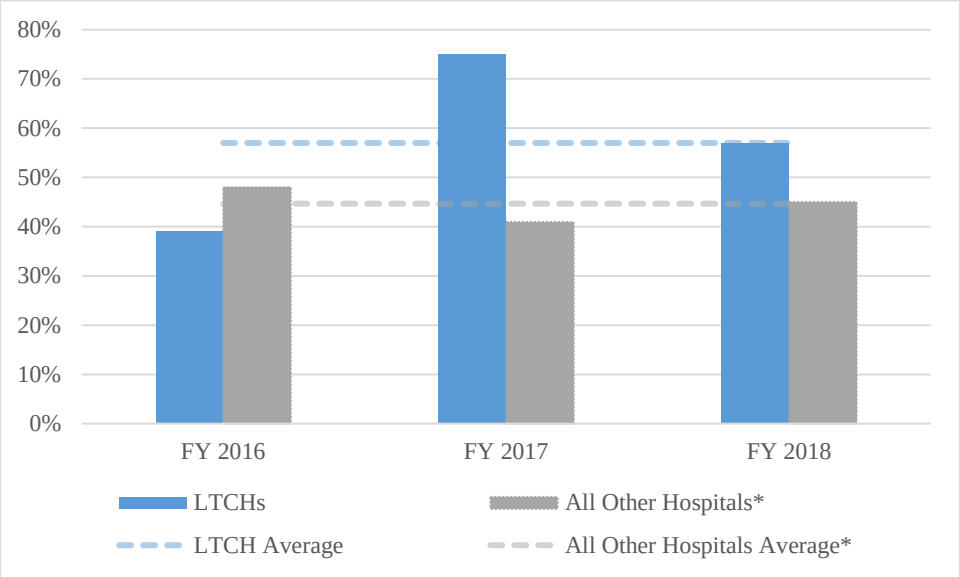
*All Other Hospital Subtypes are specific to acute care hospitals and do not include psychiatric hospitals.

Graph 17
Number of 60-Day Validation Surveys and Averages
LTCHs and All Other Hospital Subtypes
FYs 2016–2018



*All Other hospital subtypes are specific to acute care hospitals and do not include psychiatric hospitals. Total number of Medicare-participating LTCHs is 388 and the total number of Medicare-participating hospitals minus the LTCHs is 3,752.

Graph 18
Overall Disparity Rates and Averages LTCHs and All Other Hospital Subtypes
FYs 2016–2018



*All Other hospital subtypes are specific to acute care hospitals and do not include psychiatric hospitals. Total number of Medicare-participating LTCHs is 388 and the total number of Medicare-participating hospitals minus the LTCHs is 3,752.

Table 31
Comparison of 60-Day Health and PE Validation Survey Results for LTCHs and All Other Hospital Subtypes
FYs 2016–2018

	LTCHs - All Other Conditions			LTCHs PE			All Other Hospitals - All Other Conditions			All Other Hospitals PE		
Validation Survey Analysis	FY 2016	FY 2017	FY 2018	FY 2016	FY 2017	FY 2018	FY 2016	FY 2017	FY 2018	FY 2016	FY 2017	FY 2018
SA Surveys with Condition-Level Deficiencies	6	8	6	1	3	2	22	20	25	30	26	20
AO Surveys with Missed Comparable Deficiencies	6	8	6	1	3	2	18	16	21	28	26	27
Disparity Rate	**33%**	**67%**	**57%**	**6%**	**25%**	**14%**	**23%**	**19%**	**45%**	**35%**	**31%**	**28%**

Graph 19
Comparison of 60-Day Health and PE Validation Survey Disparity Rate Results for LTCHs and All Other Hospital Subtypes
FYs 2016–2018

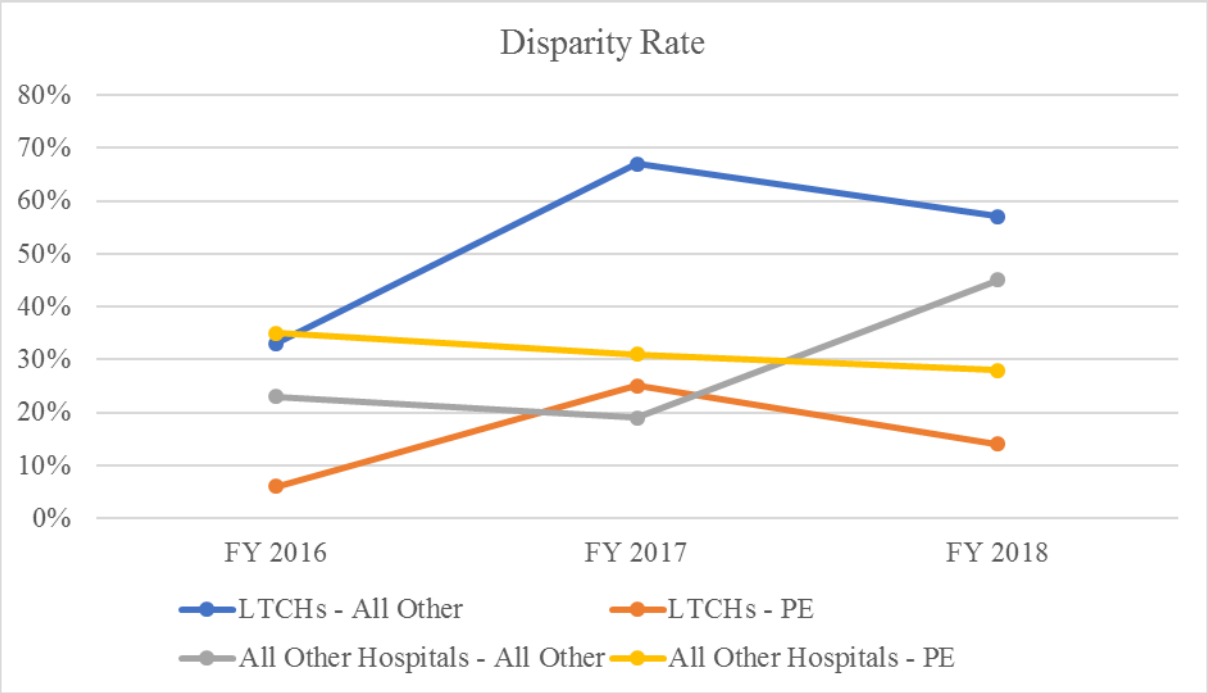
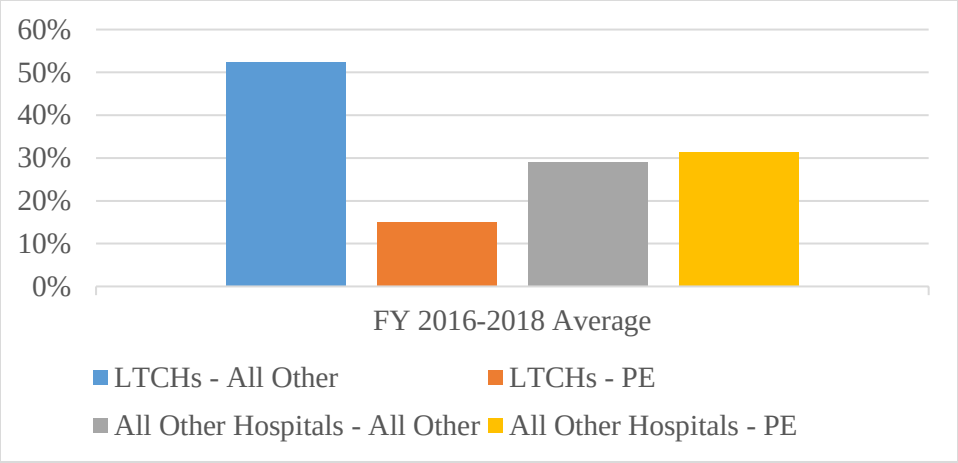


Table 32
Comparison of Averages
60-Day Health and PE Validation Survey Results for LTCHs and All Other Hospital Subtypes
FYs 2016–2018

	FYs 2016–2018 Average LTCHs All Other Conditions	FYs 2016–2018 Average LTCHs PE	FYs 2016–2018 Average All Other Hospitals All Other Conditions	FYs 2016–2018 Average All Other Hospitals PE
SA Surveys with Condition-Level Deficiencies	6.67	2.00	22.33	25.33
AO Surveys with Missed Comparable Deficiencies	6.67	2.00	18.33	27.00
Disparity Rate	**52%**	**15%**	**29%**	**31%**

*All Other Hospital Subtypes are specific to acute care hospitals and do not include psychiatric hospitals.

Graph 20
Comparison of Averages
60-Day Health and PE Validation Survey Disparity Rate Results for LTCHs and All Other Hospital Subtypes
FYs 2016-2018



From FYs 2016–2018, there is a 37-percent difference between the overall average disparity rates in LTCHs' PE and other condition-level deficiencies, and a 2-percent difference in all other hospitals' PE and other condition-level deficiencies. When comparing the drivers of the average disparity rates, PE is the primary driver in all other hospital subtypes while all other conditions is the primary driver for LTCHs. In FY 2018, PE is still the primary driver for all other hospital subtypes, comprising 28 percent of the disparity rate. For LTCHs, the primary drivers in FY 2018 are Governing Body, QAPI, PE, and Organ, Tissue, and Eye Procurement. Each condition yielded a 14-percent disparity rate.

In FY 2018, the most frequent disparate condition-level deficiencies for all other hospital subtypes and LTCHs were PE, Infection Control, Governing Body, QAPI and Organ, Tissue, and Eye Procurement.

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 Program (VRP) pilot to overhaul the validation survey process. The VRP workgroup includes CMS staff, as well as management and staff from State Agencies and the AOs. (See Section 6 for more details). CMS has also participated in AO surveyor training sessions, delivering analysis findings directly to the AO's survey cadre. In October 2018, the 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.

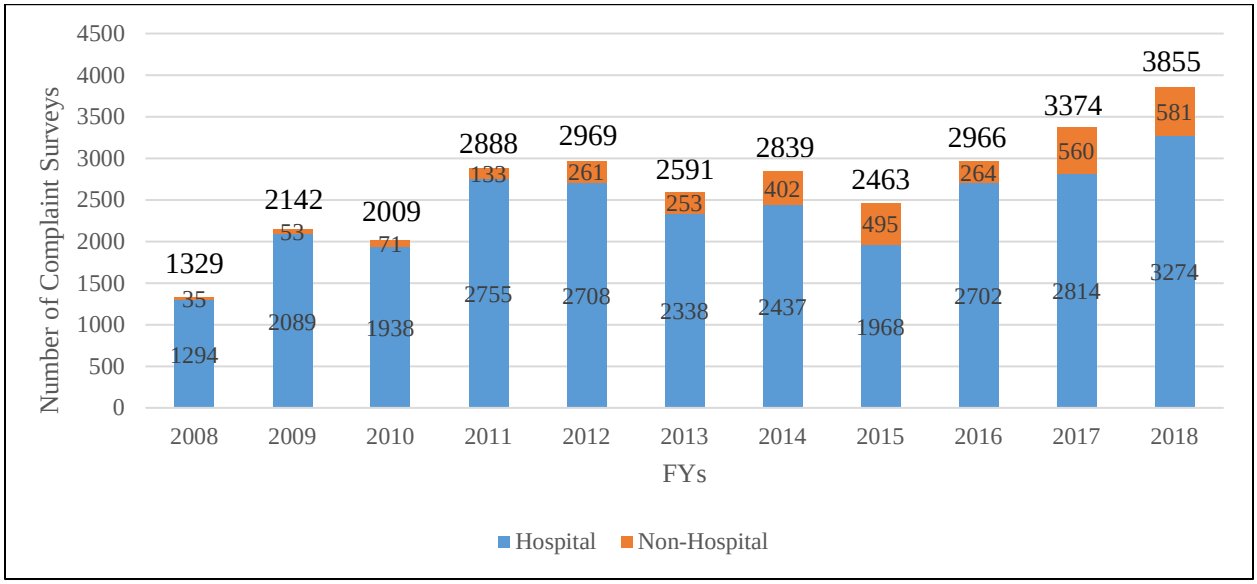
[13] https://www.cms.gov/newsroom/press-releases/cms-strengthen-oversight-medicares-accreditation-organizations

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 Regional Office determines it to be appropriate, a full survey of all the CoPs and CfCs will be conducted. In FY 2018, CMS conducted a total of 3,855 complaint surveys. This total comprised 3,274 hospital surveys, and 581 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 2008-2018



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
- 2011: 2,755 hospital surveys 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

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 2016-2018.

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 CoPs, and the PE conditions cited by the SAs. The health and safety summary report identifies each SA CoP finding and identifies the comparable and non-comparable AO deficiency citations. If the AO has comparable findings to all 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 all the SA cited deficiencies, the survey is determined to be a disparate survey.

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.

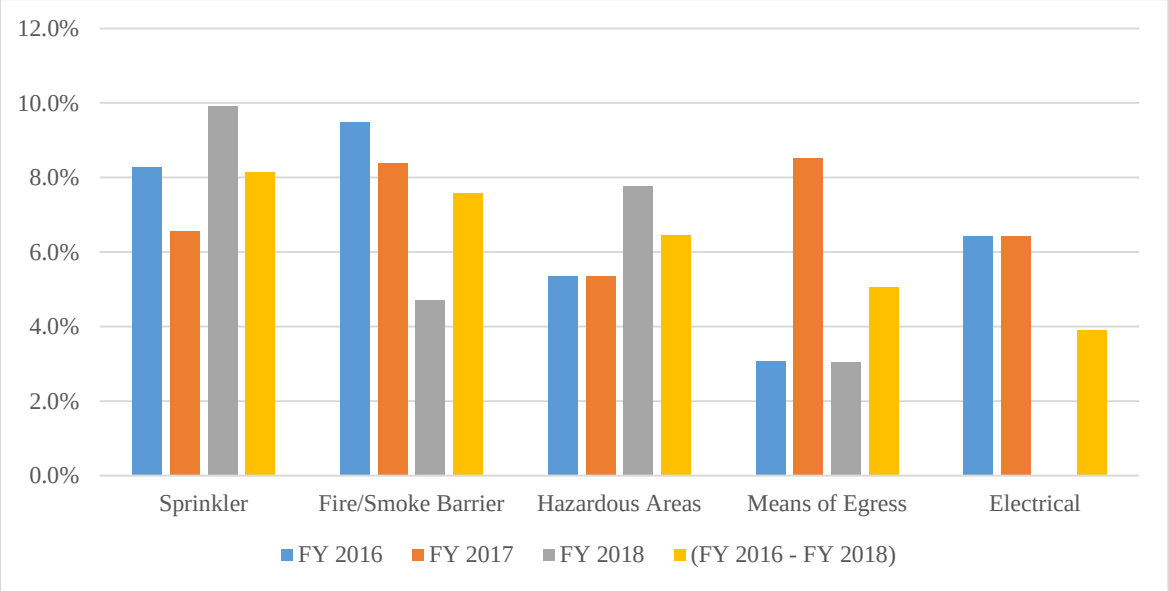
Findings

The PE and Infection Control conditions are the top disparate citations for hospitals, psychiatric hospitals, ASCs, and CAHs. From FY 2016 through FY 2018, the PE condition was found to be in the top three disparate citations for all four of the program types and the Governing Body condition was one of the top five 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 and Hazardous Areas noted in the top five missed citations for FY 2016 through FY 2018 for hospitals, psychiatric hospitals and CAHs. The other two LSC categories were found to be listed in the top five missed citations

for at least three out of the four program types. The LSC category descriptions can be found in Appendix C.
The graphs below discuss, 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

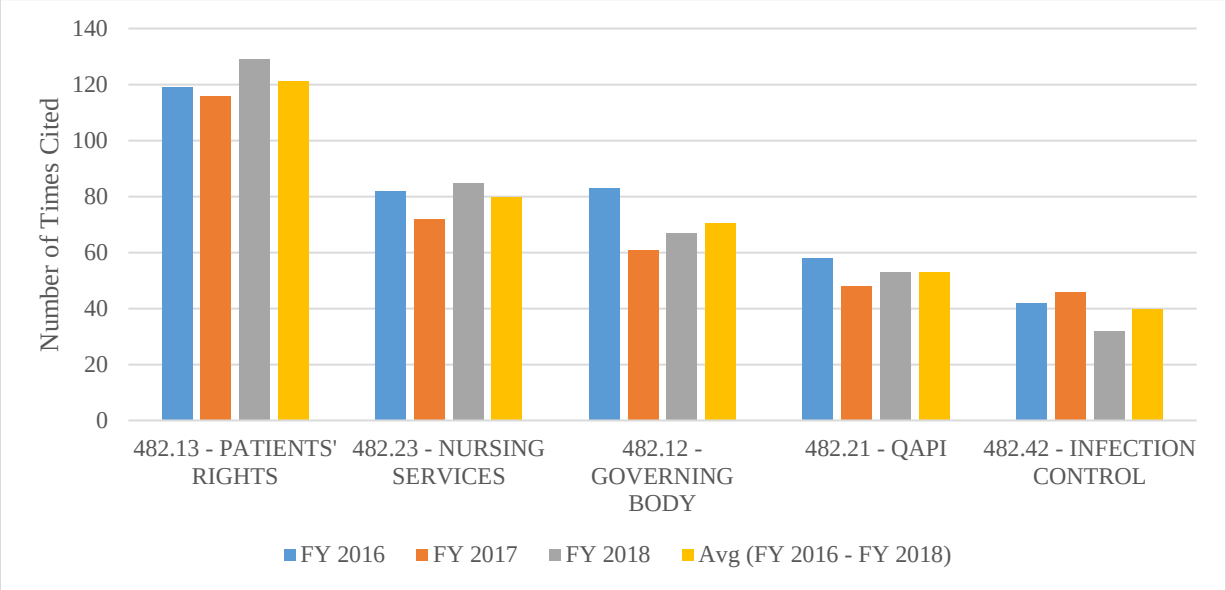
Graph 22
Top Five Hospital and LTCH
LSC Category Disparity Rates
FYs 2016–2018



Out of hospital and LTCH validation surveys, 2,072 LSC category citations were cited by the SAs in FY 2016 through FY 2018. The Sprinkler citation disparity rate increased from 6.6 percent in FY 2017 to 9.9 percent in FY 2018. The Fire/Smoke Barrier citation disparity rate decreased from 8.4 percent in FY 2017 to 4.7 percent in FY 2018. The Electrical LSC category citation was one of the top five disparate citations from FY 2016 to FY 2017. In FY 2018, the Electrical LSC category was cited 44 times by the SAs but this category was not found to be disparate.

From FY 2016 to FY 2018, the top two most frequently cited LSC categories were Sprinkler, with 331 SA citations, and Fire/Smoke Barrier, with 295 SA citations. The AOs missed 169 comparable citations for Sprinkler (8.2-percent disparity rate) and 157 comparable citations for Fire/Smoke Barrier (7.6-percent disparity rate). From FY 2016 to FY 2018, a total of 646 missed LSC category citations comprised the top five disparate LSC categories, resulting in 66-percent missed LSC category citations for hospitals and LTCHs.

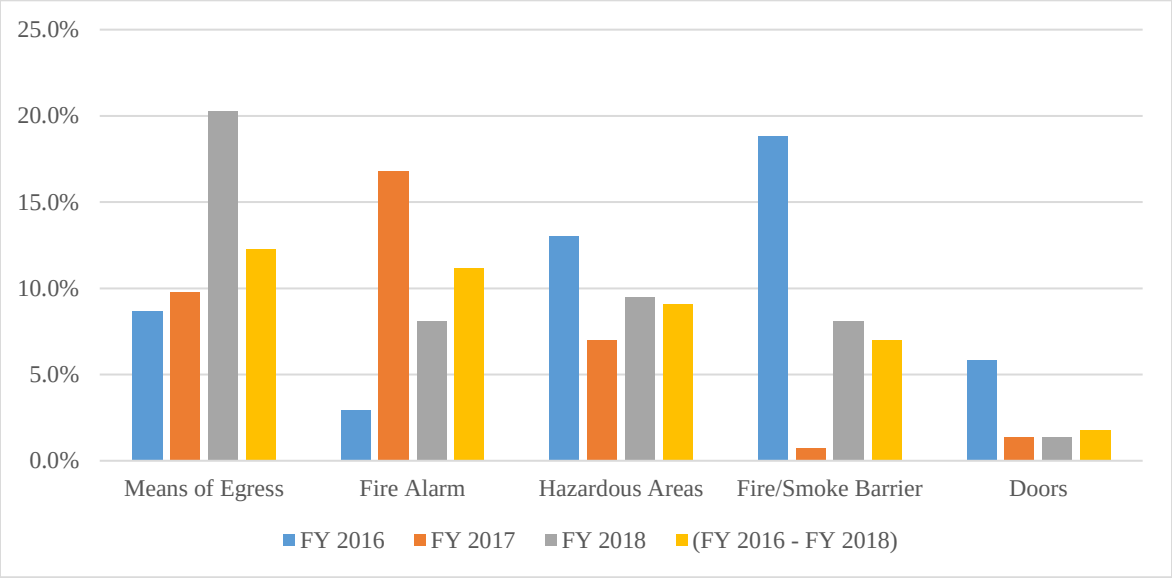
Graph 23
Top 5 Hospital and LTCH Condition-Level Deficiencies Cited During Complaint Surveys
FYs 2016-2018



From FYs 2016 to 2018, there were a total of 1,467 condition-level deficiencies cited for AO accredited hospital and LTCH facilities during complaint surveys. During that time, the most frequently cited condition was Patient's Rights, cited 364 times. The next most frequently cited condition was Nursing Services, cited 239 times. The number of Patient Rights, Nursing Services, Governing Body, and QAPI citations increased from FY 2017 to FY 2018, however, they all decreased from FY 2016 to FY 2017.

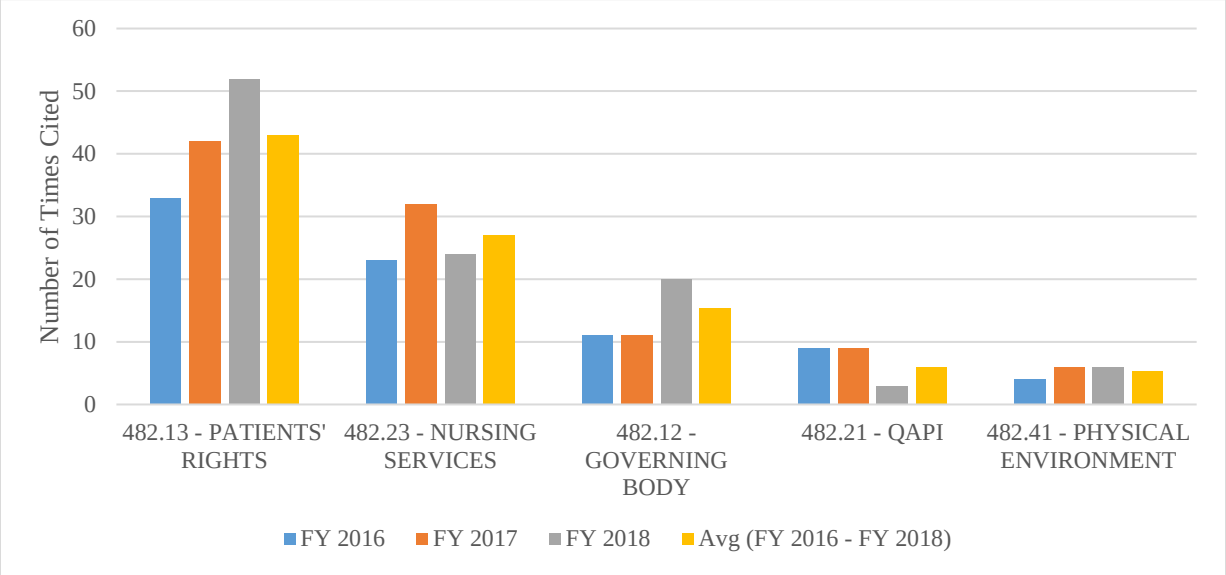
Psychiatric Hospital

Graph 24
Top Five Psychiatric Hospital
LSC Category Disparity Rates
FYs 2016–2018



From FY 2016 to FY 2018, 63 psychiatric validation surveys were performed and 286 LSC category citations were cited by the SAs. The top two most frequently cited LSC categories for FY 2016 to FY 2018 were Means of Egress with 49 SA citations, and Fire Alarm with 42 SA citations. TJC missed 35 comparable citations for Means of Egress and 32 comparable citations for Fire Alarm, resulting in a 12-percent LSC category disparity rate and a 11-percent category disparity rate, respectively. Fire/Smoke Barrier issues were the number one disparate LSC category in FY 2016 with a disparity rate of 19 percent which decreased to 8 percent in FY 2018. The top five disparate LSC category disparities make up 90 percent of all the LSC category disparities for FY 2016 to FY 2018.

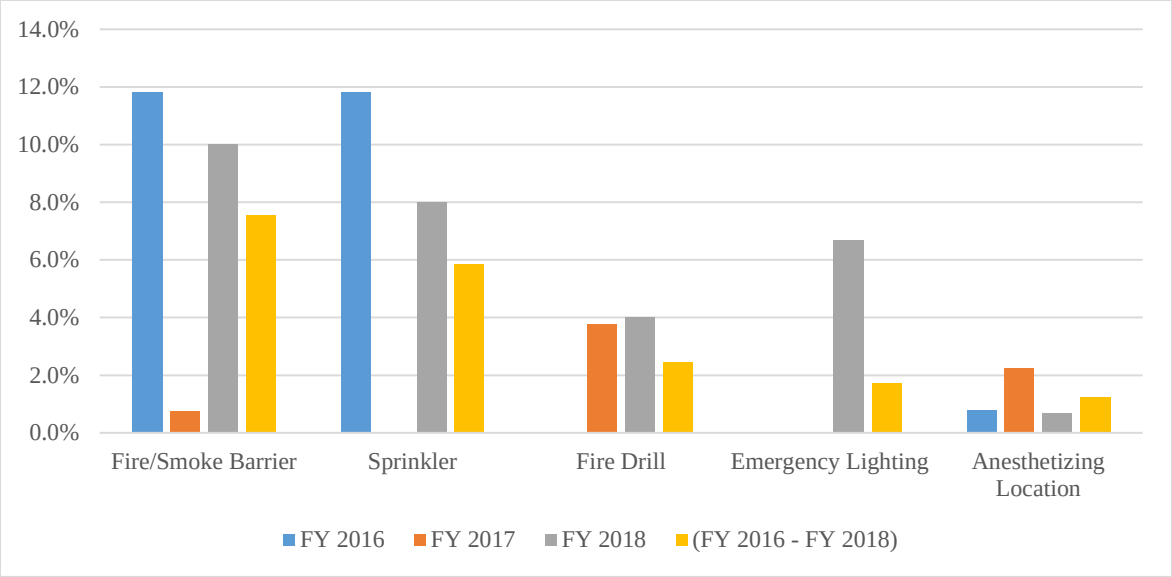
Graph 25
Top 5 Psychiatric Hospital Condition-Level Deficiencies Cited During Complaint Surveys
FYs 2016–2018



From FY 2016 to FY 2018, there were a total of 332 condition-level deficiencies cited for AO accredited psychiatric hospitals during complaint surveys. During that time, the most frequently cited condition was Patient's Rights, cited 129 times. The next most frequently cited condition was Nursing Services, cited 81 times. The number of Patient Rights citations steadily increased from FY 2016 to FY 2018, while the number of Nursing Services citations decreased from 32 citations in FY 2017 to 24 citations in FY 2018.

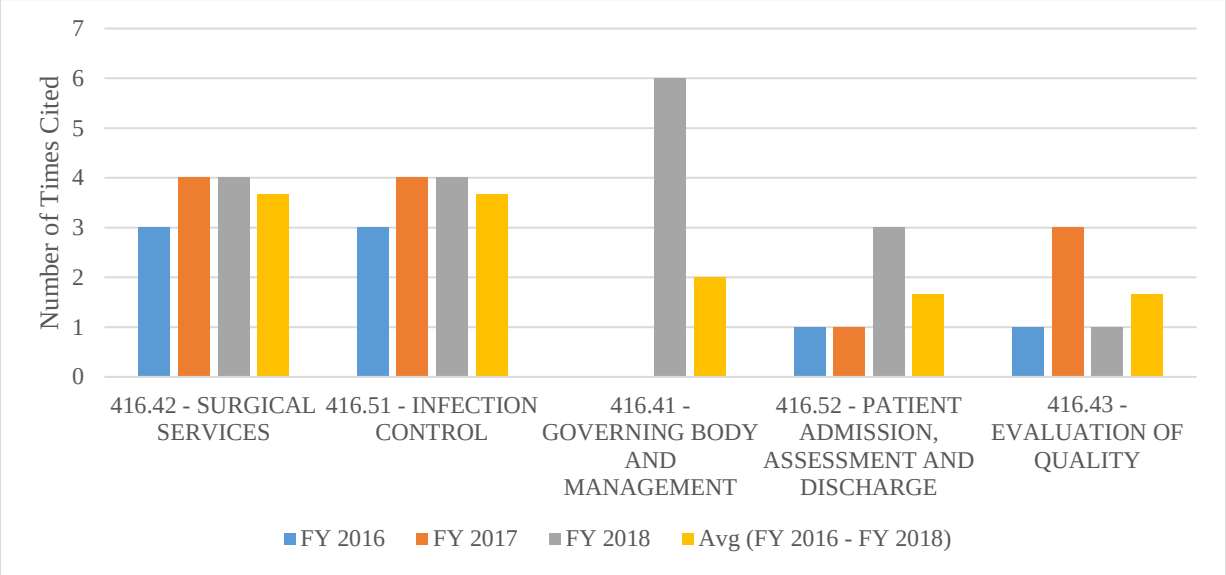
Ambulatory Surgery Center

Graph 26
Top Five ASC
LSC Category Disparity Rates
FYs 2016–2018



Out of 205 ASC validation surveys performed from FY 2016 to FY 2018, 410 LSC category citations were cited by the SAs. The most frequently cited LSC category for FY 2016 through FY 2018 was Fire/Smoke Barrier even though this category was only found to be missed by the AOs one time in FY 2017. From FY 2016 to FY 2018, the SAs cited the Fire/Smoke Barrier LSC category 83 times. Thirty-one of the citations were missed by the AOs resulting in an 8-percent LSC citation disparity rate; however, this disparity decreased from 12 percent in FY 2016 to 10 percent in FY 2018. A total of 77 missed LSC category citations comprised the top five disparate LSC categories, resulting in 94 percent of the missed LSC category citations for ASCs.

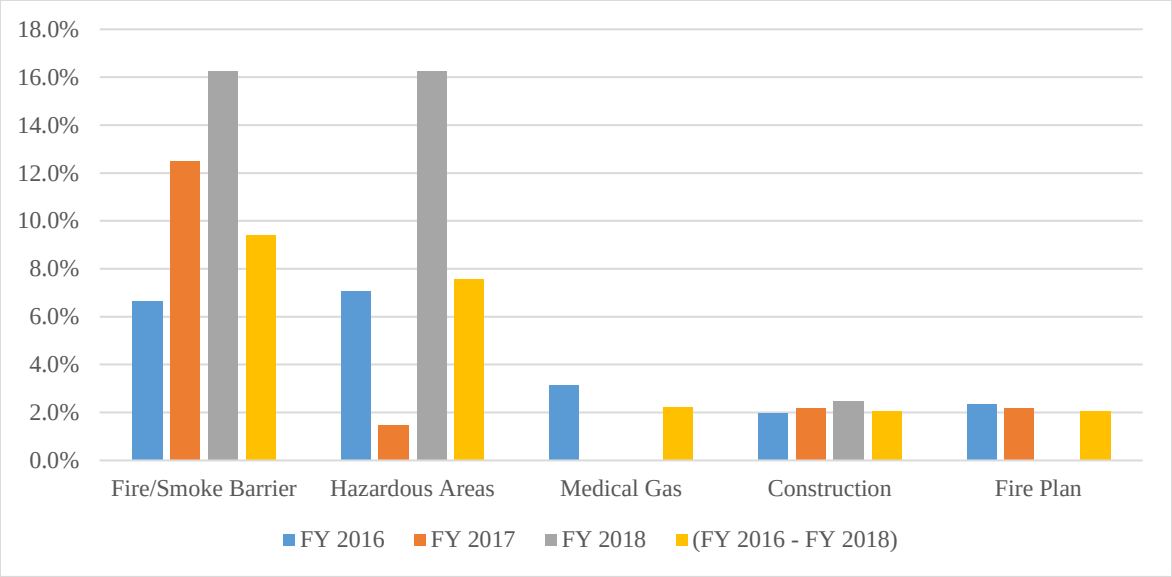
Graph 27
Top 5 ASC Condition-Level Deficiencies Cited
During Complaint Surveys
FYs 2016-2018



From FY 2016 to FY 2018, there were a total of 54 condition-level deficiencies cited for AO accredited ASCs during complaint surveys. During that time, the most frequently cited conditions were Surgical Services and Infection Control, both cited 11 times. Surgical Services and Infection Control were both cited three times in FY 2016, and both were cited four times in FY 2017 and FY 2018, an increase of 33 percent.

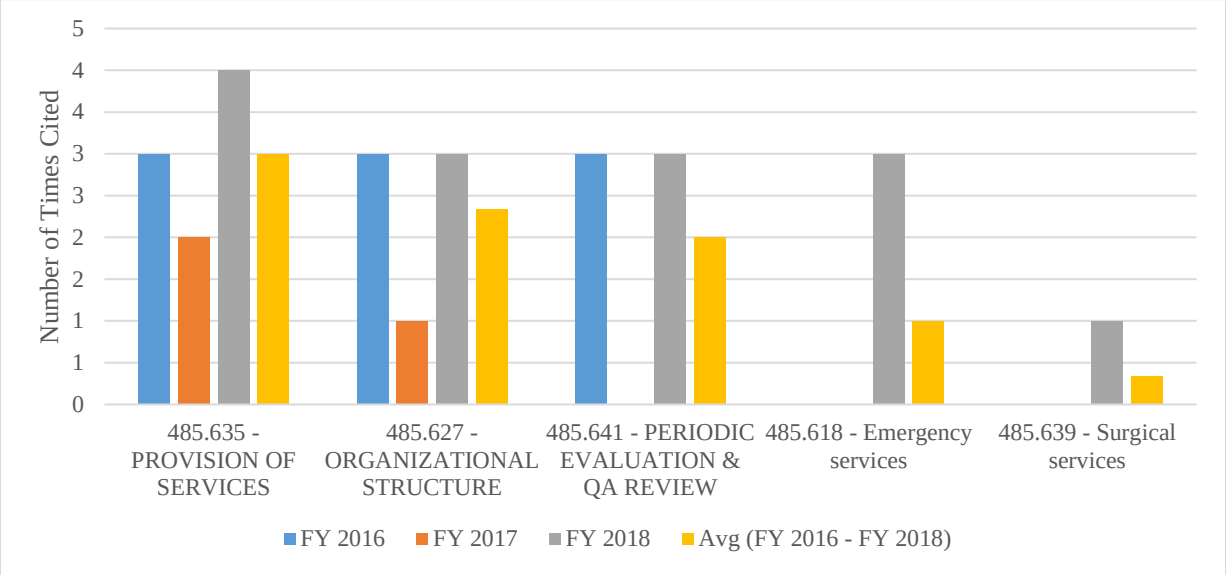
Critical Access Hospital

Graph 28
Top Five CAH
LSC Category Disparity Rates
FYs 2016–2018



Out of 83 CAH validation surveys performed from FY 2016 to FY 2018, 489 LSC category citations were cited by the SAs. Fire/Smoke Barrier was the most frequently cited LSC category with 91 citations. The AOs missed 46 comparable LSC category citations over the three-year period. This resulted in a 9-percent LSC citation disparity rate. The second most frequently cited category was Hazardous Areas. The disparity rate for the Hazardous Areas category increased from 7 percent in FY 2016 to 16 percent in FY 2018. There was a total of 114 missed LSC category citations in the top 5 disparate LSC categories out of a total of 148 missed citations. The top five disparate LSC category citations comprised 77 percent of all the missed LSC category citations for CAHs.

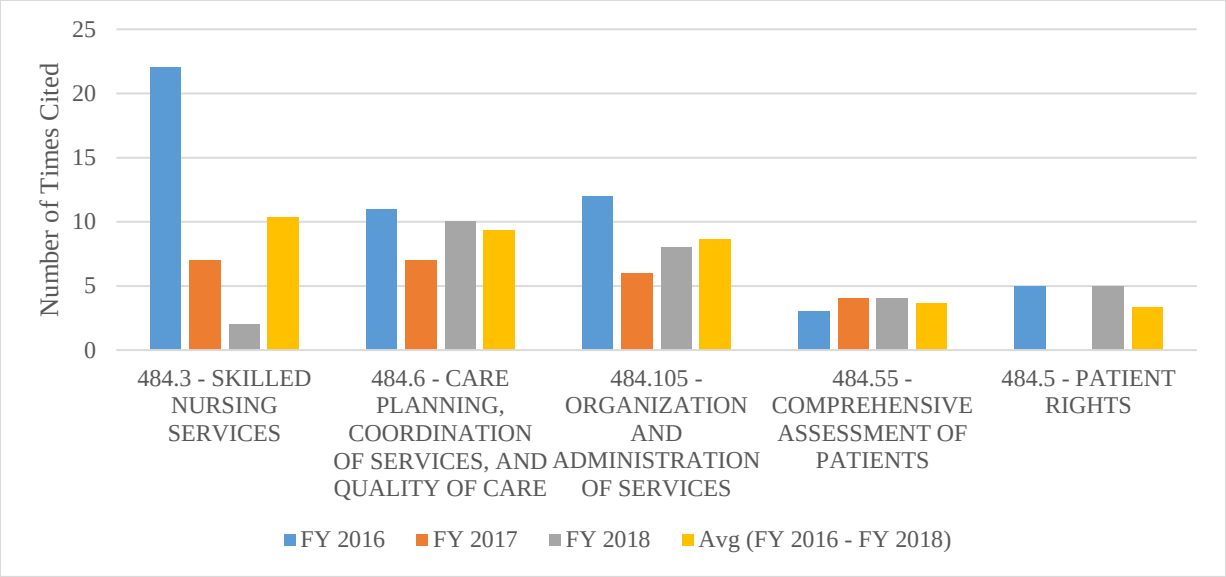
Graph 29
Top 5 CAH Condition-Level Deficiencies Cited
During Complaint Surveys
FYs 2016–2018



From FY 2016 to FY 2018, there were a total of 27 condition-level deficiencies cited for AO accredited ASCs during complaint surveys. During that time, the most frequently cited condition was Provision of Services, cited nine times. The next most frequently cited conditions were Organizational Structure and Periodic Evaluation & QA Review, cited seven and six times respectively. Although the graph depicts the total number of top five condition-level deficiencies cited from FY 2016 to FY 2018, only the top two of the five conditions had citations for all three years.

Home Health Agency

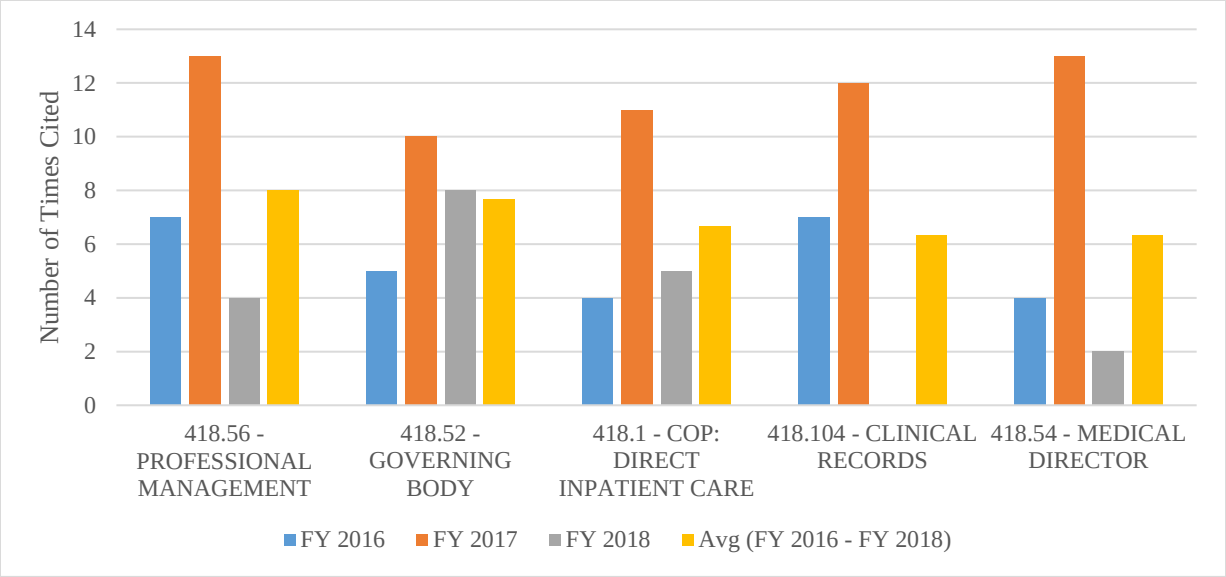
Graph 30
Top 5 HHA Condition-Level Deficiencies Cited
During Complaint Surveys
FYs 2016–2018



From FY 2016 to FY 2018, there were a total of 297 condition-level deficiencies cited for AO accredited HHAs during complaint surveys. During that time, the most frequently cited condition was Skilled Nursing Services, cited 31 times. The next most frequently cited condition was Care planning, Coordination of Services, and Quality of Care cited 28 times. The number of Skilled Nursing Services citations decreased by 19 citations from FY 2016 to FY 2018.

Hospice

Graph 31
Top 5 Hospice Condition-Level Deficiencies Cited
During Complaint Surveys
FYs 2016–2018



From FY 2016 to FY 2018, there were a total of 167 condition-level deficiencies cited for AO accredited Hospice facilities during complaint surveys. During that time, the most frequently cited condition was Professional Management, cited 24 times. The next most frequently cited condition was Governing Body, cited 23 times. The least cited condition was Medical Director and Clinical records, both cited 19 times. In FY 2017, there were 99 condition-level deficiencies cited for AO accredited Hospice facilities during complaint surveys which accounts for 59 percent of the deficiencies cited for all three years. The top five citations found during complaint surveys for Hospice facilities accounts for 63 percent of all of the citations during that same period of time.

Conclusion

CMS has identified the top conditions and LSC Categories driving the disparity rate. The PE/Environment is one of the leading disparate conditions, accounting for 22 to 33 percent of all disparate surveys from FY 2016 to FY 2018 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. Fire/Smoke Barrier remains the top disparate LSC category from FY 2016 to FY 2018 which accounts for nearly 21% of all of the missed LSC category citations for the three years. Hazardous Areas is the second highest top disparate LSC category FY 2016 to FY 2018 and accounts for nearly 16 percent of the missed LSC category citations for FY 2016 to FY 2018. Fire/Smoke Barrier, Hazardous Areas, Sprinkler, Means of Egress, and Doors are the top five missed LSC Citations for the PE/Environment conditions and these top five disparities account for 69 percent of all of the missed LSC category citations. Among the AOs with a CMS-approved hospital accreditation program and LTCHs, AOA has the highest average health and safety disparity rate for FY 2016 to FY 2018 at 37 percent and AOA also has the highest average PE disparity rate at 69 percent. AAAHC had the lowest average health and safety (22 percent) and PE disparity rate (17 percent) for ASCs while AAASF had the highest average health and safety (41 percent) and PE (32 percent) rate for FY 2016 to FY 2018. TJC was the only AO with a valid sample size for CAHs and their average health and safety and PE disparity rates for FY 2016 to FY 2018 were 17 percent and 32 percent respectively.

Recommendations

<u>Accrediting Organizations Need to Focus Their Interventions on Their Top Disparate Conditions.</u>

Each AO needs to develop interventions focusing on their high-volume disparate CoPs. If the AOs were to focus on the top disparate CoPs with the highest disparity rates, they would have an opportunity to positively impact their disparity rate. For example, for FY 2018, if the AOs would address the top five disparate CoPs for hospitals, they could potentially eliminate 77 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 CoPs 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 Section 5 of this report 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 2018. Currently, 38 percent (13,137 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 10 CMS-recognized AOs and 22 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 2018, 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 Program (VRP) Pilot

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 AO's provide. This model, which was began in March 2017 and continues to be utilized in FY 2018, includes 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 has strengthened 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 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://surveyortraining.cms.hhs.gov/. In FY 2018, 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

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 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 Program Pilot

In March 2018, CMS appointed a workgroup to redesign the validation survey process. The overall goal of the Validation Redesign Program (VRP) pilot 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 appropriate SA and the AO, 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 will evaluate 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 2018 reporting period, there were a total of six VRP direct observation validation surveys conducted. Future VRP surveys will be conducted in the FY 2019 and FY 2020 reporting periods.

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 259,967 CLIA certified facilities at the beginning of calendar year (CY) 2018. 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 17,967 laboratories every 2 years. CMS-approved AOs conduct on-site surveys of an additional 15,454 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 2018 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 systematic problems in the organization's accreditation process that the AO's requirements are no longer equivalent to CLIA requirements.

[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.

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 2018. 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 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.

[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.

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: 20%*

In FY 2018, approximately 200 laboratories used their AABB accreditation for CLIA program purposes. Five validation surveys were conducted resulting in one laboratory being cited with condition-level deficiencies for lack of proficiency testing (PT) enrollment. AABB findings were not comparable to the CLIA condition level thus yielding a disparity rate of 20%. (See Table 33.)

*When the sample of validation surveys is five, one disparate case causes a mathematical outcome that can be disproportionate and must be viewed in that context as well as the historical context.

AABB has had a history of 0 percent disparity in 17 annual validation reviews prior to this year and has taken measures to ensure proper PT enrollment by all AABB-accredited laboratories. Moreover, CMS has required AABB to report on its corrective actions and whether those measures have been effective and sustained. CMS views this to be the most appropriate action in light of the small pool of validation surveys and AABB's history of no disparities (0 percent) in previous CLIA validation reviews.

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 three deemed facilities. No CLIA validation surveys were conducted during the FY 2018 survey cycle. (See Table 33.)

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

Rate of disparity: N/A

For CLIA purposes, approximately 129 laboratories used their AAHHS/HFAP accreditation. Validation surveys were conducted in 4 AAHHS/HFAP-accredited laboratories. Due to the low number of validation surveys conducted, no additional data is reported. (See Table 33.)

American Society for Histocompatibility and Immunogenetics

Rate of disparity: N/A

Approximately 112 laboratories used their ASHI accreditation for CLIA purposes. A total of two validation surveys were conducted in ASHI-accredited laboratories. Due to the low number of validation surveys conducted, no additional data is reported. (See Table 33.)

COLA

Rate of disparity: 5.7 percent

In FY 2018, 6,510 laboratories used their COLA accreditation for CLIA program purposes. A total of 158 validation surveys were conducted in COLA-accredited laboratories. Twelve laboratories were cited with condition-level deficiencies. In nine laboratories, however, COLA noted comparable findings for only some or none of the CLIA condition-level deficiencies cited; thus, there were nine disparate cases yielding a disparity rate of 5.7 percent. (See Table 33)

College of American Pathologists

Rate of disparity: 9.7 percent

In FY 2018, 6,364 laboratories used their CAP accreditation for CLIA program purposes. A total of 113 validation surveys were conducted in CAP-accredited laboratories. Thirteen laboratories were cited with CLIA condition-level deficiencies. In 11 laboratories, CAP findings weren't comparable to the CLIA condition-level deficiencies cited; thus, there were 11 disparate cases for a disparity rate of 9.7 percent. (See Table 33.)

The Joint Commission

Rate of disparity: 11.1 percent

In FY 2018, 2,136 laboratories used their TJC accreditation for CLIA program purposes. During this validation period, a total of 45 validation surveys were conducted in TJC-accredited laboratories. Five laboratories were cited with CLIA condition-level deficiencies. TJC findings were not comparable to the CLIA condition-level deficiencies cited; thus, there were five disparate cases yielding a disparity rate of 11.1 percent. (See Table 33.)

Table 33
Validation Survey Results for Clinical Laboratories
FY 2018

Number of—	AABB	A2LA	AAHHS/HFAP	ASHI	CAP	COLA	TJC	Total
Accredited Labs	200	3	129	112	6,364	6,510	2,136	15,454
Validation Surveys	5	0	4	2	113	158	45	327
Surveys with Condition-Level Deficiencies	1	*N/A	*N/A	*N/A	13	12	5	33
Surveys with One or More Condition-Level Deficiencies Missed by AO	1	*N/A	*N/A	*N/A	11	9	5	28
Disparity Rate	20%	*N/A	*N/A	*N/A	**9.7%**	**5.7%**	**11.1%**	**8.6%**

*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 2017-2018

	AAAASF		AAAHC		ACHC		AAHHS/HFAP		CHAP		CIHQ		DNV GL		IMQ		TCT		TJC	
	FY17	FY18	FY17	FY18	FY17	FY18	FY17	FY18	FY17	FY18	FY17	FY18	FY17	FY18	FY17	FY18	FY17	FY18	FY17	FY18
ASSURE Database																				
Denied initial survey with condition-level findings	95	95	100	100	100	100	**NA	100	91	100	**NA	**NA	**NA	75	*NA	**NA	100	100	99	83
Timeliness of facility notification of survey results	100	95	92	93	100	100	100	97	97	93	93	100	93	96	*NA	88	99	97	100	100
CMS notified timely of withdrawals	96	98	87	83	97	100	100	100	81	89	**NA	**NA	81	100	*NA	*NA	**NA	63	93	100
No pending survey > 5 months	100	100	100	100	100	100	100	100	100	100	100	100	100	100	*NA	100	100	100	100	100
Facility Notification Letters																				
Notification letters contain all required information	98	100	91	90	100	100	100	99	100	99	94	93	98	100	*NA	47	96	94	99	99

	AAAASF		AAAHC		ACHC		AAHHS/HFAP		CHAP		CIHQ		DNV GL		IMQ		TCT		TJC	
	FY17	FY18	FY17	FY18	FY17	FY18	FY17	FY18	FY17	FY18	FY17	FY18	FY17	FY18	FY17	FY18	FY17	FY18	FY17	FY18
ASSURE is updated consistent with letters	86	93	83	86	97	98	98	95	94	86	63	66	94	97	*NA	84	95	80	88	69
Survey Schedule																				
Number of surveys performed matches number reported in ASSURE	99	98	95	93	99	100	100	100	98	99	94	100	100	99	*NA	100	97	97	98	99

*NA: No information available for calculation.

**NA: Not applicable due to sample size less than five.

APPENDIX B: Fiscal Year 2018 Life Safety Code and Health & Safety Disparity Rates

Accrediting Organizations

American Association for Accreditation of Ambulatory Surgery Facilities, Inc.

Ambulatory Surgery Centers

AAAASF (FY 2018 ASC Surveys)	All CoPs	PE	Health & Safety
Number of 60-Day Validation Surveys	7	7	7
Number of Surveys with Conditions Missed by AO	4	2	4
Disparity Rate	57.14%	28.57%	57.14%

Appendix B Table 1: AAAASF
ASC Disparity Rate
FY 2018

CoPs	Facilities with CoP(s)	Matching Surveys	Disparate Surveys	Disparity Rate
Governing Body and Management	3	0	3	43%
Quality Assessment & Performance Improvement	3	0	3	43%
Medical Staff	3	0	3	43%
Infection Control	3	0	3	43%
Environment	3	1	2	29%

Appendix B Table 2: AAAASF
Top Five Disparate CoPs for ASCs
93 Percent of all Disparate Findings

Category	Total Cited by SA	Missed by AO	Disparity Rate
Sprinkler	5	5	23.81%
EES	3	3	14.29%
Fire Alarm	3	2	9.52%
Generator	3	1	4.76%
Emergency Lighting	2	1	4.76%

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

Accreditation Association for Ambulatory Health Care, Inc

Ambulatory Surgery Centers

AAAHC (FY 2018 ASC Surveys)	All CoPs	PE	Health & Safety
Number of 60-Day Validation Surveys	30	30	30
Number of Surveys with Conditions Missed by AO	11	6	9
Disparity Rate	36.67%	20.00%	30.00%

Appendix B Table 4: AAAHC
ASC Disparity Rate
FY 2018

CoPs	Facilities with CoP(s)	Matching Surveys	Disparate Surveys	Disparity Rate
Environment	12	5	7	23.33%
Infection Control	9	4	5	16.67%
Governing Body and Management	8	4	4	13.33%
Surgical Services	4	1	3	10.00%

Appendix B Table 5: AAAHC
Top Disparate CoPs for ASCs
84 Percent of all Disparate Surveys

Category	Total Cited by SA	Missed by AO	Disparity Rate
Fire/Smoke Barrier	23	14	20.59%
Emergency Lighting	6	5	7.35%
Fire Drill	6	3	4.41%
Sprinkler	7	2	2.94%
Flammable & Combustible Storage	3	1	1.47%

Appendix B Table 6: AAAHC
Top Five Missed LSC Citations for ASCs
86 Percent of all Missed Citations

Accreditation Commission for Health Care

Home Health Agency

ACHC (FY 2018 HHA Surveys)	All CoPs	Health & Safety
Number of 60-Day Validation Surveys	12	12
Number of Surveys with Conditions Missed by AO	2	2
Disparity Rate	16.67%	16.67%

Appendix B Table 7: ACHC
HHA Disparity Rate
FY 2018

CoPs	Facilities with CoP(s)	Matching Surveys	Disparate Surveys	Disparity Rate
Clinical Records	1	0	1	8.33%
Comprehensive Assessment of Patients	2	1	1	8.33%
Care Planning, Coordination, and Quality of Care	2	1	1	8.33%
Skilled Professional Services	3	1	2	16.67%

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

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

Hospitals

AAHHS/HFAP (FY 2018 Hospital Surveys)	All CoPs	PE	Health & Safety
Number of 60-Day Validation Surveys	9	9	9
Number of Surveys with Conditions Missed by AO	9	4	5
Disparity Rate	100.00%	44.44%	55.56%

Appendix B Table 9: AAHHS/HFAP
Hospital Disparity Rate
FY 2018

CoP	Facilities with CoP	Matching Surveys	Disparate Surveys	Disparity Rate
Physical Environment	8	4	4	44.44%
Infection Control	4	0	4	44.44%
Surgical Services	3	1	2	22.22%
Governing Body	1	0	1	11.11%
QAPI	1	0	1	11.11%

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

Category	Total Cited by SA	Missed by AO	Disparity Rate
Fire/Smoke Barrier	22	13	13.83%
Sprinkler	14	12	12.77%
Means of Egress	18	9	9.57%
Hazardous Areas	8	5	5.32%
Electrical	6	4	4.26%
Elevators	2	2	2.13%
Emergency Lighting	3	1	1.06%
Flammable & Combustible Storage	2	1	1.06%
EES	1	1	1.06%
Interior Finish	1	1	1.06%

Appendix B Table 11: AAHHS/HFAP
Top 10 Missed LSC Citations for Hospitals
98 Percent of all Missed Citations

Critical Access Hospitals

AAHHS/HFAP (FY 2018 CAH Surveys)	All CoPs	PE	Health & Safety
Number of 60-Day Validation Surveys	1	1	1
Number of Surveys with Conditions Missed by AO	1	1	NA
Disparity Rate	100.00%	100.00%	NA

Appendix B Table 92: AAHHS/HFAP
CAH Disparity Rate
FY 2018

CoP	Facilities with CoP	Matching Surveys	Disparate Surveys	Disparity Rate
Physical Plant and Environment	2	1	1	100.00%

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

Category	Total Cited by SA	Missed by AO	Disparity Rate
Fire/Smoke Barrier	5	4	16.67%
Sprinkler	5	2	8.33%
Electrical	3	2	8.33%
Flammable & Combustible Storage	2	1	4.17%
Anesthetizing Location	1	1	4.17%
Elevators	1	1	4.17%
Furnishings & Decorations	1	1	4.17%
Generator	1	1	4.17%

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

Community Health Accreditation Partner

Home Health Agency

CHAP (FY 2018 HHA Surveys)	All CoPs	Health & Safety
Number of 60-Day Validation Surveys	36	36
Number of Surveys with Conditions Missed by AO	6	6
Disparity Rate	16.67%	16.67%

Appendix B Table 125: CHAP
HHA Disparity Rate
FY 2018

CoPs	Facilities with CoPs	Matching Surveys	Disparate Surveys	Disparity Rate
Skilled Professional Services	2	1	1	2.78%
Establishment of Emergency Program	2	1	1	2.78%
Clinical Records	2	1	1	2.78%
Home Health Aide Services	2	1	1	2.78%
Care Planning, Coordination, and Quality of Care	2	1	1	2.78%
Skilled Professional Services	2	1	1	2.78%

Appendix B Table 136: CHAP
Top Six Disparate CoPs for HHAs
56 Percent of all Disparate Surveys

Hospice

CHAP (FY 2018 Hospice Surveys)	All CoPs	Health & Safety
Number of 60-Day Validation Surveys	17	17
Number of Surveys with Conditions Missed by AO	4	4
Disparity Rate	23.53%	23.53%

Appendix B Table 147: CHAP
Hospice Disparity Rate
FY 2018

CoPs	Facilities with CoP(s)	Matching Surveys	Disparate Surveys	Disparity Rate
Hospice Aide and Homemaker Services	3	1	2	11.76%
IDG, Care Planning, Coordination of Services	2	0	2	11.76%
Quality Assessment & Performance Improvement	2	0	2	11.76%
Establishment of the Emergency Program	2	1	1	5.88%
Infection Control	1	0	1	5.88%

Appendix B Table 18: CHAP
Top Five Disparate CoPs for Hospice
67 Percent of all Disparate Surveys

DNV GL-Healthcare

Hospitals

DNV GL (FY 2018 Hospital Surveys)	All CoPs	PE	Health & Safety
Number of 60-Day Validation Surveys	19	19	19
Number of Surveys with Conditions Missed by AO	5	5	1
Disparity Rate	26.32%	26.32%	5.26%

Appendix B Table 19: DNV GL-Healthcare
Hospital Disparity Rate
FY 2018

CoPs	Facilities with CoP(s)	Matching Surveys	Disparate Surveys	Disparity Rate
Physical Environment	7	2	5	26.32%
Infection Control	1	0	1	5.26%
Emergency Services	1	0	1	5.26%
Governing Body	1	1	0	0.00%
Patient Rights	1	1	0	0.00%

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
Means of Egress	18	16	14.16%
Hazardous Areas	15	15	13.27%
Sprinkler	18	10	8.85%
Fire/Smoke Barrier	13	7	6.19%
Fire Alarm	8	7	6.19%
Medical Gas	6	6	5.31%
HVAC	4	4	3.54%
Doors	8	3	2.65%
Electrical	4	3	2.65%
Emergency Lighting	4	3	2.65%

Appendix B Table 21: DNV GL-Healthcare
Top 10 Missed LSC Citations for Hospitals
87 Percent of all Missed Citations

Critical Access Hospitals

DNV GL (FY 2018 CAHs)	All CoPs	PE	Health & Safety
Number of 60-Day Validation Surveys	5	5	5
Number of Surveys with Conditions Missed by AO	2	1	2
Disparity Rate	40.00%	20.00%	40.00%

Appendix B Table 162: DNV GL-Healthcare
CAHs Disparity Rate
FY 2018

CoP	Facilities with CoP	Matching Surveys	Disparate Surveys	Disparity Rate
Physical Plant and Environment	1	0	1	20.00%
Provision of Services	1	0	1	20.00%
Surgical Services	2	1	1	20.00%

Appendix B Table 173: DNV GL-Healthcare
Top Disparate CoPs for CAHs
100 Percent of all Disparate Surveys

The Joint Commission

Hospitals

TJC (FY 2018 Hospital and LTCH Surveys)	All CoPs	PE	Health & Safety
Number of 60-Day Validation Surveys	78	78	78
Number of Surveys with Conditions Missed by AO	36	20	21
Disparity Rate	46.15%	25.64%	26.92%

Appendix B Table 184: TJC
Hospital and LTCH Disparity Rate
FY 2018

CoPs	Facilities with CoPs	Matching Surveys	Disparate Surveys	Disparity Rate
Physical Environment	40	21	19	24.36%
Infection Control	24	12	12	15.38%
Governing Body	15	6	9	11.54%
Food and Dietetic Services	6	1	5	6.41%
QAPI	5	1	4	5.13%

Appendix B Table 25: TJC
Top Seven Disparate CoPs for Hospitals and LTCHs
75 Percent of all Disparate Surveys

Category	Total Cited by SA	Missed by AO	Disparity Rate
Sprinkler	85	43	9.58%
Hazardous Areas	42	31	6.90%
Fire Alarm	42	25	5.57%
Doors	51	18	4.01%
Construction	16	14	3.12%
Flammable & Combustible Storage	18	13	2.90%
Fire/Smoke Barrier	51	11	2.45%
Emergency Lighting	9	6	1.34%
Cooking Facility	7	4	0.89%
Anesthetizing Location	3	1	0.22%

Appendix B Table 2619: TJC
Top 10 Missed LSC Citations for Hospital
100 Percent of all Missed Citations

Psychiatric Hospitals

TJC (FY 2018 Psychiatric Hospital Surveys)	All CoPs	PE	Health & Safety
Number of 60-Day Validation Surveys	21	21	21
Number of Surveys with Conditions Missed by AO	8	6	7
Disparity Rate	38.10%	28.57%	33.33%

Appendix B Table 27: TJC
Psychiatric Hospital Disparity Rate
FY 2018

CoPs	Facilities with CoPs	Matching Surveys	Disparate Surveys	Disparity Rate
Physical Environment	11	5	6	28.57%
Governing Body	6	1	5	23.81%
Infection Control	7	3	4	19.05%
Special Medical Record Reqs for Psych Hospitals	12	8	4	19.05%
Food and Dietetic Services	5	2	3	14.29%

Appendix B Table 28: TJC
Top Six Disparate CoPs for Psychiatric Hospitals
81 Percent of all Disparate Surveys

Category	Total Cited by SA	Missed by AO	Disparity Rate
Means of Egress	19	15	20.27%
Hazardous Areas	8	7	9.46%
Fire Alarm	9	6	8.11%
Fire/Smoke Barrier	7	6	8.11%
Generator	6	1	1.35%
Doors	4	1	1.35%
Eye Wash	1	1	1.35%
Smoking Regulations	1	1	1.35%
Sprinkler	7	0	0.00%

Appendix B Table 29: TJC
Missed LSC Citations for Psychiatric Hospitals
100 Percent of all Missed Citations

Ambulatory Surgery Center

TJC (FY 2018 ASC Surveys)	All CoPs	PE	Health & Safety
Number of 60-Day Validation Surveys	21	21	21
Number of Surveys with Conditions Missed by AO	9	7	3
Disparity Rate	42.86%	33.33%	14.29%

Appendix B Table 200: TJC
ASC Disparity Rate
FY 2018

CoPs	Facilities with CoPs	Matching Surveys	Disparate Surveys	Disparity Rate
Environment	14	7	7	33.33%
Quality Assessment & Performance Improvement	3	1	2	9.52%
Basic Requirements	1	0	1	4.76%
Governing Body and Management	1	0	1	4.76%
Surgical Services	1	0	1	4.76%
Nursing Services	1	0	1	4.76%
Laboratory and Radiologic services	1	0	1	4.76%
Patient Rights	2	1	1	4.76%
Patient Admission, Assessment and Discharge	1	0	1	4.76%

Appendix B Table 211: TJC
Top Nine Disparate CoPs for ASCs
100 Percent of all Disparate Surveys

Category	Total Cited by SA	Missed by AO	Disparity Rate
Sprinkler	13	5	8.20%
Fire Drill	9	4	6.56%
Emergency Lighting	4	4	6.56%
Electrical	3	3	4.92%
Fire/Smoke Barrier	12	2	3.28%
Flammable & Combustible Storage	2	2	3.28%
Fire Alarm	6	1	1.64%
Construction	1	1	1.64%
Medical Gas	4	0	0.00%
Hazardous Areas	2	0	0.00%

Appendix B Table 222: TJC
Top 10 Missed LSC Citations for ASCs
100 Percent of all Missed Citations

Home Health Agency

TJC (FY 2018 HHA Surveys)	All CoPs	Health & Safety
Number of 60-Day Validation Surveys	33	33
Number of Surveys with Conditions Missed by AO	7	7
Disparity Rate	21.21%	21.21%

Appendix B Table 233: TJC
HHA Disparity Rate
FY 2018

CoPs	Facilities with CoPs	Matching Surveys	Disparate Surveys	Disparity Rate
Patient Rights	4	2	2	6.06%
Care Planning, Coordination, and Quality of Care	5	3	2	6.06%
Home Health Aide Services	2	0	2	6.06%
Organization and Administration of Services	1	0	1	3.03%
Clinical Records	1	0	1	3.03%
Organization, Services & Administration	1	0	1	3.03%
Acceptance of Patients, POC, Med Super	3	2	1	3.03%
Skilled Nursing Service	1	0	1	3.03%
Comprehensive Assessment of Patients	1	0	1	3.03%
Skilled Professional Services	1	0	1	3.03%

Appendix B Table 244: TJC
Top Disparate CoPs for HHAs
100 Percent of all Disparate Surveys

Hospice

TJC (FY 2018 Hospice Surveys)	All CoPs	Health & Safety
Number of 60-Day Validation Surveys	7	7
Number of Surveys with Conditions Missed by AO	1	1
Disparity Rate	14.29%	14.29%

Appendix B Table 35: TJC
Hospice Disparity Rate
FY 2018

CoPs	Facilities with CoP	Matching Surveys	Disparate Surveys	Disparity Rate
Infection Control	2	1	1	14.29%

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

Critical Access Hospital

TJC (FY 2018 CAH Surveys)	All CoPs	PE	Health & Safety
Number of 60-Day Validation Surveys	11	11	11
Number of Surveys with Conditions Missed by AO	4	3	2
Disparity Rate	36.36%	27.27%	18.18%

Appendix B Table 37: TJC
CAH Disparity Rate
FY 2018

CoPs	Facilities with CoPs	Matching Surveys	Disparate Surveys	Disparity Rate
Physical Plant and Environment	6	3	3	27.27%
Provision of Services	2	1	1	9.09%
Establishment of the Emergency Program	1	0	1	9.09%
Emergency Services	1	0	1	9.09%

Appendix B Table 38: TJC
Disparate CoPs for CAHs
100 Percent of all Disparate Surveys

Category	Total Cited by SA	Missed by AO	Disparity Rate
Hazardous Areas	6	6	17.14%
Fire/Smoke Barrier	8	5	14.29%
Doors	4	3	8.57%
Means of Egress	6	1	2.86%
Construction	1	1	2.86%
Elevators	1	1	2.86%
EES	1	1	2.86%
Electrical	2	0	0.00%
Medical Gas	2	0	0.00%
Sprinkler	2	0	0.00%

Appendix B Table 39: TJC
Top Ten Missed LSC Citations for CAHs
100 Percent of all Missed Citations

Program Types

Hospital

ALL AOs (FY 2018 Hospital and LTCH Surveys)	All CoPs	PE	Health & Safety
Number of 60-Day Validation Surveys	107	107	107
Number of Surveys with Conditions Missed by AO	50	29	27
Disparity Rate	46.73%	27.10%	25.23%

Appendix B Table 40: Hospital Disparities FY 2018

CoPs	Facilities with CoPs	Matching Surveys	Disparate Surveys	Disparity Rate
Physical Environment	55	27	28	26.2%
Infection Control	29	12	17	15.9%
Governing Body	17	7	10	9.3%
QAPI	6	1	5	4.7%
Food and Dietetic Services	6	1	5	4.7%

Appendix B Table 251: Top Five Disparate CoPs for Hospitals
77 Percent of all Disparate Surveys

Category	Total Cited by SA	Missed by AO	Disparity Rate
Sprinkler	117	65	9.91%
Hazardous Areas	65	51	7.77%
Fire/Smoke Barrier	86	31	4.73%
Fire Alarm	56	31	4.73%
Means of Egress	71	20	3.05%
Flammable & Combustible Storage	22	16	2.44%
Construction	19	14	2.13%
Doors	66	11	1.68%
Emergency Lighting	16	10	1.52%
Cooking Facility	10	5	0.76%

Appendix B Table 262: Top 10 Missed LSC Citations for Hospitals
97 Percent of all Missed Citations

Psychiatric Hospital

ALL AOs (FY 2018 Psychiatric Hospital Surveys)	All CoPs	PE	Health & Safety
Number of 60-Day Validation Surveys	21	21	21
Number of Surveys with Conditions Missed by AO	8	6	7
Disparity Rate	38.10%	28.57%	33.33%

Appendix B Table 273: Psychiatric Hospital Disparities FY 2018

CoPs	Facilities with CoPs	Matching Surveys	Disparate Surveys	Disparity Rate
Physical Environment	11	5	6	28.57%
Governing Body	6	1	5	23.81%
Infection Control	7	3	4	19.05%
Special Medical Record Reqs for Psych Hospitals	12	8	3	14.29%
Food and Dietetic Services	5	2	3	14.29%

Appendix B Table 44: Top Five Disparate CoPs for Psychiatric Hospitals
81 Percent of all Disparate Surveys

Category	Total Cited by SA	Missed by AO	Disparity Rate
Means of Egress	19	15	20.27%
Hazardous Areas	8	7	9.46%
Fire Alarm	9	6	8.11%
Fire/Smoke Barrier	7	6	8.11%
Generator	6	1	1.35%
Doors	4	1	1.35%
Eye Wash	1	1	1.35%
Smoking Regulations	1	1	1.35%
Sprinkler	7	0	0.00%

Appendix B Table 45: Top Nine Missed LSC Citations for Psychiatric Hospitals
100 Percent of all Missed Citations

Ambulatory Surgery Center

ALL AOs (FY 2018 ASC Surveys)	All CoPs	PE	Health & Safety
Number of 60-Day Validation Surveys	58	58	58
Number of Surveys with Conditions Missed by AO	24	15	16
Disparity Rate	41.38%	25.86%	27.59%

Appendix B Table 46: ASC Disparities FY 2018

CoPs	Facilities with CoPs	Matching Surveys	Disparate Surveys	Disparity Rate
Environment	29	13	16	28%
Governing Body and Management	12	4	8	14%
Infection Control	16	8	8	14%
Quality Assessment & Performance Improvement	11	4	7	12%
Surgical Services	5	1	4	7%
Medical Staff	8	4	4	7%

Appendix B Table 47: Top Six Disparate CoPs for ASCs
84 Percent of all Disparate Surveys

Category	Total Cited by SA	Missed by AO	Disparity Rate
Fire/Smoke Barrier	36	15	10.00%
Sprinkler	25	12	8.00%
Emergency Lighting	12	10	6.67%
Fire Drill	15	6	4.00%
Fire Alarm	14	3	2.00%
Flammable & Combustible Storage	5	3	2.00%
Construction	3	2	1.33%
EES	3	1	0.67%
Anesthetizing Location	1	1	0.67%

Appendix B Table 48: Top Nine Missed LSC Citations for ASCs
100 Percent of all Missed Citations

Critical Access Hospital

ALL AOs (FY 2018 CAH Surveys)	All CoPs	PE	Health & Safety
Number of 60-Day Validation Surveys	17	17	17
Number of Surveys with Conditions Missed by AO	7	5	4
Disparity Rate	41.18%	29.41%	23.53%

Appendix B Table 49: CAH Disparities FY 2018

CoPs	Facilities with CoPs	Matching Surveys	Disparate Surveys	Disparity Rate
Physical Plant and Environment	9	4	5	29%
Provision of Services	3	1	2	12%
Emergency Services	1	0	1	6%
Establishment of the Emergency Program	1	0	1	6%
Surgical Services	2	1	1	6%

Appendix B Table 50: Top Five Disparate CoPs for CAHs
100 Percent of all Disparate Surveys

Category	Total Cited by SA	Missed by AO	Disparity Rate
Fire/Smoke Barrier	17	13	16.25%
Hazardous Areas	13	13	16.25%
Means of Egress	9	2	2.50%
Electrical	6	2	2.50%
Construction	2	2	2.50%
Elevators	2	2	2.50%
Doors	4	1	1.25%
Flammable & Combustible Storage	2	1	1.25%
Anesthetizing Location	1	1	1.25%
Emergency Lighting	1	1	1.25%

Appendix B Table 51: Top 10 Missed LSC Citations for CAHs
95 Percent of all Missed Citations

Hospice

ALL AOs (FY 2018 Hospice Surveys)	All CoPs	Health & Safety
Number of 60-Day Validation Surveys	32	32
Number of Surveys with Conditions Missed by AO	5	5
Disparity Rate	15.63%	15.63%

Appendix B Table 52: Hospice Disparities FY 2018

CoPs	Facilities with CoP(s)	Matching Surveys	Disparate Surveys	Disparity Rate
IDG, Care Planning, Coordination of Services	3	1	2	6.25%
Quality Assessment & Performance Improvement	3	1	2	6.25%
Infection Control	3	1	2	6.25%
Hospice Aide and Homemaker Services	3	1	2	6.25%
IDG, Care Planning, Coordination of Services	3	1	2	6.25%
Quality Assessment & Performance Improvement	3	1	2	6.25%
Infection Control	3	1	2	6.25%
Hospice Aide and Homemaker Services	3	1	2	6.25%

Appendix B Table 53: Top Eight Disparate CoPs for Hospice Facilities
62 Percent of all Disparate Surveys

Home Health Agency

ALL AOs (FY 2018 HHA Surveys)	All CoPs	Health & Safety
Number of 60-Day Validation Surveys	81	81
Number of Surveys with Conditions Missed by AO	15	15
Disparity Rate	18.52%	18.52%

Appendix B Table 54: HHA Disparities FY 2018

CoPs	Facilities with CoPs	Matching Surveys	Disparate Surveys	Disparity Rate
Care Planning, Coordination, and Quality of Care	9	5	4	4.94%
Skilled Professional Services	6	2	4	4.94%
Clinical Records	4	1	3	3.70%
Home Health Aide Services	4	1	3	3.70%
Acceptance of Patients, POC, Med Super	4	2	2	2.47%
Skilled Nursing Service	2	0	2	2.47%
Patient Rights	4	2	2	2.47%
Comprehensive Assessment of Patients	3	1	2	2.47%

Appendix B Table 55: Top Eight Disparate CoPs for HHAs
81 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^{o} F and flammable materials that have a flash point at or below 100^{o} 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.