



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

Ref: QSO: 19-01-AO/CLIA

DATE: October 04, 2018

TO: State Survey Agency Directors

FROM: Director
Quality, Safety & Oversight Group

SUBJECT: FY 2017 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 2017 annual RTC details the review, validation, and oversight of AOs FY 2016 Medicare accreditation programs and 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.

Additional AO Oversight Initiatives:

- 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 overall performance data for the AOs themselves.
- CMS is also testing a more streamlined, effective way to assess AOs' ability to ensure that facilities and suppliers comply with CMS requirements.

Background

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

State Agency surveyors conduct the validation surveys that are the basis for the analysis in the RTC. We appreciate the tremendous work of the State surveyors that has made it possible for CMS to fulfill its AO oversight responsibilities and complete the annual report to Congress. Currently, CMS has approved accreditation programs for the following Medicare facility types: hospitals, psychiatric hospitals, critical access hospitals (CAHs), home health agencies (HHAs), hospices, ambulatory surgery centers (ASCs), outpatient physical therapy and speech-language pathology services (OPTs), and rural health clinics (RHCs).

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

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

Additional Oversight Initiatives

Posting AO Performance Data:

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 overall performance data for the AOs themselves. The list will include only hospitals at this time, however CMS hopes to be able to have the same publically available information for other providers and suppliers at a future time.

Please see https://qcor.cms.gov/hosp_cop/HospitalCOPs.html

The Validation Program:

CMS is testing a more streamlined, effective 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 will eliminate the second state-conducted validation survey and instead use direct observation during the original AO-run survey to evaluate the AO surveyors' ability to assess compliance with CMS Conditions of Participation.

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: FY2017 Report to Congress

cc: Survey and Certification Regional Office Management

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

FISCAL YEAR 2017



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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), outpatient physical therapy and speech-language pathology services (OPTs), and rural health clinics (RHCs).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 process⁷; and

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

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) 2016 (October 1, 2015 – September 30, 2016), 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 2009; 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 2016, including the number of initial and renewal accreditation surveys performed and the number of facilities denied.

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 2016 AO performance measures and the results for each AO; and comparison of FYs 2015 and 2016 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 2014–2016 are presented by facility type for each AO. The FY 2016 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).

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 and Health & Safety Disparity Rates Analysis

The most frequently disparate CoPs, Life Safety Code (LSC) and health and safety disparity rates, and an overall depiction of the disparity rates for individual AOs 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 2016.

Section 7 – Clinical Laboratory Improvement Amendments Validation Program

Clinical Laboratory Improvement Amendments (CLIA) legislative authority and mandate, validation reviews, and evaluation of AO performance.

Appendix A – Performance Measures

Table 1 compares the performance measure results by AO for comparable FYs 2015–2016 performance measures discussed in Section 3.

Appendix B – Fiscal Year 2016 Life Safety Code and Health & Safety Disparity Rates

Detailed FY 2016 LSC and health and safety statistics for each program type and AO as discussed in Section 5.

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 provides 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 summarizes the initial, renewal, and other reviews conducted by CMS.

Table 1
CMS Review
of AO Medicare Accreditation Programs
FYs 2009–2016

Type of Review and CMS Decision	FY 2009	FY 2010	FY 2011	FY 2012	FY 2013	FY 2014	FY 2015	FY 2016
Initial Applications								
• Decision: Full approval	1	1	3	1	1	1	0	1
• Decision: Denied	0	0	0	0	0	0	0	0
• Incomplete application	0	0	0	2	0	0	1	1
• Application withdrawn	1	2	1	1	1	0	0	0
Renewal Applications								
• Decision: Full approval	6	1	0	3	6	4	6	1
• Decision: Denied	0	0	0	0	0	0	0	0
• Decision: Conditional approval	1	2	0	0	0	0	0	0
• Decision: Final approval removing conditional status	1	2	0	0	0	0	0	0
Total Reviews of Initial and Renewal Applications	10	8	4	7	8	5	7	3
Focused Reviews								
• Standards review	4	15	18	20	3	25	12	23
• Survey process review	4	12	10	5	0	1	5	5
• Issue review and resolution	*	*	44	22	41	11	3	16
• Performance review	1	2	3	3	0	4	3	1
Total Focused Reviews	9	29	75	50	44	41	23	45

*Data was not collected for these issues during this timeframe.

From FY 2009 through FY 2016, CMS completed 52 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 316 focused reviews. In total, 368 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 eight provider or supplier program types: hospital, psychiatric hospital, CAH, HHA, hospice, ASC, OPT, and RHC. As of September 30, 2016, 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 2016

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
AOA/HFAP	American Osteopathic Association/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

Table 3
Approved Medicare Accreditation Programs by AO
FY 2016

AO	Hospital	Psych Hospital	CAH	HHA	Hospice	ASC	OPT	RHC	Total
AAAASF						X	X	X	3
AAAHC						X			1
ACHC				X	X				2
AOA/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

The number of CMS-approved Medicare accreditation programs has grown steadily over the past several years resulting in 22 approved programs in FY 2016.

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, 2012 through November 27, 2018. The final notice announcing this decision was published in the *Federal Register* (77 FR 70446) (November 26, 2012), and can be accessed at <http://www.gpo.gov/fdsys/pkg/FR-2012-11-26/pdf/2012-28640.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 22, 2015 through April 22, 2019. The final notice announcing this decision was published in the *Federal Register* (80 FR 21244) (April 17, 2015), and can be accessed at <http://www.gpo.gov/fdsys/pkg/FR-2015-04-17/pdf/2015-08917.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.gpo.gov/fdsys/pkg/FR-2016-02-25/pdf/2016-04092.pdf>.

Accreditation Association for Ambulatory Health Care, Inc.

Ambulatory Surgery Center

AAAHHC's ASC Medicare accreditation program was initially approved December 19, 1996. AAAHC's current term of approval is effective December 20, 2012 through December 20, 2018. The final notice announcing this decision was published in the *Federal Register* (77 FR 70783) (November 27, 2012), and can be accessed at <https://www.gpo.gov/fdsys/pkg/FR-2012-11-27/pdf/2012-28728.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 <http://www.gpo.gov/fdsys/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 <http://www.gpo.gov/fdsys/pkg/FR-2013-11-05/pdf/2013-26374.pdf>.

American Osteopathic Association/Healthcare Facilities Accreditation Program

Hospital

AOA/HFAP has had an approved hospital Medicare accreditation program since 1965. Although its hospital program is mentioned by name in the Act, it is also explicitly subject to the Secretary's review and approval. AOA/HFAP's current term of approval is effective September 25, 2013 through September 25, 2019. The final notice announcing this decision was published in the *Federal Register* (78 FR 53149) (August 28, 2013), and can be accessed at <http://www.gpo.gov/fdsys/pkg/FR-2013-08-28/pdf/2013-21008.pdf>.

Critical Access Hospital

AOA/HFAP's CAH Medicare accreditation program was initially approved December 27, 2001. AOA/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 <http://www.gpo.gov/fdsys/pkg/FR-2013-11-29/pdf/2013-28521.pdf>.

Ambulatory Surgery Center

AOA/HFAP's ASC Medicare accreditation program was initially approved January 30, 2003. AOA/HFAP's current term of approval is effective October 23, 2013 through October 23, 2017. The final notice announcing this approval was published in the *Federal Register* (77 FR 59616) (September 28, 2012), and can be accessed at <http://www.gpo.gov/fdsys/pkg/FR-2012-09-28/pdf/2012-23996.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, 2012 through March 31, 2018. The final notice announcing this decision was published in the *Federal Register* (77 FR 17072) (March 23, 2012), and can be accessed at <http://www.gpo.gov/fdsys/pkg/FR-2012-03-23/pdf/2012-6598.pdf>.

Hospice

CHAP's hospice Medicare accreditation program was initially approved April 20, 1999. CHAP's current term of approval is effective November 20, 2012 through November 20, 2018. The final notice announcing this decision was published in the *Federal Register* (77 FR 64344) (October 19, 2012), and can be accessed at <http://www.gpo.gov/fdsys/pkg/FR-2012-10-19/pdf/2012-25467.pdf>.

Center for Improvement in Healthcare Quality

Hospital

CIHQ's hospital Medicare accreditation program was initially approved for a 4-year term effective July 26, 2013 through July 26, 2017. The final notice announcing this approval was published in the *Federal Register* (78 FR 45231) (July 26, 2013), and can be accessed at <http://www.gpo.gov/fdsys/pkg/FR-2013-07-26/pdf/2013-18014.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 September 26, 2012 through September 26, 2018. The final notice announcing this decision was published in the *Federal Register* (77 FR 51537) (August 24, 2012), and can be accessed at <http://www.gpo.gov/fdsys/pkg/FR-2012-08-24/pdf/2012-20199.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 <http://www.gpo.gov/fdsys/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.gpo.gov/fdsys/pkg/FR-2016-04-29/pdf/2016-10165.pdf>.

The Compliance Team

Rural Health Clinics

TCT's RHC Medicare accreditation program was initially approved for a 4-year term effective July 18, 2014 through July 18, 2018. The final notice announcing this approval was published in the *Federal Register* (79 FR 42019) (July 18, 2014), and can be accessed at <http://www.gpo.gov/fdsys/pkg/FR-2014-07-18/pdf/2014-16735.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 <http://www.gpo.gov/fdsys/pkg/FR-2014-06-27/pdf/2014-15103.pdf>.

Psychiatric Hospital

TJC's psychiatric hospital Medicare accreditation program was initially approved for a 4-year period effective February 25, 2011 through February 25, 2015. TJC's current term of approval is effective February 25, 2015 through February 25, 2019. The final notice announcing this decision was published in the *Federal Register* (80 FR 9466) (February 23, 2015), and can be accessed at <http://www.gpo.gov/fdsys/pkg/FR-2015-02-23/pdf/2015-03559.pdf>.

Performance Review:

Based on the serious nature of the corporate on-site findings during a November 3–5, 2015 corporate on-site visit and validation survey disparity rates for FYs 2013, 2014, and 2015, an accreditation program review was opened for TJC's CMS-approved psychiatric hospital accreditation program December 17, 2015.

In accordance with CMS regulation at § 488.8(c), TJC was given 6 months to correct identified areas of non-compliance and adopt comparable requirements. The 6-month review period ended June 14, 2016. At that time, it was determined that TJC failed to satisfactorily demonstrate compliance, or implement and sustain improvements based on the requirements outlined in TJC's plans of correction (POCs) dated January 15, 2016; March 30, 2016; and June 15, 2016.

In accordance with CMS regulation at § 488.8(c)(3), CMS placed TJC's psychiatric hospital accreditation program on probation for 6 months. TJC had an opportunity to implement the approved corrective actions during the probationary period which ended December 17, 2016. CMS had 60 calendar days from the end of the probationary period to conduct a corporate on-site visit and issue written determination, including supportive findings, as to whether or not TJC's CMS-approved psychiatric hospital accreditation program continued to meet the Medicare requirements.

On January 24–26, 2017, CMS conducted a survey observation to determine whether programmatic changes identified in TJC’s POC had been fully implemented; and whether these changes resulted in compliance and survey process comparability to that of Medicare. Overall, the survey team performed well. On January 31, 2017 through February 2, 2017, CMS conducted a corporate on-site visit to determine whether programmatic changes identified in the POCs had been fully implemented; and whether the changes resulted in compliance and survey process comparability to that of CMS. As a result, on February 15, 2017, CMS recommended approval of TJC’s psychiatric hospital accreditation program, with the option to exercise Immediate Jeopardy in accordance with 42 CFR § 488.8(d). CMS continues to work closely with TJC and monitor their psychiatric hospital accreditation program activity.

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, 2011 through November 21, 2017. The final notice announcing this decision was published in the *Federal Register* (76 FR 59134) (September 23, 2011), and can be accessed at <http://www.gpo.gov/fdsys/pkg/FR-2011-09-23/pdf/2011-24496.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 <http://www.gpo.gov/fdsys/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 <http://www.gpo.gov/fdsys/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 <http://www.gpo.gov/fdsys/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 2016, AOs were responsible for assuring compliance with Medicare conditions for 40 percent (12,495) 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 2016

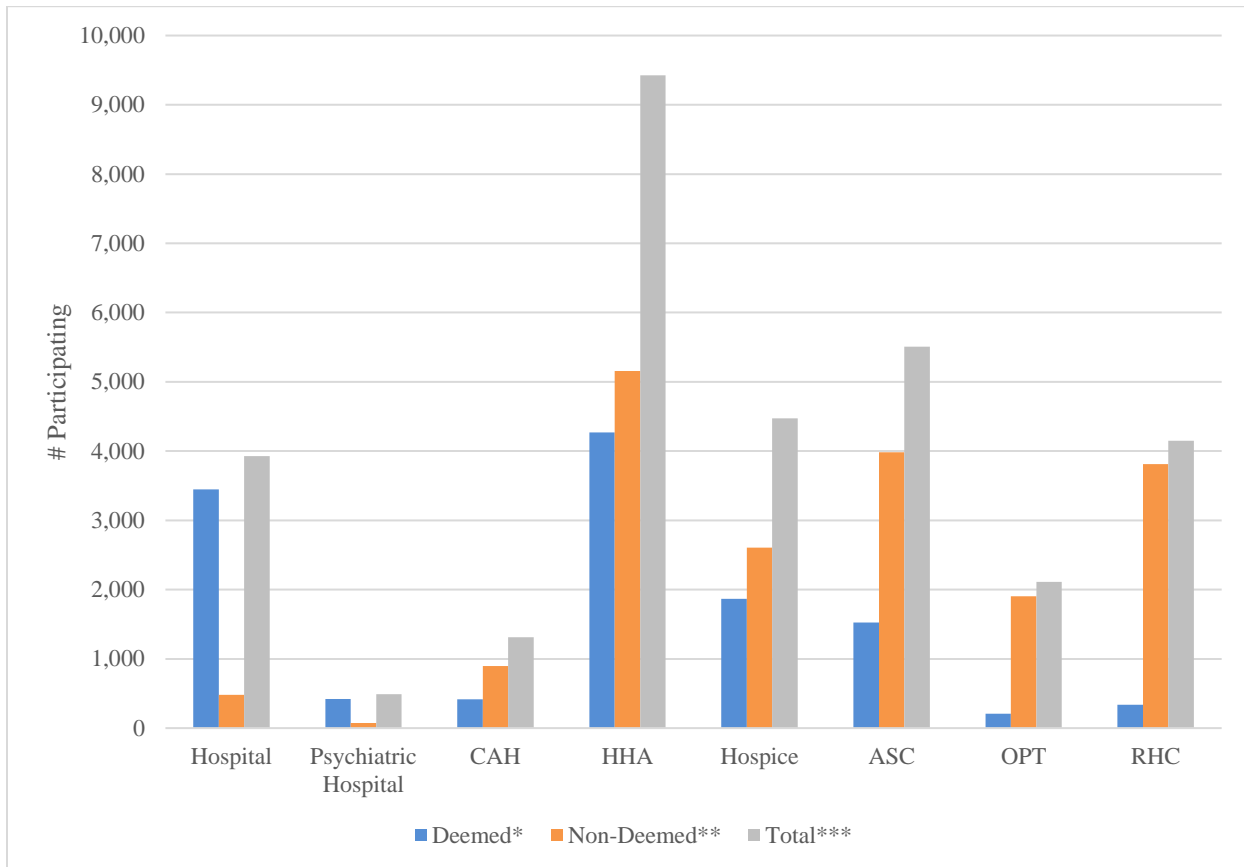
Program Type	Deemed* (percentage)	Non-Deemed** (percentage)	Total***
Hospital	3,448 (88)	481 (12)	3,929
Psychiatric Hospital	419 (85)	72 (15)	491
CAH	418 (32)	895 (68)	1,313
HHA	4,271 (45)	5,145 (55)	9,425
Hospice	1,867 (42)	2,606 (58)	4,473
ASC	1,527 (28)	3,982 (72)	5,509
OPT	206 (10)	1,905 (90)	2,111
RHC	339 (8)	3,812 (92)	4,151
Total	12,495 (40)	18,907 (60)	31,402

*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 by CMS Data Team 2/13/2017.

**Graph 1
Deemed & Non-Deemed Medicare-Participating Facilities
Program Types with a Medicare Accreditation Program Option
FY 2016**



*As reported by AOs in ASSURE.

**Surveyed by an SA for compliance with Medicare conditions.

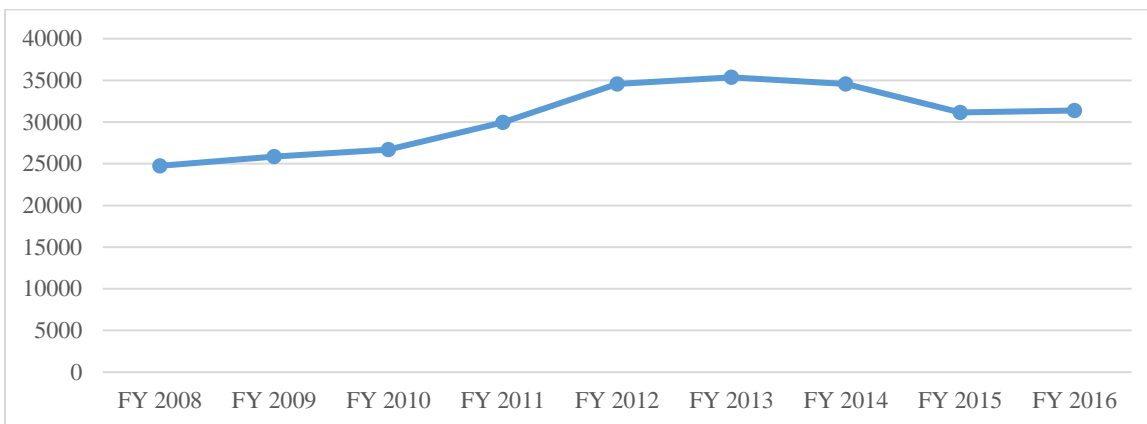
***As reported by CMS Data Team 2/13/2017.

In FY 2016, 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 88 percent for hospitals to a low of 8 percent for RHCs. Hospitals have historically had the largest percentage of facilities participating in Medicare via accreditation and deemed status until this year.

Growth in Medicare Deemed Facilities

The total number of Medicare-participating health care facilities across all program types has increased 26 percent from 24,752 in FY 2008 to 31,402 in FY 2016. 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. (See Graph 2.)

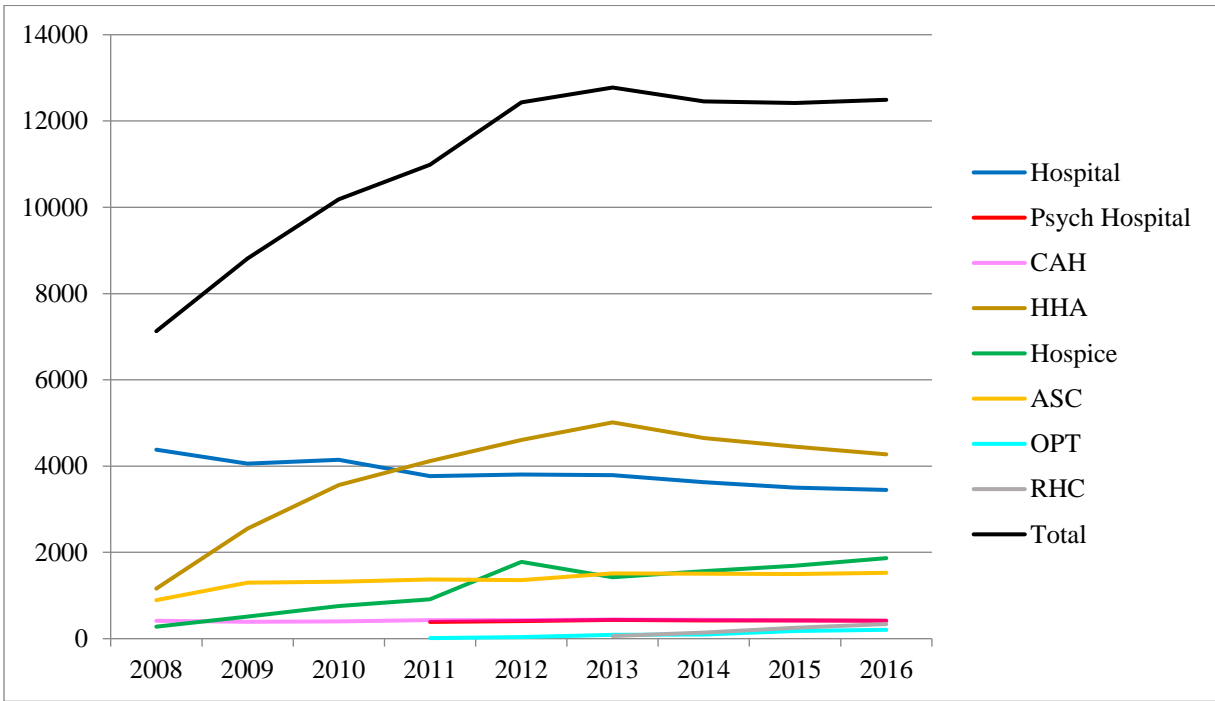
Graph 2
Medicare-Participating Health Care Facilities
FYs 2008–2016



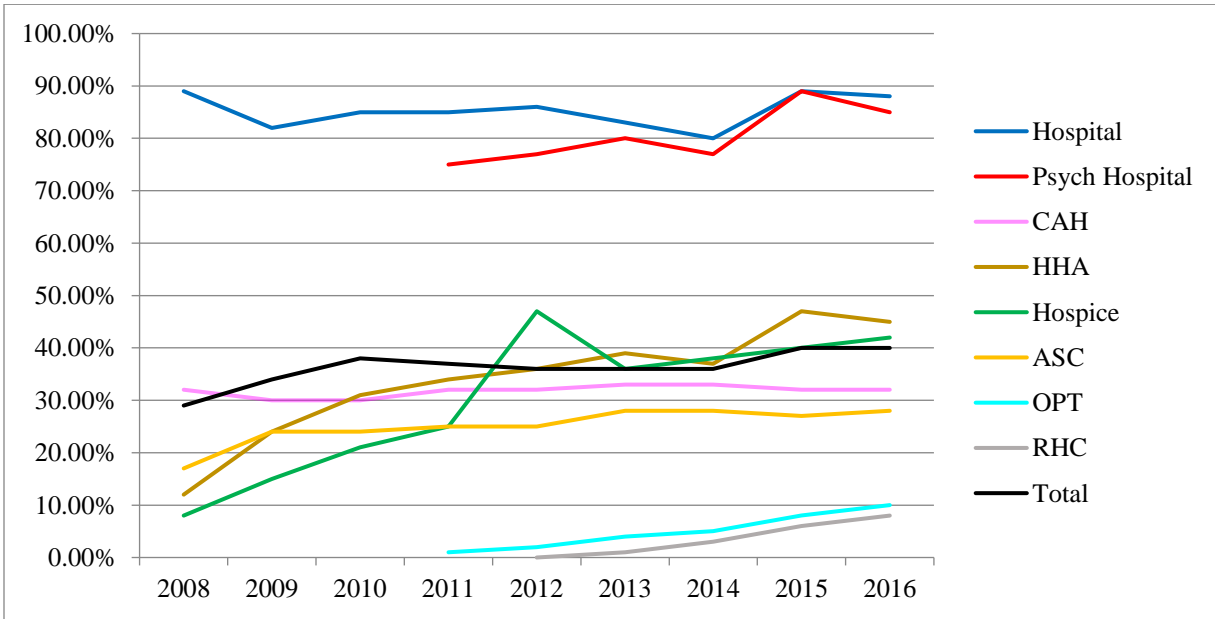
The growth in the number of deemed facilities is likely attributable, in part, to CMS’ workload priorities for SAs. The long-standing CMS policy for SAs has been that initial surveys for newly enrolling facilities with an approved accreditation option have a lower priority as compared to statutorily 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 2008–2016**



**Graph 4
Deemed Facilities as Percentage of Medicare-Participating Facilities by Program Type
FYs 2008-2016**



- **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 27 percent, the growth in deemed facilities during that same period was much larger.
 - The number of facilities participating in Medicare via deemed status increased from 7,128 in FY 2008 to 12,415 in FY 2015, a 74-percent increase.
 - The number of facilities participating in Medicare via deemed status increased from 12,415 in FY 2015 to 12,495 in FY 2016, 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 40 percent.
- **Hospital:** The number of Medicare-participating hospitals was largely unchanged between FYs 2008 and 2016. 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.
 - The number of deemed hospitals decreased from 4,381 in FY 2008 to 3,500 in FY 2015, a reduction of 20 percent. (Please note: this decrease in percentage is adjusted based on the separate reporting of 419 deemed psychiatric hospitals.)
 - The number of deemed hospitals decreased from 3,500 in FY 2015 to 3,448 in FY 2016, a reduction of 1 percent.
 - The proportion of all Medicare-participating hospitals that were deemed decreased by 1 percent from FY 2015 to FY 2016.
- **Psychiatric Hospital:** The number of Medicare-certified psychiatric hospitals decreased from 516 in FY 2011 to 491 in FY 2016, a 5-percent decrease.
 - The number of deemed psychiatric hospitals increased from 388 in FY 2011 to 424 in FY 2015, a 9-percent increase.
 - The number of deemed psychiatric hospitals decreased from 424 in FY 2015 to 419 in FY 2016, a reduction of 1 percent.
 - The proportion of all Medicare-participating psychiatric hospitals which were deemed increased from 75 percent in FY 2011 to 85 percent in FY 2016.
- **CAH:** The number of Medicare-certified CAHs was essentially unchanged with 1,310 in FY 2008 to 1,313 in FY 2016.
 - The number of deemed CAHs increased slightly from 415 in FY 2008 to 420 in FY 2015, a 1-percent increase.
 - The number of deemed CAHs decreased from 420 in FY 2015 to 418 in FY 2016, a less than 1-percent decrease.
 - The proportion of all Medicare-certified deemed CAHs remained at 32 percent in FY 2016.

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 decreased from 9,893 in FY 2008 to 9,425 in FY 2016, a 5-percent decrease.
 - The number of deemed HHAs increased from 1,161 in FY 2008 to 4,450 in FY 2015, a 283-percent increase.
 - The number of deemed HHAs decreased from 4,450 in FY 2015 to 4,271 in FY 2016, a 4-percent decrease.
 - The proportion of all Medicare-certified HHAs which were deemed nearly quadrupled from 12 percent in FY 2008 to 45 percent in FY 2016.
- **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 4,473 in FY 2016, a 32-percent increase. There has also been corresponding significant growth in the number and proportion of deemed hospices.
 - The number of deemed hospices increased from 278 in FY 2008 to 1,694 in FY 2015, a 509-percent increase.
 - The number of deemed hospices increased from 1,694 in FY 2015 to 1,867 in FY 2016, a 10-percent increase.
 - The proportion of all Medicare-certified hospices which were deemed increased five-fold from 8 percent in FY 2008 to 42 percent in FY 2016.
- **ASC:** The number of Medicare-certified ASCs increased from 5,217 in FY 2008 to 5,509 in FY 2016, a 6-percent increase.
 - The number of deemed ASCs increased significantly from 893 in FY 2008 to 1,499 in FY 2015, a 68-percent increase.
 - The number of deemed ASCs increased from 1,499 in FY 2015 to 1,527 in FY 2016, a 2-percent increase.
 - The proportion of all Medicare-certified ASCs which were deemed increased from 17 percent in FY 2008 to 28 percent in FY 2016.
- **OPT:** The number of Medicare-certified OPTs decreased from 2,471 in FY 2011 to 2,111 in FY 2016, a 15-percent decrease.
 - The number of deemed OPTs increased from 13 in FY 2011 to 175 in FY 2015, a 1,246-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.
 - The number of deemed OPTs increased from 175 in FY 2015 to 206 in FY 2016, an 18-percent increase.
 - The proportion of all Medicare-certified OPTs which were deemed increased from 1 percent in FY 2011 to 10 percent in FY 2016.

- **RHC:** The number of Medicare-certified RHCs increased slightly from 4,108 in FY 2012 to 4,151 in FY 2016, a 1-percent increase.
 - The number of deemed RHCs increased from 3 in FY 2012 to 253 in FY 2015, an 8,333-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.
 - The number of deemed RHCs increased from 253 in FY 2015 to 339 in FY 2016, a 34-percent increase.
 - The proportion of all Medicare-certified RHCs which were deemed increased from less than 1 percent in FY 2012 to 8 percent in FY 2016.

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 renewal 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 2016, the AOs reported having performed 1,353 initial surveys and 3,860 renewal surveys. The total number of deemed status facilities in FY 2016 was 12,516. The total number of facilities denied was 387. (See Table 5.)

Table 5
Total Number of Deemed Facilities
Initial Surveys and Renewal Surveys
by AO Accreditation Program
FY 2016

Program Type/ AOs	Total Deemed Facilities	Initial Surveys	Renewal Surveys	Denials
Hospital				
AOA/HFAP	122	0	41	0
CIHQ	39	5	0*	2
DNV GL	264	9	86	7
TJC	3,035	33	1,171	7
Hospital Total	3,460	47	1,298	16
Psychiatric Hospital				
TJC	419	67	133	4
Psychiatric Hospital Total	419	67	133	4
CAH				
AOA/HFAP	27	0	10	1
DNV GL	66	1	18	3
TJC	325	5	115	1
CAH Total	418	6	143	5
HHA				
ACHC	682	94	139	40
CHAP	1,989	248	576	130
TJC	1,605	114	541	48
HHA Total	4,276	456	1,256	218
Hospice				
ACHC	215	42	33	8
CHAP	761	118	224	43
TJC	892	172	217	25
Hospice Total	1,868	332	474	76
ASC				
AAAASF	174	42	58	9
AAAH	767	122	238	18
AOA/HFAP	28	1	8	0
TJC	561	72	158	16
ASC Total	1,530	237	462	43

Program Type/ AOs	Total Deemed Facilities	Initial Surveys	Renewal Surveys	Denials
OPT				
AAAASF	206	66	35	10
OPT Total	206	66	35	10
RHC				
AAAASF	194	54	58	8
TCT	145	88	1	7
RHC Total	339	142	59	15
Total	12,516	1,353	3,860	387

Source: As reported by the AOs in ASSURE.

*The CIHQ Hospital accreditation program received initial approval in the latter part of FY 2013. Therefore, no renewal surveys were due to be conducted in FY 2016.

Note: The total number of deemed facilities on this table includes 21 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 and Web-ASSURE import file uploads, 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 2016 Accrediting Organization Performance Measures

In FY 2016, AOs were scored on their performance on 10 measures in 4 key performance focus areas: ASSURE Database, Facility Notification Letters, Survey Schedule, and Formal Correspondence. (See Table 6.)

Table 6
AO Performance Measures
FY 2016

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 no-match** lists as measured by:
 - The timeliness of electronic submission of no-match data follow-up activity
 - The evidence of no-match reconciliation

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 accuracy and completeness of the letters submitted as measured by:
 - All required attachments are included.
- The notification letters contain all required information.
- The data in ASSURE is being updated consistent with the letters.

Survey Schedule:

AOs are asked to submit a monthly schedule which documents surveys completed in the past month as well as scheduled surveys for the current and subsequent 2 months. Performance in this area is based on:

- The accuracy of monthly survey schedules (specifically, no instances of arrival of the SA to conduct a validation survey and being informed that the accreditation survey had not been conducted as indicated on the survey schedule)
- 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

Formal Correspondence:

AOs should submit a response to formal CMS correspondence addressing issues of concern. Performance in this area was based on:

- The timely responses to formal correspondence (on or before the specified due date)

*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.

**Records in ASSURE undergo a “matching” process on a nightly basis. This process attempts to match records within ASSURE to records held in the National Database. When the system is unable to automatically match records, these are noted as being a “no-match.”

Significant Changes for Fiscal Year 2016 Accrediting Organization Performance Measures**Retired Fiscal Year 2016 Performance Measures**

In FY 2016, CMS retired six of the FY 2015 performance measures in three key performance focus areas.

ASSURE Database:

- Accuracy and completeness of deemed facility data in ASSURE
 - The number of CMS Certification Numbers (CCNS) present (not missing more than 180 days)
- The timeliness of conduction triennial (renewal) surveys
- The timeliness of uploading Web-ASSURE import files

Facility Notification Letters:

- Accuracy and completeness of the letters submitted as measured by:
 - Do not contain duplicate notices
- The data in ASSURE are being corrected to address previous quarter CMS-identified deficiencies.

Survey Schedule:

- The timeliness of reporting changes in the survey schedule and incorporating these changes in the next survey schedule submission (and in the proper format)

New Fiscal Year 2016 Performance Measures

CMS added one new performance measure in one key performance focus area in FY 2016.

ASSURE Database:

- The timeliness of notifying facilities of survey results

Performance Measure Results

The FY 2015 and FY 2016 performance data for all AOs is presented below in two tables. The first table, Table 7, presents results for performance measures that were monitored in FYs 2015 and 2016. A comparison is presented by FY for these measures. The second table, Table 8, presents results for performance measures specific to FY 2016, including the addition of one new measure. Therefore, the data in Table 8 cannot be directly compared to the FY 2015 performance measure results and are presented independently. Both tables present 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 tables.

Table 7
Performance Measure Results (Percentage) for All AOs
Comparable Measures for FYs 2015–2016

	FY 2015	FY 2016
Denied initial surveys with condition-level findings	81	93
Timely electronic submission of no-match data follow-up*	97	100
Evidence of no-match reconciliation*	100	100
Letters submitted with attachments	100	96
Notification letters contain all required information	96	98
ASSURE is updated consistent with the letters	87	91
AO conducted survey as reported on survey schedule	100	100
Number of surveys performed matches number reported in ASSURE	96	96
Responses to CMS on or before specified due date	100	100

*CIHQ had no “no-match” records in FY 2015. TCT had no “no-match” records in FY 2016.

Table 8
Performance Measure Results (Percentage) for All AOs
FY 2016
(Not Comparable to FY 2015 Measures)

Performance Measure Results (Percentage) for All AOs FY 2016 (Not Comparable to FY 2015 Measures)	FY 2016
Timeliness of facility notification of survey results	96

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

1. ASSURE Database

- In FY 2015, five AOs scored 100 percent for the measure “Denied initial surveys with conditions.” However, four of the AOs demonstrated opportunity for improvement with scores ranging from 17 percent to 83 percent. In FY 2016, five of the AOs excelled, scoring 100 percent for the same measure. Two of the AOs had sample sizes less than five; therefore, weren’t able to calculate a score for this measure. Two of the AOs showed opportunity for improvement with scores of 68 percent and 83 percent respectively during that same time. Although overall AO performance has improved 12 percentage points since the last reported year, CMS continues to work with the AOs that demonstrate an opportunity for improvement. CMS has participated in one-on-one discussions and reviews with these AOs in an attempt to improve performance in this area.
- In FY 2015, the AOs excelled on the measure “Timely electronic submission of no-match data follow-up” with the exception of one AO who scored 75 percent, showing opportunity for improvement and one AO who had 0 “no-match” records. Typically, the smaller AOs have applicable records matched to a record already in the Automated Survey Processing Environment (ASPEN) system. In FY 2016, all of the AOs excelled, scoring 100 percent with the exception of one AO who had 0 “no-match” records for the same measure.
- All of the AOs excelled on the measure “Evidence of no-match reconciliation” in both FYs 2015 and 2016 with the exception of one AO who had 0 “no-match” records in FY 2015 and one AO who had the same scenario in FY 2016.
- In FY 2016, one new performance measure was introduced: “Timeliness of facility notification of survey results.” For this measure, five of the AOs excelled, scoring 100 percent. Two of the AOs performed well, scoring 98 percent and 99 percent respectively. Two of the AOs showed opportunity for improvement with scores of 74 percent and 93 percent.
- The following measures were retired at the end of FY 2016, due to sustained high performance: “Timely electronic submission of no-match data follow-up activity” and “Evidence of no-match reconciliation.” CMS reviews the performance measure scores annually to determine which measures, if any, can be retired prior to the next FY.

2. Facility Notification Letters

- In FY 2015, all of the AOs scored 100 percent for the measure “Letters Submitted with Attachments.” In FY 2016, six of the AOs excelled, scoring 100 percent for the same measure. Two of the AOs performed well, scoring 95 percent and 96 percent respectively. One AO showed opportunity for improvement with a score of 75 percent.
- In FY 2015, two of the AOs excelled, scoring 100 percent for the measure “Letters contain all required information.” Five of the AOs performed well, scoring 95 to 99 percent. Two of the AOs showed opportunity for improvement with scores of 88 percent and 92 percent respectively. In FY 2016, four of the AOs excelled, scoring 100 percent for the same measure. Three of the AOs performed well with one AO scoring 98 percent and two of the AOs scoring 99 percent. Two of the AOs showed opportunity for improvement with scores of 91 percent and 94 percent respectively. Two of the AOs excelled in both FYs 2015 and 2016 for the same measure.
- In FY 2015, three of the AOs performed well, scoring 96 percent to 98 percent for the measure “ASSURE is updated consistent with letters.” Six of the AOs showed opportunity for improvement with scores ranging from 76 percent to 90 percent. In FY 2016, one AO excelled, scoring 100 percent for the same measure. Three AOs performed well with two of the AOs scoring 96 percent and the third AO scoring 99 percent. Five AOs showed opportunity for improvement with scores ranging from 78 percent to 92 percent.
- The following measure was retired at the end of FY 2016, due to sustained high performance: “All required attachments are included.” CMS reviews the performance measure scores annually to determine which measures, if any, can be retired prior to the next FY.

3. Survey Schedule

- All AOs excelled, scoring 100 percent for the measure, “AO conducted survey as reported on the survey schedule,” for both FYs 2015 and 2016.
- In FY 2015, three AOs excelled, scoring 100 percent for the measure, “Number of surveys performed matches the number reported in ASSURE.” Four of the AOs performed well with scores ranging from 97 percent to 99 percent. Two of the AOs showed opportunity for improvement, with scores of 84 percent and 87 percent respectively. In FY 2016, three AOs excelled, scoring 100 percent for the same measure. Three of the AOs performed well with one AO scoring 98 percent and two of the AOs scoring 99 percent. Three of the AOs showed opportunity for improvement with scores ranging from 86 percent to 94 percent. For both FYs 2015 and 2016, two of the AOs excelled for the same measure.
- The following measure was retired at the end of FY 2016, due to sustained high performance: “AO conducted surveys reported on survey schedule.” CMS reviews the performance measure scores annually to determine which measures, if any, can be retired prior to the next FY.

4. Formal CMS Correspondence

- In FY 2015, all AOs scored 100 percent for the measure “Responses to CMS on or before specified due date.” Although all AOs excelled, the Formal CMS Correspondence measure was not recommended for retirement at the end of FY 2015 due to the recent history of performance scores lower than 100 percent by several of the AOs.
- In FY 2016, all AOs excelled, scoring 100 percent for this measure with the exception of one AO who did not have a sample size large enough to calculate the measure. The AO’s sample size was less than five.
- CMS continues to work closely with AOs to improve performance in areas that need improvement as well as to maintain high levels of performance in other areas. The goal is for all AOs to consistently score at or near 100 percent on all measures to ensure that AOs are effectively managing their Medicare accreditation programs and communicating vital program information to CMS.
- The following measure was retired at the end of FY 2016, due to sustained high performance: “Responses to CMS on or before specified due date.” This was the only performance measure associated with the key focus area: Formal CMS Correspondence. CMS reviews the performance measure scores annually to determine which measures, if any, can be retired prior to the next FY.

Accrediting Organization Specific Discussion (See Appendix A for data)

American Association for Accreditation of Ambulatory Surgery Facilities, Inc.

For the performance measures that can be compared to FY 2015 scores, AAAASF continued to excel on two of the three ASSURE Database performance measures, one of three Facility Notification Letters performance measures, one of two Survey Schedule performance measures, and the Formal Correspondence performance measure. AAAASF continued to perform well on the measures, “notification letters contain all required information,” and “number of surveys performed matches number reported in ASSURE.” AAAASF continued to show opportunity for improvement for the measure, “ASSURE is updated consistent with letters.” AAAASF excelled on the measure “denied initial surveys with condition-level findings in FY 2016,” a measure on which they demonstrated opportunity for improvement in FY 2015. AAAASF performed well on the new FY 2016 measure, “timeliness of facility notification of survey results.” For all measures where AAAASF demonstrated an opportunity for improvement, CMS worked with the AO to determine possible causes and provided guidance on improving future scores. In summary, AAAASF excelled on 6 of 10 measures in FY 2016.

Accreditation Association for Ambulatory Health Care, Inc.

For the performance measures that can be compared to FY 2015 scores, AAAHC continued to excel on two of the three ASSURE Database performance measures, one of the three Facility Notification Letters performance measures, one of two Survey Schedule performance measures, and the Formal Correspondence performance measure. AAAHC continues to demonstrate opportunity for improvement for the performance measures “notification letters contain all required information,” “ASSURE is updated consistent with letters,” and “number of surveys performed matches number reported in ASSURE.” AAAHC excelled on the measure “timely electronic submission of no-match data follow-up” in FY 2016, a measure on which they

demonstrated opportunity for improvement in FY 2015. AAAHC also showed opportunity for improvement for the new FY 2016 measure “timeliness of facility notification of survey results.” For all measures where AAAHC demonstrated an opportunity for improvement, CMS worked with the AO to determine possible causes and provided guidance on improving future scores. In summary, AAAHC excelled on 6 of 10 measures in FY 2016.

Accreditation Commission for Health Care

For the performance measures that can be compared to FY 2015 scores, ACHC continued to excel on all three ASSURE Database performance measures, two of the three Facility Notification Letters performance measures, both Survey Schedule performance measures, and the Formal Correspondence performance measure. ACHC continued to perform well on the measure “ASSURE is updated consistent with letters.” ACHC excelled on the new FY 2016 measure “timeliness of facility notification of survey results.” Overall, ACHC excelled on each of the FY 2016 comparable measures except for “ASSURE is updated consistent with letters.” CMS worked with ACHC and provided guidance on improving future scores. In summary, ACHC excelled on 9 of 10 performance measures in FY 2016.

American Osteopathic Association/Healthcare Facilities Accreditation Program

For the performance measures that can be compared to FY 2015 scores, AOA/HFAP continued to excel in two of the three ASSURE Database performance measures, both Survey Schedule performance measures, and the Formal Correspondence performance measure. For the ASSURE Database performance measure “Denied initial survey with condition-level findings,” AOA/HFAP did not have a sufficient sample size in FY 2016 to calculate this measure, therefore, a comparison cannot be made. For the performance measure “letters submitted with attachments,” AOA/HFAP demonstrated an opportunity for improvement in FY 2016. In FY 2015, AOA/HFAP excelled on this measure. For the new FY 2016 measure “timeliness of facility notification of survey results,” AOA/HFAP excelled. For all measures where AOA/HFAP demonstrated an opportunity for improvement, CMS worked with the AO to determine possible causes and provided guidance on improving future scores. In summary, AOA/HFAP excelled on 8 of 10 performance measures in FY 2016.

Community Health Accreditation Partner

For the performance measures that can be compared to FY 2015 scores, CHAP continued to excel on all three ASSURE Database performance measures “letters submitted with attachments,” “AO conducted survey as reported on survey schedule,” and the Formal Correspondence performance measure. CHAP continued to perform well on the measures “notification letters contain all required information,” and “numbers of surveys performed matches number reported in ASSURE.” CHAP continued to show opportunity for improvement for the measure “ASSURE is updated consistent with letters.” CHAP showed opportunity for improvement for the new FY 2016 performance measure, “timeliness of facility notification of survey results.” For all measures where CHAP demonstrated an opportunity for improvement, CMS worked with the AO to determine possible causes and provided guidance on improving future scores. In summary, CHAP excelled on 6 of 10 applicable measures in FY 2016.

Center for Improvement in Healthcare Quality

For the performance measures that can be compared to FY 2015 scores, CIHQ continued to excel on one of the three Facility Notification Letters performance measures, one of the two Survey Schedule performance measures, and the Formal Correspondence performance measure. CIHQ continued to perform well on the measure “ASSURE is updated consistent with letters.” For the ASSURE Database performance measures “timely electronic submission of no-match data follow-up,” and “evidence of no-match reconciliation,” CIHQ had 0 “no-match” records in FY 2015, therefore, a comparison cannot be made. For the FY 2016 ASSURE Database performance measure “denied initial surveys with condition-level findings,” CIHQ did not have a sufficient sample size to calculate this measure; therefore, a comparison cannot be made. In FY 2016, CIHQ showed opportunity for improvement for the measure “number of surveys performed matches number reported in ASSURE.” In FY 2015, they excelled on the same measure. While CIHQ performed well for the measure “letters submitted with attachments,” they previously excelled for the same measure in FY 2015. For the new FY 2016 measure “timeliness of facility notification of survey results,” CIHQ excelled. For all measures where CIHQ demonstrated an opportunity for improvement, CMS worked with the AO to determine possible causes and provided guidance on improving future scores. In summary, CIHQ excelled on 6 of 10 performance measures in FY 2016.

DNV GL-Healthcare

For the performance measures that can be compared to FY 2015 scores, DNV GL continued to excel on two of the three ASSURE Database performance measures, one of the three Facility Notification Letters performance measures, one of the two Survey Schedule performance measures, and the Formal Correspondence performance measure. DNV GL continued to show opportunity for improvement for the measure “denied initial surveys with condition-level findings. However, for the measure “ASSURE is updated consistent with letters,” DNV GL performed well compared to the prior FY for which they showed opportunity for improvement. DNV GL excelled on the measures “notification letters contain all required information,” and “number of surveys performed matches number reported in ASSURE.” For the new FY 2016 measure “timeliness of facility notification of survey results,” DNV GL excelled. For all measures where DNV GL demonstrated an opportunity for improvement, CMS worked with the AO to determine possible causes and provided guidance on improving future scores. In summary, DNV GL excelled on 8 of 10 measures in FY 2016.

The Compliance Team

For the performance measures that can be compared to FY 2015 scores, TCT continued to excel on one of the three Facility Notification Letters performance measures, and one of the two Survey Schedule performance measures. For the ASSURE Database performance measures “timely electronic submission of no-match data follow-up,” and “evidence of no-match reconciliation,” TCT had 0 “no-match” records in FY 2016; therefore, a comparison cannot be made. For the Formal Correspondence performance measure “responses to CMS on or before specified due date,” TCT did not have a sufficient sample size in FY 2016 to calculate this measure; therefore, a comparison cannot be made. TCT continued to show opportunity for improvement for the measures “notification letters contain all required information,” “ASSURE

is updated consistent with letters,” and “number of surveys performed matches number reported in ASSURE.” TCT excelled on the measure “denied initial surveys with condition-level findings.” For the new FY 2016 measure “timeliness of facility notification of survey results,” TCT performed well. For all measures where TCT demonstrated an opportunity for improvement, CMS worked with the AO to determine possible causes and provided guidance on improving future scores. In summary, TCT excelled on 3 of 10 performance measures in FY 2016.

The Joint Commission

For the performance measures that can be compared to FY 2015 scores, TJC continued to excel on two of the three ASSURE Database performance measures, one of the two Survey Schedule performance measures, and the Formal Correspondence performance measure. TJC continued to perform well on the measures “notification letters contain all required information,” and “number of surveys performed matches number reported in ASSURE.” TJC continued to show opportunity for improvement for the measures “denied initial surveys with condition-level findings,” and “ASSURE is updated consistent with letters.” For the new FY 2016 measure, “timeliness of facility notification of survey results,” TJC excelled. For all measures where TJC demonstrated an opportunity for improvement, CMS worked with the AO to determine possible causes and provided guidance on improving future scores. Overall, TJC excelled on 5 of 10 measures in FY 2016.

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; 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.

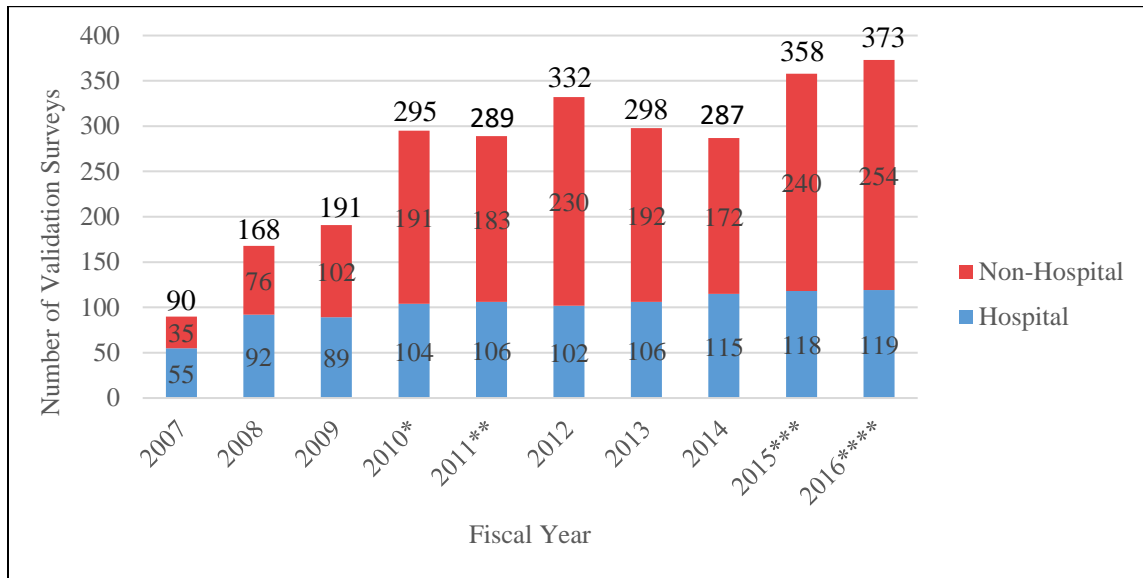
Note: The discussion in this section of the methodology for and results of CMS validation of the AOs' Medicare accreditation programs is based only upon analysis of the 60-day representative sample validation surveys.

Prior to 2009, Section 1875 of the Act required CMS to report to Congress annually only on TJC's hospital program.⁹ Nevertheless, in FY 2007, CMS began conducting 60-day representative sample 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 2016, CMS conducted a total of 373 representative sample 60-day validation surveys for 6 facility types across AOs.¹⁰ This total comprised 119 hospital surveys (including 21 psychiatric hospitals) and 254 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 In FY 2016, OPT, which includes the newly accredited TCT, 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 2007-2016**



*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.

Since 2007, CMS has worked to strengthen its oversight of AOs. FYs 2014–2015 showed an increase in the amount of surveys conducted. These increases were due to the availability of additional mid-year AO validation program budget funds. FYs 2015–2016 showed a slight increase in the number of surveys conducted as well. The recent history of validation survey samples is as follows:

- 2014: 115 hospital and 172 non-hospital surveys totaling 287 surveys
- 2015: 118 hospital and 240 non-hospital surveys totaling 358 surveys
- 2016: 119 hospital and 254 non-hospital surveys totaling 373 surveys

These numbers represent a 314-percent increase in the overall number of validation surveys conducted, from 90 in FY 2007 to 373 in FY 2016. During the same time period, the number of non-hospital validation surveys conducted increased by 626 percent, from 35 surveys in FY 2007 to 254 surveys in FY 2016. The number of hospital validation surveys conducted increased by 116 percent, from 55 surveys in FY 2007 to 119 surveys in FY 2016.

60-Day Validation Surveys

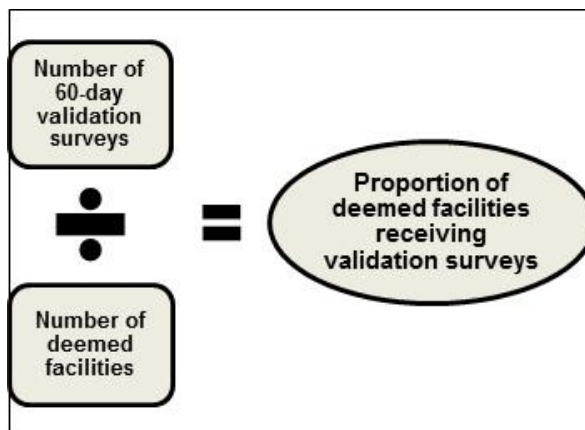
The purpose of 60-day validation surveys is to assess the AO’s ability to ensure compliance with Medicare conditions. These validation surveys are on-site full surveys completed by SA surveyors no later than 60 days after the end date of an AO’s Medicare accreditation program full survey. The SA performs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

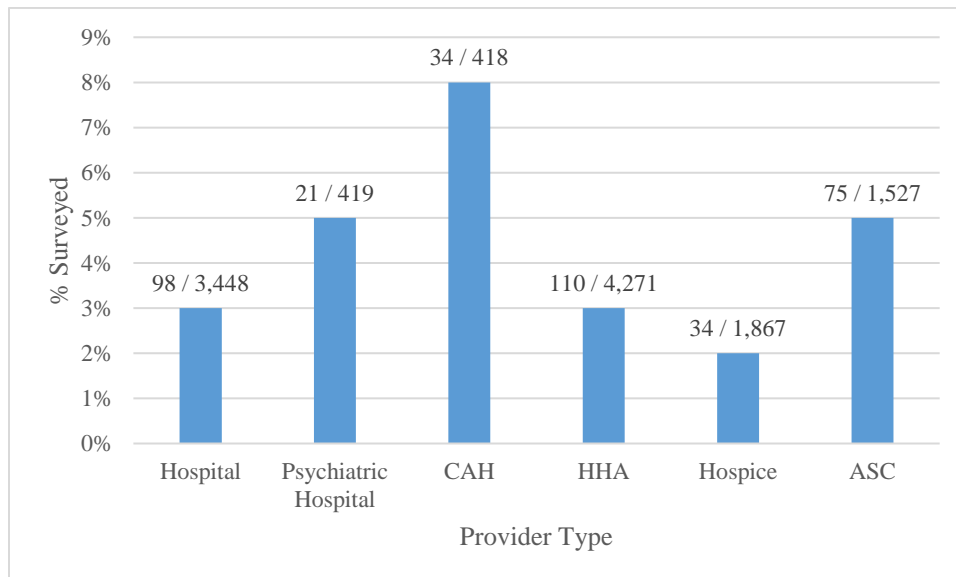


The proportion of deemed facilities that received a 60-day validation survey in FY 2016 is as follows:

- **Hospitals:** Three percent of deemed hospitals received a validation survey in FY 2016 (98 validation surveys conducted out of 3,448 deemed facilities).
- **Psychiatric Hospitals:** Five percent of deemed psychiatric hospitals received a validation survey in FY 2016 (21 validation surveys conducted out of 419 deemed facilities).
- **CAHs:** Eight percent of deemed CAHs received a validation survey in FY 2016 (34 validation surveys conducted out of 418 deemed facilities).
- **HHAs:** Three percent of deemed HHAs received a validation survey in FY 2016 (110 validation surveys conducted out of 4,271 deemed facilities).
- **Hospices:** Two percent of deemed hospices received a validation survey in FY 2016 (34 validation surveys conducted out of 1,867 deemed facilities).
- **ASCs:** Five percent of deemed ASCs received a validation survey in FY 2016 (76 validation surveys conducted out of 1,527 deemed facilities).

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

Graph 6
60-Day Validation Surveys Performed by Provider Type
FY 2016



Validation Analysis

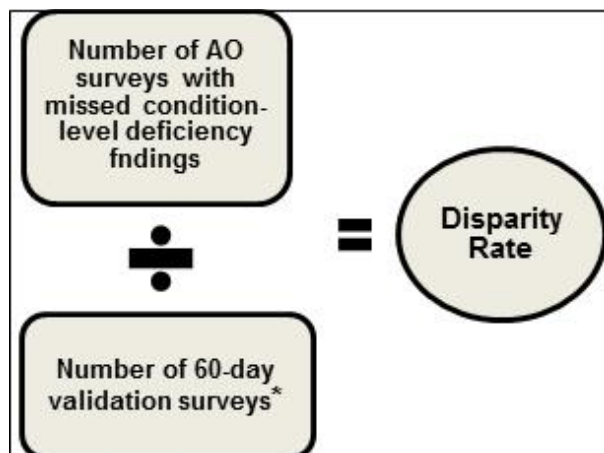
Condition-Level Deficiencies and Disparity Rate

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 or not the SA cited condition-level deficiencies.

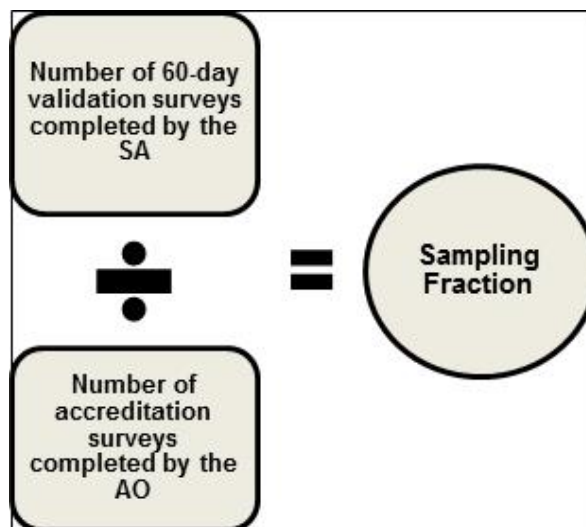
The methodology for the disparity rate is set by regulation at 42 CFR § 488.1. The numerator is the number of surveys where the AO did not cite a comparable serious (condition-level) deficiency as cited by the SA. The denominator is the total number of surveys in the 60-day representative validation 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, no matter how small the program.

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 2014 through FY 2016 by facility type. (See Table 9.)

**Table 9
60-Day Validation Survey Results for Each Facility Type
FYs 2014–2016**

	FY 2014	FY 2015	FY 2016
HOSPITAL			
60-Day Validation Sample Surveys	103	102	98
SA Surveys with Condition-Level Deficiencies	41	42	50
AO Surveys with Missed Comparable Deficiencies	39	40	45
Disparity Rate	38%	39%	46%
Sampling Fraction	.09	.08	.07
PSYCHIATRIC HOSPITAL			
60-Day Validation Sample Surveys	12	16	21
SA Surveys with Condition-Level Deficiencies	10	12	12
AO Surveys with Missed Comparable Deficiencies	9	11	12
Disparity Rate	75%	69%	57%
Sampling Fraction	.08	.10	.11
CRITICAL ACCESS HOSPITAL			
60-Day Validation Sample Surveys	27	33	34
SA Surveys with Condition-Level Deficiencies	16	15	16
AO Surveys with Missed Comparable Deficiencies	14	15	15
Disparity Rate	52%	45%	44%
Sampling Fraction	.17	.18	.24

	FY 2014	FY 2015	FY 2016
HOME HEALTH AGENCY			
60-Day Validation Sample Surveys	75	104	110
SA Surveys with Condition-Level Deficiencies	16	23	23
AO Surveys with Missed Comparable Deficiencies	11	17	20
Disparity Rate	15%	16%	18%
Sampling Fraction	.04	.05	.06
HOSPICE			
60-Day Validation Sample Surveys	16	34	34
SA Surveys with Condition-Level Deficiencies	3	4	6
AO Surveys with Missed Comparable Deficiencies	1	3	6
Disparity Rate	6%	9%	18%
Sampling Fraction	.02	.04	.04
AMBULATORY SURGERY CENTER			
60-Day Validation Sample Surveys	54	69	75
SA Surveys with Condition-Level Deficiencies	22	31	28
AO Surveys with Missed Comparable Deficiencies	17	29	26
Disparity Rate	31%	42%	35%
Sampling Fraction	.09	.09	.11

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 2012–2016. This lower deficiency rate is primarily due to these facility types not having deficiencies related to PE conditions. There is no PE condition for HHAs since these services are provided in the patient’s home. Although hospices do have a PE condition, a number of hospice services are provided in the patient’s home as well.

In FY 2016, the disparity rates for psychiatric hospitals and ASCs decreased by 12 percent and 8 percent respectively from FY 2015. The remaining program types’ disparity rates increased from FYs 2015 to 2016 with the exception of CAHs which had a 1-percent decrease. Hospices had the largest increase in the disparity rate of all the program types from FYs 2015 to 2016, with a 9-percent increase.

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 2014 to 2016. (See Tables 10-15.)

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. Due to decreased funding in FY 2013, the sample size decreased for each program type, with the exception of psychiatric hospitals and CAHs. In FY 2014, the number of validation surveys for CAHs, HHAs, Hospices and ASCs decreased, also as a result of decreased funding. In FYs 2015 and 2016, the number of validation surveys for these same program types increased with the exception of Hospices which remained the same. Only hospitals showed a decrease in the number of surveys performed from FY 2014 to FY 2016. 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 2014–2016 60-day validation surveys for individual AOs have been combined in the tables below to provide a more robust and reliable estimate of the disparity rates.

Hospital

The AOs with hospital programs in FY 2016 were AOA/HFAP, CIHQ, DNV GL, and TJC. (See Table 10 and Graphs 7-10.)

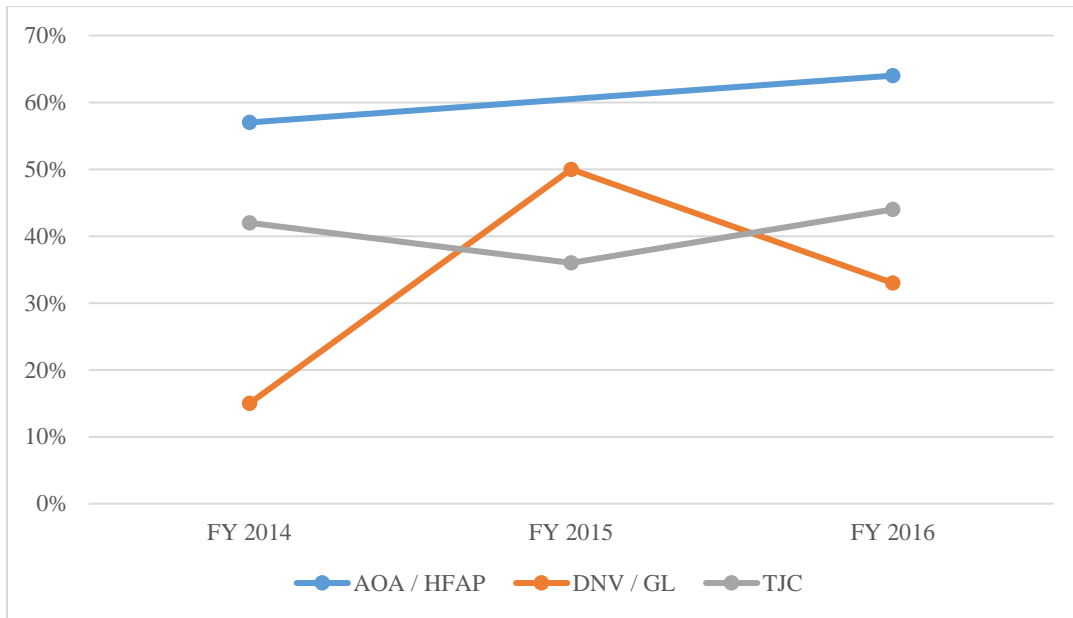
Table 10
Hospital 60-Day Validation Survey Results by AO
FYs 2014–2016

- Emp	AOA/HFAP			CIHQ		DNV GL			TJC			Total
	FY 2014	FY 2015	FY 2016	FY 2015	FY 2016	FY 2014	FY 2015	FY 2016	FY 2014	FY 2015	FY 2016	FYs 2014–2016
60-Day Validation Sample Surveys	7	4	14	1	1	20	8	15	76	89	68	303
SA Surveys with Condition-Level Deficiencies	4	*N/A	10	*N/A	*N/A	3	5	5	34	33	34	128
AO Surveys with Missed Comparable Deficiencies	4	*N/A	9	*N/A	*N/A	3	4	5	32	32	30	119
Overall Disparity Rate	57%	*N/A	64%	*N/A	*N/A	15%	50%	33%	42%	36%	44%	39%
Health and Safety Disparity Rate	14%	*N/A	14%	*N/A	*N/A	10%	25%	26%	17%	15%	25%	19%
Physical Environment Disparity Rate	57%	*N/A	64%	*N/A	*N/A	10%	25%	20%	37%	25%	25%	28%
Sampling Fraction	.11	*N/A	.34	*N/A	*N/A	.20	.07	.16	.07	.08	.06	.08

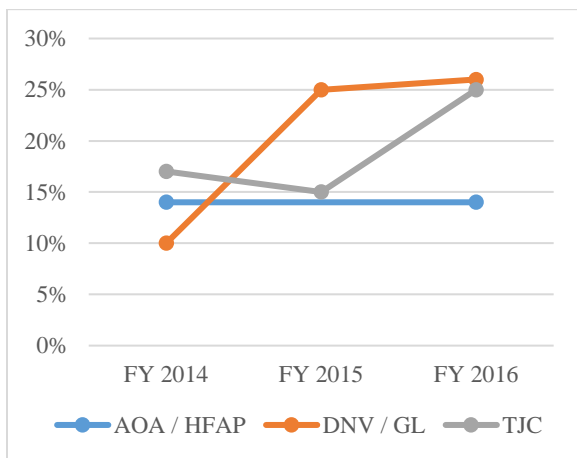
*N/A: When a minimum sample size of five is not achieved for an AO, no data is reported given the lack of statistical significance.

Note: CIHQ hospital accreditation program received initial CMS approval July 2013. No CIHQ selections in FY 2014.

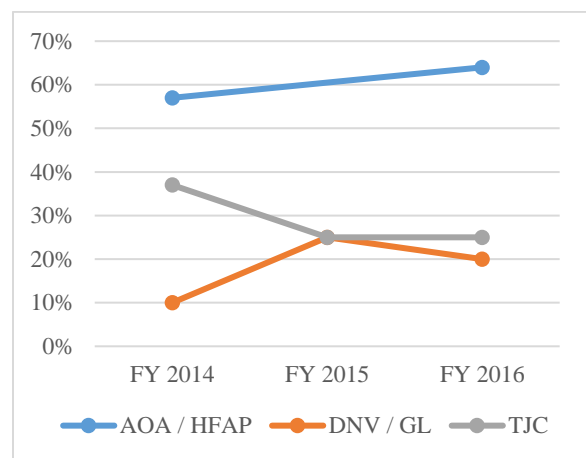
Graph 7
Hospital 60-Day Validation Survey
Overall Disparity Rate Results by AO
FYs 2014–2016



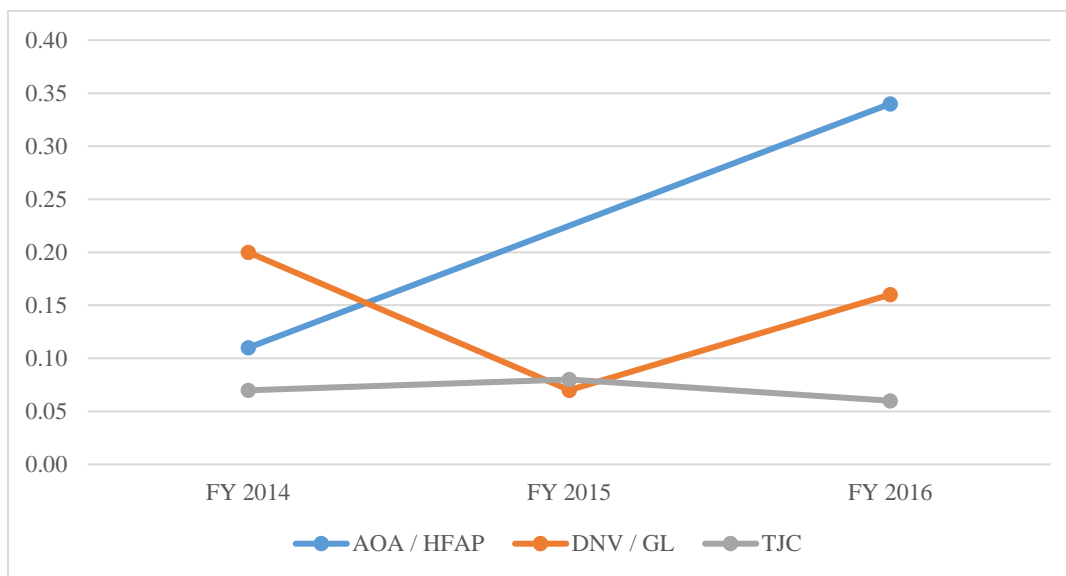
Graph 8
Hospital 60-Day Validation Survey
Health and Safety Disparity Rate Results
by AO
FYs 2014-2016



Graph 9
Hospital 60-Day Validation Survey PE
Disparity Rate Results
by AO
FYs 2014-2016



Graph 10
Hospital 60-Day Validation Survey Sampling Fraction Results
by AO
FYs 2014–2016



- AOA/HFAP:** In FY 2016, the overall disparity rate was 64 percent based on the completion of 14 validation surveys. The number of validation surveys conducted represents a 34-percent sample of the surveys conducted by AOA/HFAP. The FY 2016 overall disparity rate is 7 percentage points higher than the overall disparity rate for FY 2014. The overall disparity rate for FY 2014 was based on an 11-percent sample of surveys conducted during that period. In FY 2016, AOA/HFAP’s PE disparity rate was 50 percentage points higher than the health and safety disparity rate. In FY 2016, the SA cited PE at the condition level 19 times. AOA/HFAP missed 9 comparable deficiencies resulting in a disparity rate of 64 percent. The FY 2016 PE disparity rate is 7 percentage points higher than the FY 2014 PE disparity rate.
- CIHQ:** As a result of being a newly accredited AO, CIHQ completed only one validation survey in FY 2016. Therefore, no additional data are reported.
- DNV GL:** In FY 2016, the overall disparity rate was 33 percent based on the completion of 15 validation surveys. The number of validation surveys conducted represents a 16-percent sample of the surveys conducted by DNV GL. The FY 2016 overall disparity rate is 18 percentage points higher than the overall disparity rate for FY 2014. The FY 2014 overall disparity rate was based on a 20-percent sample of the surveys conducted during that period. In FY 2016, DNV GL’s health and safety disparity rate was 6 percentage points higher than the PE disparity rate. The primary drivers of DNV GL’s health and safety disparity rate were Governing Body and Infection Control. The SAs cited Governing Body at the condition level four times. DNV GL missed four comparable deficiencies resulting in a 27-percent disparity rate. The SAs cited Infection Control at the condition level five times. DNV GL missed four comparable deficiencies also resulting in a disparity rate of 27 percent. The FY 2016 PE disparity rate is 10 percentage points higher than the FY 2014 PE disparity rate.

- TJC:** In FY 2016, the overall disparity rate was 44 percent based on the completion of 68 validation surveys. The number of validation surveys conducted represents a 6-percent sample of surveys conducted by TJC. The FY 2016 overall disparity rate is 2 percentage points higher than the disparity rate for FY 2014. The overall disparity rate in FY 2014 was based on a 7-percent sample of surveys conducted during that period. While both the health and safety and PE disparity rates were 25 percent in FY 2016, the PE disparity rate decreased 12 percentage points and the health and safety disparity rate increased 8 percentage points from FY 2014 to FY 2016.

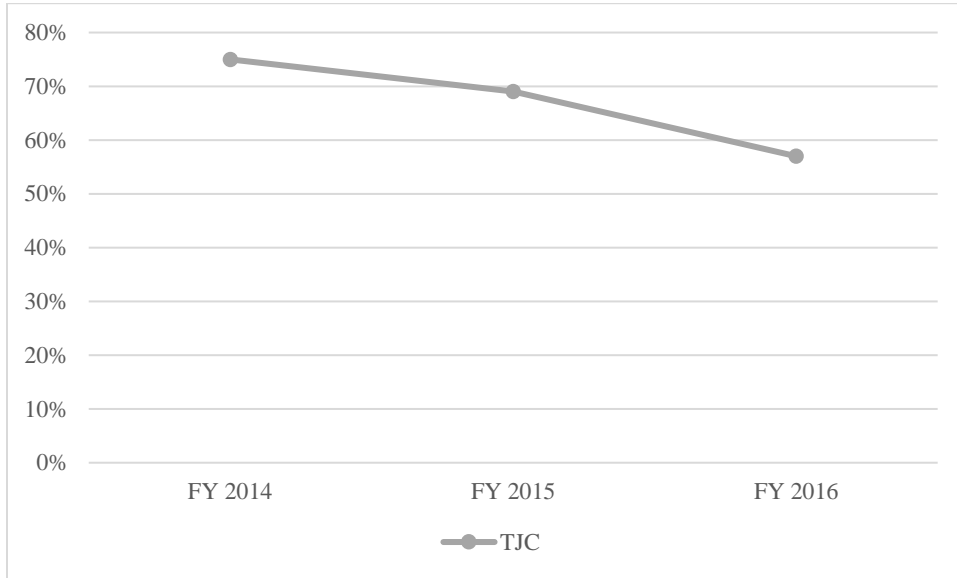
Psychiatric Hospital

TJC was the only AO with a CMS-approved psychiatric hospital Medicare accreditation program in FY 2016. The psychiatric hospital program was initially approved by CMS in FY 2011. (See Table 11 and Graphs 11-14.)

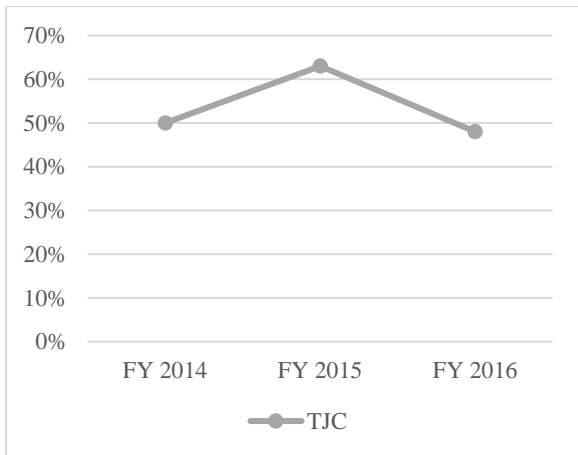
Table 11
Psychiatric Hospital 60-Day Validation Survey Results by AO
FYs 2014–2016

	TJC			Total
	FY 2014	FY 2015	FY 2016	FYs 2014–2016
60-Day Validation Sample Surveys	12	16	21	49
SA Surveys with Condition-Level Deficiencies	10	12	12	34
AO Surveys with Missed Comparable Deficiencies	9	11	12	32
Overall Disparity Rate	75%	69%	57%	65%
Health and Safety Disparity Rate	50%	63%	48%	53%
Physical Environment Disparity Rate	33%	38%	19%	29%
Sampling Fraction	.08	.10	.11	.10

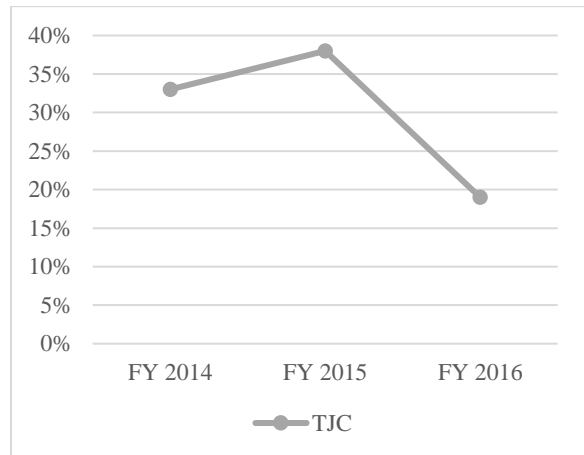
Graph 11
Psychiatric Hospital 60-Day Validation Survey
Overall Disparity Rate Results by AO
FYs 2014–2016



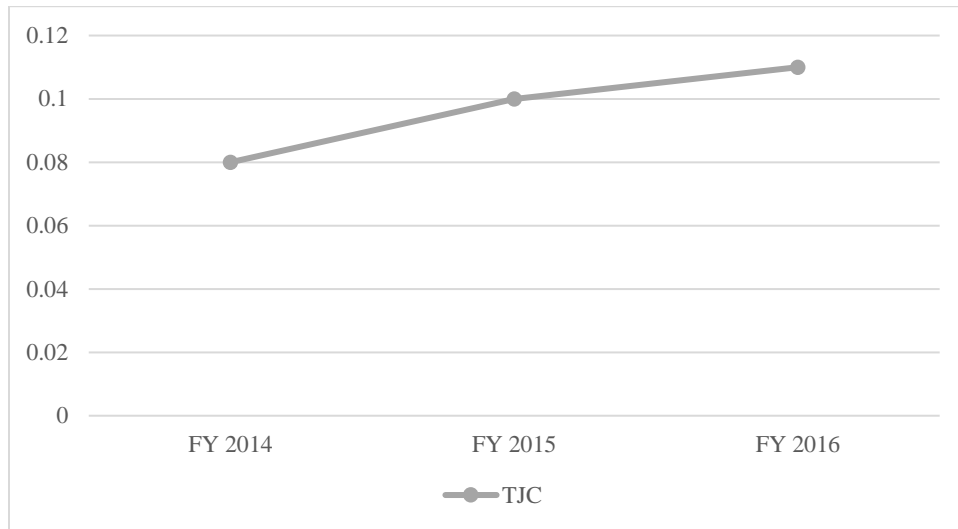
Graph 12
Psychiatric Hospital 60-Day Validation Survey Health and Safety Disparity Rate Results by AO FYs 2014-2016



Graph 13
Psychiatric Hospital 60-Day Validation Survey PE Disparity Rate Results by AO FYs 2014-2016



Graph 14
Psychiatric Hospital 60-Day Validation Survey Sampling Fraction Results
by AO
FYs 2014–2016



- TJC:** In FY 2016, the overall disparity rate was 57 percent based on the completion of 21 validation surveys. The number of validation surveys completed represents an 11-percent sample of the surveys conducted by the TJC. The FY 2016 overall disparity rate is 18 percentage points lower than the disparity rate for FY 2014. The FY 2014 disparity rate was based on an 8-percent sample of the surveys conducted during that period. In FY 2016, TJC’s health and safety disparity rate was 29 percentage points higher than the PE disparity rate. The primary driver of TJC’s health and safety disparity rate was the Special medical record requirements CoP for psychiatric hospitals. The SAs cited PE at the condition level 13 times. TJC missed 7 comparable deficiencies resulting in a 33-percent disparity rate. The FY 2016 health and safety disparity rate is 2 percentage points lower than the FY 2014 health and safety disparity rate. The FY 2016 PE disparity rate is 14 percentage points lower than the FY 2014 PE disparity rate.

It is important to note that TJC’s psychiatric hospital program was placed on a performance review and subsequent probation, largely due to a 75-percent overall disparity rate in FY 2014. Since then, as previously noted, the overall disparity rate has decreased by 18 percentage points since FY 2014. With the significant changes that TJC has implemented in its psychiatric hospital accreditation program throughout FYs 2015 and 2016, it is expected that this disparity rate will continue to decline. A summary of TJC’s performance review can be found in Section 1.

Critical Access Hospital

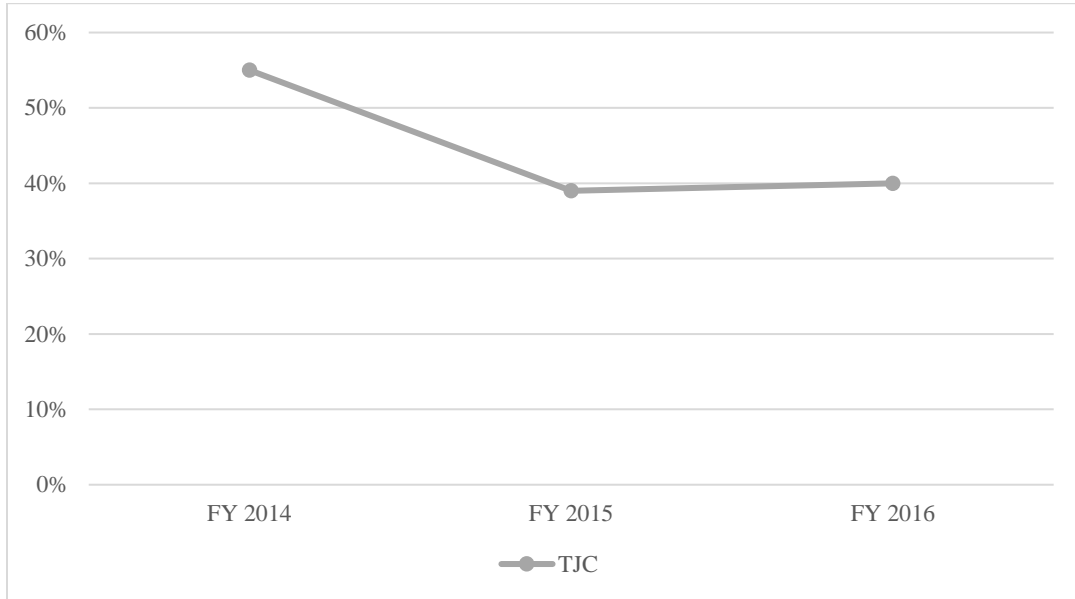
The AOs with CAH accreditation programs in FY 2016 were AOA/HFAP, DNV GL, and TJC. (See Table 12 and Graphs 15-18.)

Table 12
CAH 60-Day Validation Survey Results
by AO
FYs 2014–2016

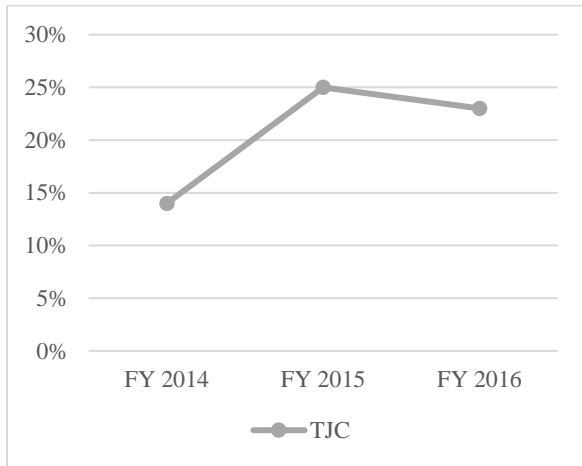
	AOA/HFAP			DNV GL			TJC			Total
	FY 2014	FY 2015	FY 2016	FY 2014	FY 2015	FY 2016	FY 2014	FY 2015	FY 2016	FYs 2014–2016
60-Day Validation Sample Surveys	1	3	2	4	2	2	22	28	30	94
SA Surveys with Condition-Level Deficiencies	*N/A	*N/A	*N/A	*N/A	*N/A	*N/A	13	11	13	37
AO Surveys with Missed Comparable Deficiencies	*N/A	*N/A	*N/A	*N/A	*N/A	*N/A	12	11	12	35
Overall Disparity Rate	*N/A	*N/A	*N/A	*N/A	*N/A	*N/A	55%	39%	40%	37%
Health and Safety Disparity Rate	*N/A	*N/A	*N/A	*N/A	*N/A	*N/A	14%	25%	23%	23%
Physical Environment Disparity Rate	*N/A	*N/A	*N/A	*N/A	*N/A	*N/A	41%	21%	33%	33%
Sampling Fraction	*N/A	*N/A	*N/A	*N/A	*N/A	*N/A	.22	.19	.25	.19

*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.

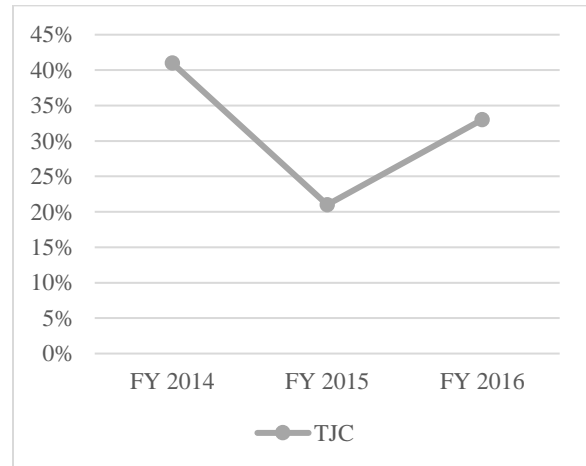
Graph 15
CAH 60-Day Validation Survey
Overall Disparity Rate Results by AO
FYs 2014–2016



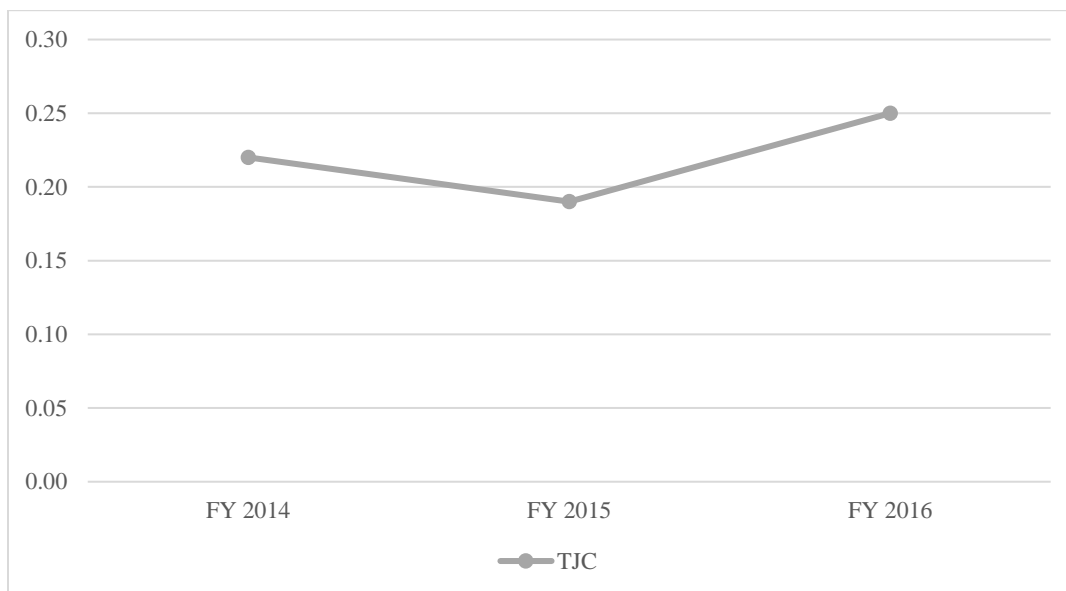
Graph 16
CAH 60-Day Validation Survey Health
and Safety Disparity Rate Results by AO
FYs 2014-2016



Graph 17
CAH 60-Day Validation Survey PE
Disparity Rate Results by AO
FYs 2014-2016



Graph 18
CAH 60-Day Validation Survey
Sampling Fraction Results by AO
FYs 2014–2016



- **AOA/HFAP:** In FY 2016, due to the low number of deemed CAHs due for resurvey, only two validation surveys were conducted. Therefore, no additional data are reported.
- **DNV GL:** In FY 2016, due to the low number of deemed CAHs due for resurvey, only two validation surveys were conducted. Therefore, no additional data are reported.
- **TJC:** In FY 2016, the overall disparity rate was 40 percent based on the completion of 30 validation surveys. The number of validation surveys conducted represents a 25-percent sample of the surveys conducted by TJC. The FY 2016 overall disparity rate is 15 percentage points lower than the overall disparity rate for FY 2014. The FY 2014 disparity rate was based on a 22-percent sample of surveys conducted during that period. In FY 2016, the PE disparity rate was 10 percentage points higher than the health and safety disparity rate. The SAs cited PE at the condition level 20 times. TJC missed 10 comparable deficiencies resulting in a 33-percent disparity rate. The PE disparity rate is 8 percentage points lower than the FY 2014 PE disparity rate.

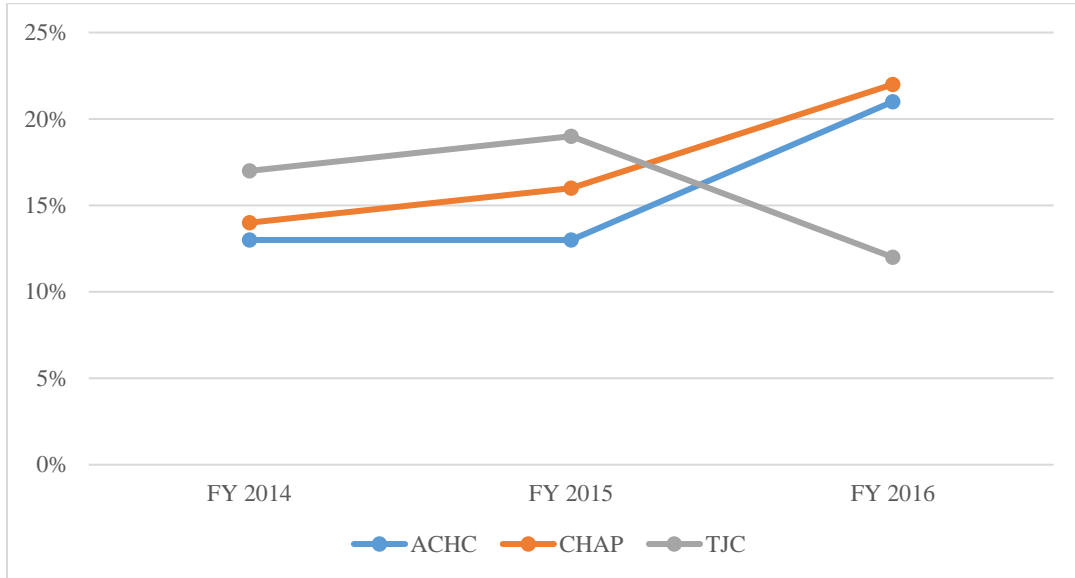
Home Health Agency

The AOs with HHA accreditation programs in FY 2016 were ACHC, CHAP, and TJC. (See Table 13 and Graphs 19-20.)

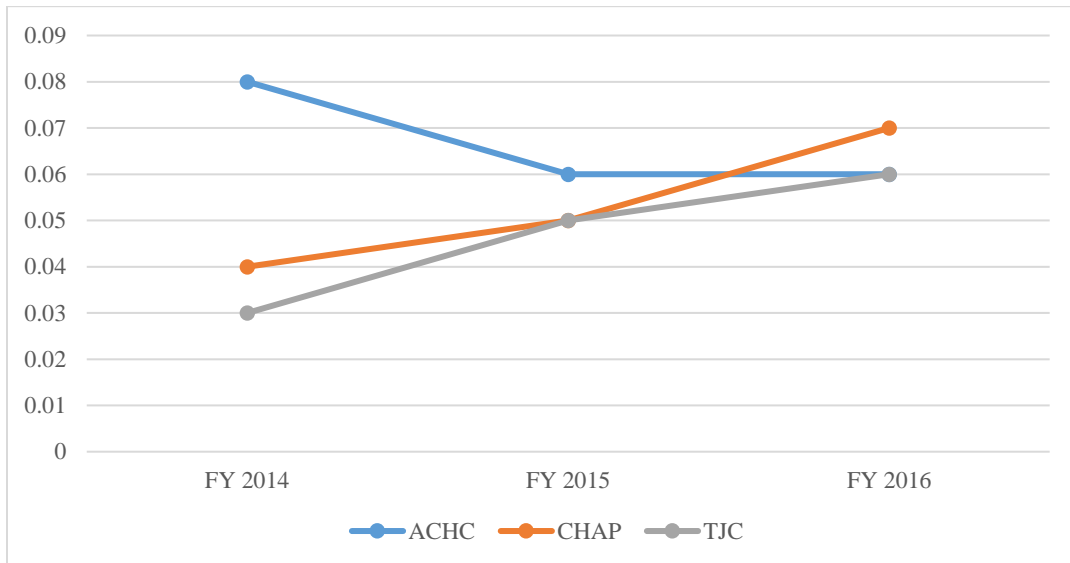
Table 13
HHA 60-Day
Validation Survey Results by AO
FYs 2014–2016

	ACHC			CHAP			TJC			Total
	FY 2014	FY 2015	FY 2016	FY 2014	FY 2015	FY 2016	FY 2014	FY 2015	FY 2016	FYs 2014–2016
60-Day Validation Sample Surveys	23	16	14	28	51	55	24	37	41	289
SA Surveys with Condition-Level Deficiencies	3	3	6	4	8	12	9	12	5	62
AO Surveys with Missed Comparable Deficiencies	3	2	3	4	8	12	4	7	5	48
Overall Disparity Rate	13%	13%	21%	14%	16%	22%	17%	19%	12%	17%
Sampling Fraction	.08	.06	.06	.04	.05	.07	.03	.05	.06	.05

Graph 19
HHA 60-Day Validation Survey
Overall Disparity Rate Results by AO
FYs 2014–2016



Graph 20
HHA 60-Day Validation Survey
Sampling Fraction Results by AO
FYs 2014–2016



- ACHC:** In FY 2016, the overall disparity rate was 21 percent based on the completion of 14 validation surveys. The number of validation surveys completed represents a 6-percent sample of surveys conducted by ACHC. The FY 2016 overall disparity rate is 8 percentage points higher than the overall disparity rate of FY 2014. The FY 2014 overall disparity rate was based on an 8-percent sample of surveys conducted during that period. In FY 2016, the primary drivers of ACHC's overall disparity rate were as follows: Acceptance of Patients, Plan of Care, Medical Supervision; Organization, Services & Administration; and Clinical Records. The Acceptance of Patients, Plan of Care, Medical Supervision condition was cited by the SAs at the condition level five times. ACHC missed two comparable deficiencies. The Organization, Services & Administration condition was cited by the SAs at the condition level four times. ACHC missed two comparable deficiencies. The Clinical Records condition was cited by the SAs at the condition level three times. ACHC missed two comparable deficiencies. Each condition yielded a 14-percent disparity rate.
- CHAP:** In FY 2016, the overall disparity rate was 22 percent based on the completion of 55 validation surveys. The number of validation surveys completed represents a 7-percent sample of the surveys conducted by CHAP. The FY 2016 overall disparity rate is 8 percentage points higher than the disparity rate for FY 2014. The overall disparity rate for FY 2014 was based on a 4-percent sample of surveys conducted during that period. In FY 2016, the primary driver of CHAP's overall disparity rate was the Acceptance of Patients, Plan of Care, Medical Supervision condition. The SAs cited this requirement at the condition level 10 times. CHAP missed six comparable deficiencies resulting in a disparity rate of 11 percent.
- TJC:** In FY 2016, the overall disparity rate was 12 percent based on the completion of 41 validation surveys. The number of validation surveys completed represents a 6-percent sample of the surveys conducted by TJC. The FY 2016 overall disparity rate is 5 percentage points lower than the overall disparity rate for FY 2014. The overall disparity rate for FY 2014 was based on a 3-percent sample of surveys conducted during that period. In FY 2016, the primary driver of TJC's overall disparity rate was the Organization, Services & Administration condition. The SAs cited this requirement at the condition level four times. TJC missed three comparable deficiencies resulting in a 7-percent disparity rate.

Hospice

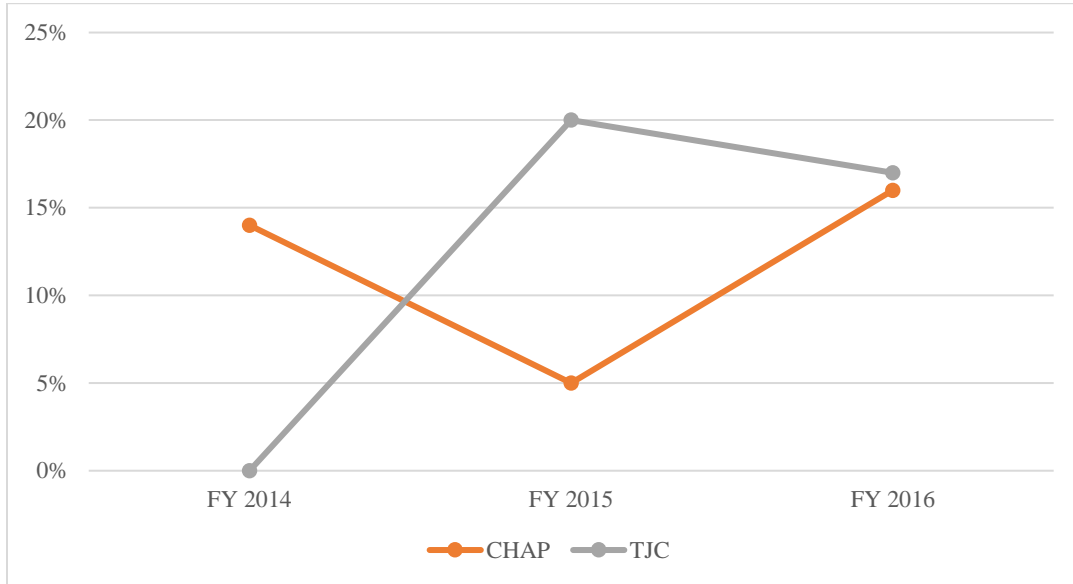
The AOs with hospice accreditation programs in FY 2016 were ACHC, CHAP and TJC. (See Table 14 and Graphs 21-22.)

Table 14
Hospice 60-Day Validation Survey Results
by AO
FYs 2014–2016

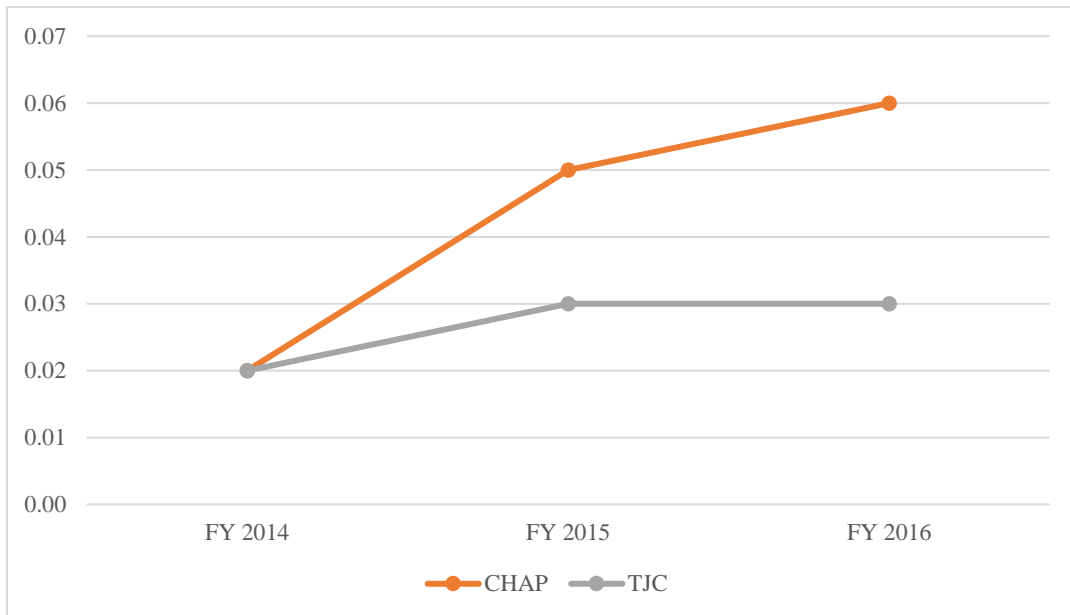
	ACHC			CHAP			TJC			Total
	FY 2014	FY 2015	FY 2016	FY 2014	FY 2015	FY 2016	FY 2014	FY 2015	FY 2016	FYs 2014-2016
60-Day Validation Sample Surveys	1	5	3	7	19	19	8	10	12	84
SA Surveys with Condition-Level Deficiencies	*N/A	0	*N/A	1	2	3	1	2	2	11
AO Surveys with Missed Comparable Deficiencies	*N/A	0	*N/A	1	1	3	0	2	2	9
Overall Disparity Rate	*N/A	0%	*N/A	14%	5%	16%	0%	20%	17%	11%
Sampling Fraction	*N/A	.06	*N/A	.02	.05	.06	.02	.03	.03	.04

*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.

Graph 21
Hospice 60-Day Validation Survey
Overall Disparity Rate Results by AO
FYs 2014–2016



Graph 22
Hospice 60-Day Validation Survey Sampling Fraction Results
by AO
FYs 2014–2016



- **ACHC:** In FY 2016, due to the low number of deemed hospices due for resurvey, only three validation surveys were conducted. Therefore, no additional data are reported.
- **CHAP:** In FY 2016, the overall disparity rate was 16 percent based on the completion of 19 validation surveys. The number of validation surveys completed represents a 6-percent sample of the surveys conducted by CHAP. The FY 2016 overall disparity rate is 2 percentage points higher than the overall disparity rate for FY 2014. The overall disparity rate for FY2014 was based on a 2-percent sample of surveys conducted during that period. In FY 2016, the primary drivers of CHAP's overall disparity rate were Organizational Environment and Interdisciplinary Group (IDG), Care Planning, Coordination of Services. The SA cited the Organizational Environment requirement at the condition level two times. CHAP missed two comparable deficiencies resulting in a disparity rate of 11 percent. The SA cited the IDG, Care Planning, Coordination of Services requirement at the condition level four times. CHAP missed two comparable deficiencies resulting in a disparity rate of 11 percent.
- **TJC:** In FY 2016, 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 the surveys performed by TJC. The overall disparity rate has increased from 0 percent in FY 2014 to 17 percent in FY 2016. The overall disparity rate for FY 2014 was based on a 2-percent sample of the surveys conducted during that period. In FY 2016, four conditions were cited by the SAs at the condition level with one citation each. These conditions were as follows: Organizational Environment; Medical Director; Patient Rights; and, Infection Control. In each instance, TJC missed one comparable deficiency. Two conditions were cited by the SAs at the condition level twice. These conditions were as follows: Quality Assessment and Performance Improvement; and, Volunteers. In both instances, TJC missed one comparable deficiency. All six condition-level citations resulted in 8-percent disparity rates, contributing equally to TJC's overall disparity rate.

Ambulatory Surgery Center

The AOs with ASC accreditation programs in FY 2016 were AAAASF, AAAHC, AOA/HFAP, and TJC. (See Table 15 and Graphs 23-26.)

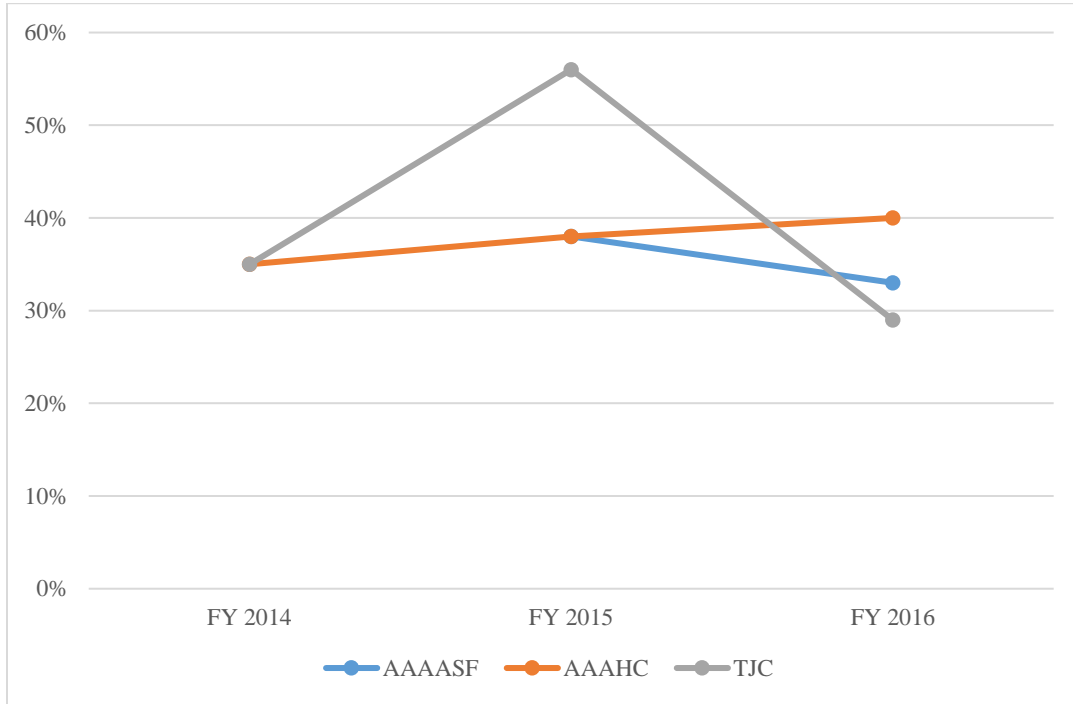
Table 15
ASC 60-Day
Validation Survey Results by AO
FYs 2014–2016

	AAAASF			AAAHC			AOA/HFAP**			TJC			Total
	FY 2014	FY 2015	FY 2016	FY 2014	FY 2015	FY 2016	FY 2014	FY 2015	FY 2016	FY 2014	FY 2015	FY 2016	FYs 2014–2016
60-Day Validation Sample Surveys	4	8	6	26	42	35	1	1	0	23	18	34	198
SA Surveys with Condition-Level Deficiencies	*N/A	3	2	13	17	15	*N/A	*N/A	*N/A	9	10	11	80
AO Surveys with Missed Comparable Deficiencies	*N/A	3	2	9	16	14	*N/A	*N/A	*N/A	8	10	10	72
Overall Disparity Rate	*N/A	38%	33%	35%	38%	40%	*N/A	*N/A	*N/A	35%	56%	29%	36%
Health and Safety Disparity Rate	*N/A	38%	17%	27%	29%	26%	*N/A	*N/A	*N/A	9%	44%	24%	25%
Physical Environment Disparity Rate	*N/A	13%	33%	19%	19%	17%	*N/A	*N/A	*N/A	26%	17%	18%	19%
Sampling Fraction	*N/A	.09	.06	.09	.11	.10	*N/A	*N/A	*N/A	.10	.08	.15	.10

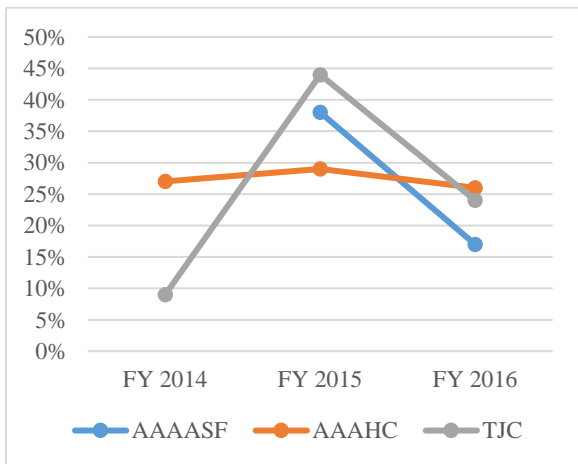
*N/A: When a minimum sample size of five is not achieved for an AO, no data is reported given the lack of statistical significance.

**Very few AOA/HFAP ASC validation survey selections have been made since FY 2012 due to the low numbers of deemed ASCs.

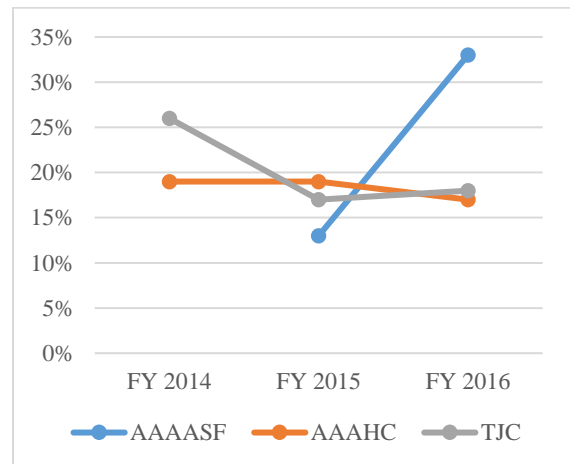
Graph 23
ASC 60-Day Validation Survey
Overall Disparity Rate Results by AO
FYs 2014–2016



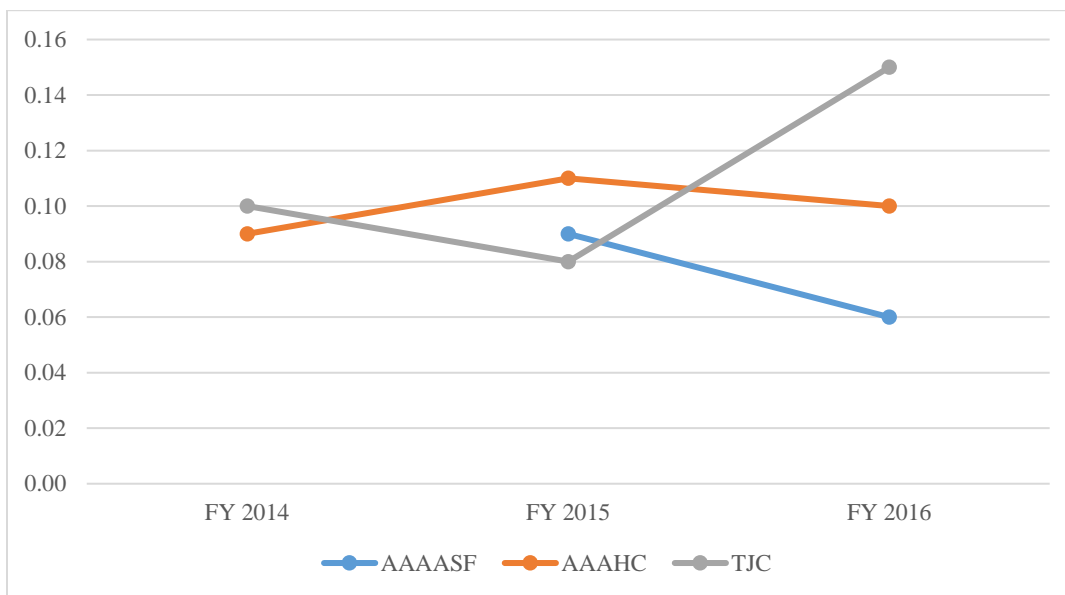
Graph 24
ASC 60-Day Validation Survey Health
and Safety Disparity Rate Results
by AO
FYs 2014-2016



Graph 25
ASC 60-Day Validation Survey PE
Disparity Rate Results
by AO
FYs 2014-2016



Graph 26
ASC 60-Day Validation Survey
Sampling Fraction Results by AO
FYs 2014–2016



- AAAASF:** In FY 2016, the overall disparity rate was 33 percent based on the completion of six validation surveys. The number of validation surveys completed represents a 6-percent sample of the surveys performed by AAAASF. The FY 2016 overall disparity rate is 5 percentage points lower than the overall disparity rate for FY 2015. The overall disparity rate for FY 2015 was based on a 9-percent sample of the surveys conducted during that period. In FY 2016, AAAASF’s PE disparity rate was 16 percentage points higher than the health and safety disparity rate. In FY 2016, the SAs cited PE at the condition level twice. AAAASF missed both comparable deficiencies resulting in a 33-percent disparity rate. The FY 2016 PE disparity rate is 20 percentage points higher than the FY 2015 PE disparity rate. The FY 2016 health and safety disparity rate is 21 percentage points lower than the FY 2015 health and safety disparity rate. FY 2014 data wasn’t comparable due to the small sample size.
- AAAHC:** In FY 2016, the overall disparity rate was 40 percent based on the completion of 35 validation surveys. The number of validation surveys completed represents a 10-percent sample of the surveys performed by AAAHC. The FY 2016 overall disparity rate is 5 percentage points higher than the overall disparity rate for FY 2014. The overall disparity rate for FY 2014 was based on a 9-percent sample of the surveys conducted during that period. In FY 2016, AAAHC’s health and safety disparity rate was 9 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 seven comparable deficiencies resulting in a disparity rate of 20 percent. The FY 2016 health and safety disparity rate is 1 percentage point lower than the FY 2014 health and safety disparity rate.

- **AOA/HFAP:** Due to the consistently low number of deemed AOA/HFAP ASCs, no validation surveys were conducted in FY 2016. Therefore, no additional data are reported.
- **TJC:** In FY 2016, the overall disparity rate was 29 percent based on the completion of 34 validation surveys. The number of validation surveys completed represents a 15-percent sample of the surveys performed by TJC. The FY 2016 overall disparity rate is 6 percentage points lower than the overall disparity rate for FY 2014. The disparity rate for FY 2014 was based on a 10-percent sample of surveys conducted during that period. In FY 2016, TJC's health and safety disparity rate was 6 percentage points higher than the PE disparity rate. The primary driver of TJC's health and safety disparity rate was Governing Body and Management. The SA cited the Governing Body and Management requirement at the condition level 11 times. TJC missed seven comparable deficiencies resulting in a disparity rate of 21 percent. The FY 2016 health and safety disparity rate is 15 percentage points higher than the FY 2014 health and safety disparity rate.

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

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

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 16-21 and Graphs 27-34.)

Table 16
Number and Type of Condition-Level Deficiencies
Cited on 60-Day Validation Surveys
Hospitals
FY 2016

Medicare Conditions* Sample Size - 98	Cited by SA	Missed by AO
Compliance with Laws	1	1
Governing Body	18	12
Patient Rights	7	5
Quality Assurance Performance Improvement (QAPI)	9	7
Medical Staff	1	1
Nursing Services	8	6
Medical Record Services	4	3
Pharmaceutical Services	5	4
Radiologic Services	4	4
Laboratory Services	1	1
Food and Dietetic Services	4	3
Utilization Review	1	1
Physical Environment*	56	29
Infection Control	22	16
Surgical Services	4	3
TOTAL	145	96

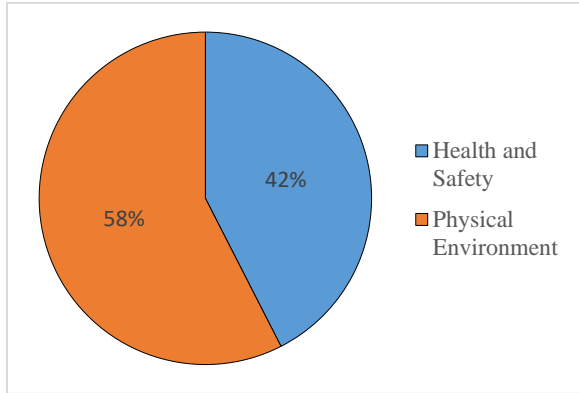
*Most frequently cited deficiency.

Note: The PE CoP 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.

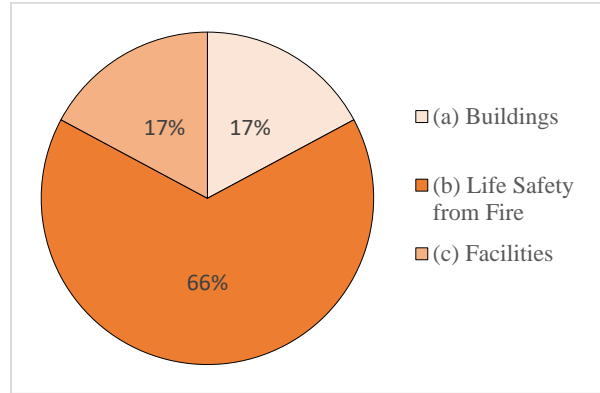
In FY 2016, the hospital sample consisted of 98 validation surveys. In this sample, the SAs cited condition-level deficiencies in 50 facilities. The PE CoP was the primary driver of the hospital disparity rate. The SAs cited PE at the condition level 56 times. The AOs missed 29 comparable deficiencies for PE. The findings were similar in FYs 2012–2015.

In FY 2016, the next most frequently SA-cited conditions were as follows: Infection Control, cited 22 times by the SAs at the condition level, and missed 16 times by the AOs; and Governing Body, cited at the condition level 18 times by the SAs, and missed 12 times by the AOs.

Graph 27
Percentage of Health and Safety vs PE
Condition-Level Deficiencies Cited on 60-
Day Validation Surveys
Hospitals
FYs 2014–2016



Graph 28
Percentage of PE Standards Cited on 60-
Day
Validation Surveys
Hospitals
FYs 2014–2016



From FY 2014 to FY 2016, there were 133 validation surveys cited with condition-level deficiencies for hospitals. Of the 133 surveys, 65 of the surveys had health and safety citations, 88 of the surveys had PE citations and 20 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 134 standards cited for the PE condition and 88 of these standards were related to Life Safety from Fire.

Table 17
Number and Type of Condition-Level Deficiencies
Cited on 60-Day Validation Surveys
Psychiatric Hospitals
FY 2016

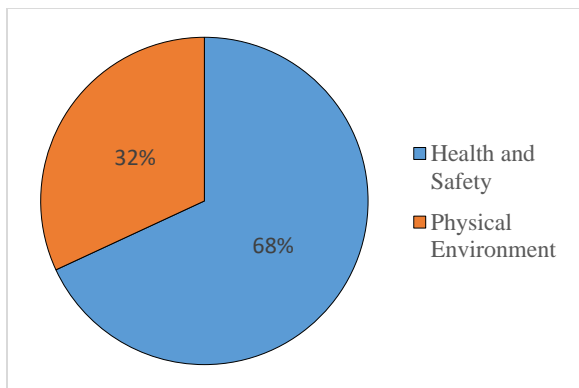
Medicare Conditions Sample Size – 21	Cited by SA	Missed by AO
Patient Rights	2	1
Nursing Services	2	1
Food and Dietetic Services	1	1
Physical Environment	8	4
Infection Control	1	1
Special Provisions Applying to Psychiatric Hospitals	1	1
Special Medical Record Requirements for Psychiatric Hospitals*	13	7
Special Staff Requirements for Psychiatric Hospitals	8	4
TOTAL	36	20

*Most frequently cited deficiency

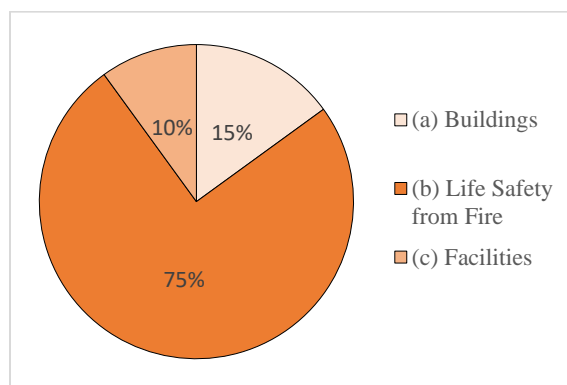
In FY 2016, the psychiatric hospital sample consisted of 21 validation surveys. In this sample, the SAs cited 12 facilities at the condition level. Special Medical Record Requirements for Psychiatric Hospitals was the primary driver of the disparity rate. The SAs cited this requirement at the condition level 13 times. The AO missed seven comparable deficiencies. The findings regarding this same condition-level deficiency were similar in FY 2015.

In FY 2016, the next most frequently SA-cited conditions for psychiatric hospitals were as follows: PE, cited eight times by the SAs and missed four times by the AOs; and, Special Staff Requirements for Psychiatric Hospitals, cited eight times by the SAs and missed seven times by the AOs.

Graph 29
Percentage of Health and Safety vs PE
Condition-Level Deficiencies Cited on 60-
Day Validation Surveys
Psychiatric Hospitals
FYs 2014–2016



Graph 30
Percentage of PE Standards Cited on 60-
Day
Validation Surveys
Psychiatric Hospitals
FYs 2014–2016



From FY 2014 to FY 2016, there were 34 validation surveys cited with condition-level deficiencies for psychiatric hospitals. Of the 34 surveys, 32 of the surveys had health and safety citations, 15 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 standards were cited for the PE condition and 15 of these standards were related to Life Safety from Fire.

Table 18
Number and Type of Condition-Level Deficiencies
Cited on 60-Day Validation Surveys
CAHs
FY 2016

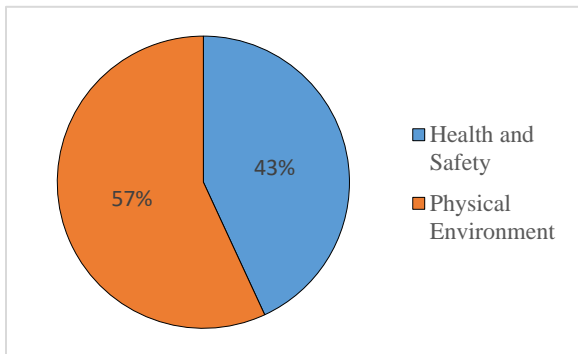
Medicare Conditions Sample Size – 34	Cited by SA	Missed by AO
Emergency Services	1	1
Physical Plant and Environment*	26	13
Organizational Structure	2	2
Provision of Services	7	4
Clinical Records	2	1
Surgical Services	5	3
Periodic Evaluation and Quality Assurance (QA) Review	2	2
TOTAL	45	26

*Most frequently cited deficiency

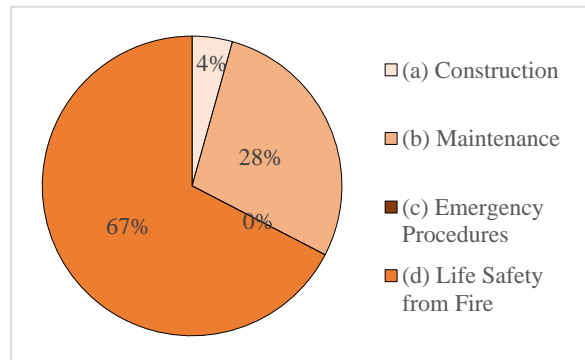
In FY 2016, the CAH sample consisted of 34 validation surveys. In this sample, 16 facilities were cited at the condition level by the SAs. Physical Plant and Environment was the primary driver of the disparity rate. The SAs cited this requirement at the condition level 26 times. The AOs missed 13 comparable deficiencies for PE, which was also the most frequently cited condition in FYs 2012–2015.

In FY 2016, the next most frequently SA-cited conditions for CAHs were as follows: Provision of Services, cited seven times by the SAs and missed four times by the AOs; and, Surgical Services cited five times by the SAs and missed three times by the AOs.

Graph 31
Percentage of Health and Safety vs PE
Condition-Level Deficiencies Cited on 60-
Day Validation Surveys
CAHs
FYs 2014–2016



Graph 32
Percentage of PE Standards Cited on
60-Day
Validation Surveys
CAHs
FYs 2014–2016



From FY 2014 to FY 2016, there were 47 validation surveys cited with condition-level deficiencies for CAHs. Of the 47 surveys, 25 of the surveys had health and safety citations, 33 of the surveys had PE citations, and 11 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. Forty-six standards were cited for the PE condition and 31 of these standards were related to Life Safety from Fire.

Table 19
Number and Type of Condition-Level Deficiencies
Cited on 60-Day Validation Surveys
HHAs
FY 2016

Medicare Conditions Sample Size – 110	Cited by SA	Missed by AO
Patient Rights	1	1
Organization, Services, and Administration	15	9
Group of Professional Personnel	5	4
Acceptance of Patients, Plan of Care & Medical Supervision*	17	9
Reporting Oasis Information	1	1
Skilled Nursing Services	9	5
Therapy Services	2	1
Medical Social Services	2	2
Home Health Aide Services	4	3
Clinical Records	9	6
Evaluation of the Agency’s Program	4	3
Comprehensive Assessment of Patients	4	3
TOTAL	73	47

*Most frequently cited deficiency

In FY 2016, the HHA sample consisted of 110 validation surveys. In this sample, the SAs cited condition-level deficiencies in 23 agencies. The Acceptance of Patients, Plan of Care & Medical Supervision was the primary driver of the HHA disparity rate. The SAs cited the Acceptance of Patients, Plan of Care & Medical Supervision at the condition level 17 times. The AOs missed nine comparable deficiencies. The findings regarding this condition-level deficiency were similar in FY 2015.

In FY 2016, the next most frequently SA cited condition was Organization, Services, and Administration, cited 15 times by the SAs at the condition level and missed nine times by the AOs.

Table 20
Number and Type of Condition-Level Deficiencies
Cited on 60-Day Validation Surveys
Hospices
FY 2016

Medicare Conditions Sample Size – 34	Cited by SA	Missed by AO
Organizational Environment	3	3
Medical Director	1	1
Short-Term Inpatient Care	1	1
Residents of SNF/NF or ICF/MR	1	1
Patient Rights	1	1
Initial & Comprehensive Assessment of Patient	3	2
Interdisciplinary Group (IDG), Care Planning, Coordination of Services	4	2
Quality Assessment & Performance Improvement*	5	3
Infection Control	1	1
Hospice Aide and Homemaker Services	2	1
Volunteers	3	2
TOTAL	21	14

*Most frequently cited deficiency

In FY 2016, the Hospice sample consisted of 34 validation surveys. In this sample, the SAs cited condition-level deficiencies in six agencies. The primary driver of the hospice disparity rate was the Quality Assessment & Performance Improvement condition. The SAs cited Quality Assessment & Performance Improvement at the condition level five times. The AOs missed three comparable deficiencies.

In FY 2016, the next most frequently SA-cited condition was IDG, Care Planning, Coordination of Services, cited four times by the SAs at the condition level and missed two times by the AOs.

Table 21
Number and Type of Condition-Level Deficiencies
Cited on 60-Day Validation Surveys
ASCs
FY 2016

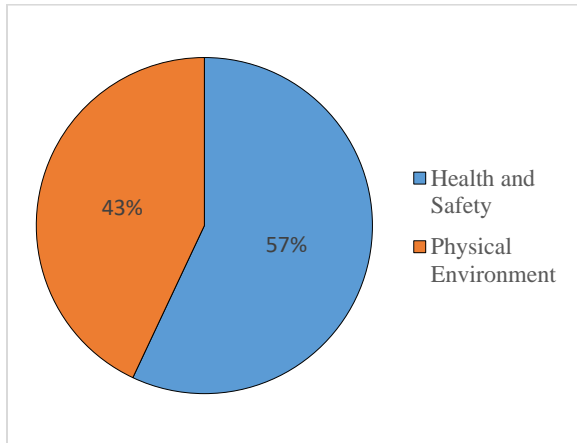
Medicare Conditions Sample Size – 75	Cited by SA	Missed by AO
Basic Requirements	4	3
Governing Body and Management	17	12
Quality Assessment & Performance Improvement	7	5
Physical Environment*	26	15
Medical Staff	2	1
Nursing Services	3	3
Medical Records	4	3
Pharmaceutical Services	5	3
Patient Rights	4	3
Infection Control	18	13
Patient Admission, Assessment and Discharge	2	2
TOTAL	92	63

*Most frequently cited deficiency

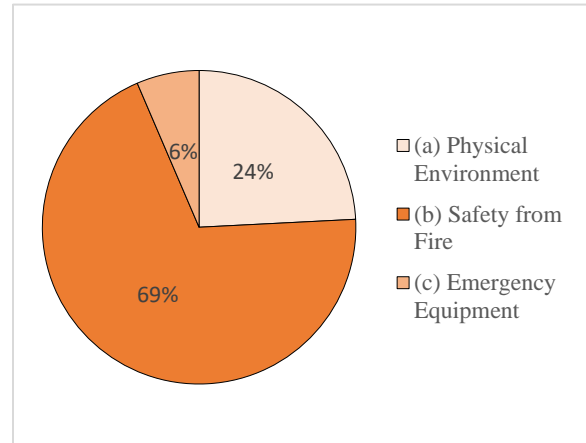
In FY 2016, the ASC sample consisted of 75 validation surveys. In this sample, the SAs cited condition-level deficiencies in 28 facilities. The primary driver of the disparity rate was the PE CoP. The SAs cited PE at the condition level 26 times. The AOs missed 15 comparable deficiencies for PE.

In FY 2016, the next most frequently SA cited condition was Infection Control, cited 18 times by the SAs at the condition level and missed 13 times by the AOs.

Graph 33
Percentage of Health and Safety vs PE
Condition-Level Deficiencies Cited on 60-
Day Validation Surveys
ASCs
FYs 2014–2016



Graph 34
Percentage of PE Standards Cited on
60-Day
Validation Surveys
ASCs
FYs 2014–2016



From FY 2014 to FY 2016, there were 85 validation surveys cited with condition-level deficiencies for ASCs. Of the 85 surveys, 57 of the surveys had health and safety citations, 43 of the surveys had PE citations, and 15 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. Sixty-two standards were cited for the PE condition and 43 of these standards were related to Safety from Fire.

Comparison of Deficiencies for Physical Environment and Other Health Conditions

The second analysis compares the validation results for condition-level deficiencies for PE conditions with the results for condition-level deficiencies for all other conditions. It also yields two disparity rates for each type of facility and AO. (See Tables 22-23 and Graph 35.)

Table 22
Number of 60-Day Validation Surveys for
Facility Types with LSC Requirements
FY 2016

Validation Survey Analysis	Hospital*	Psych Hospital	CAH	ASC
60-Day Validation Sample Surveys	98	21	34	75

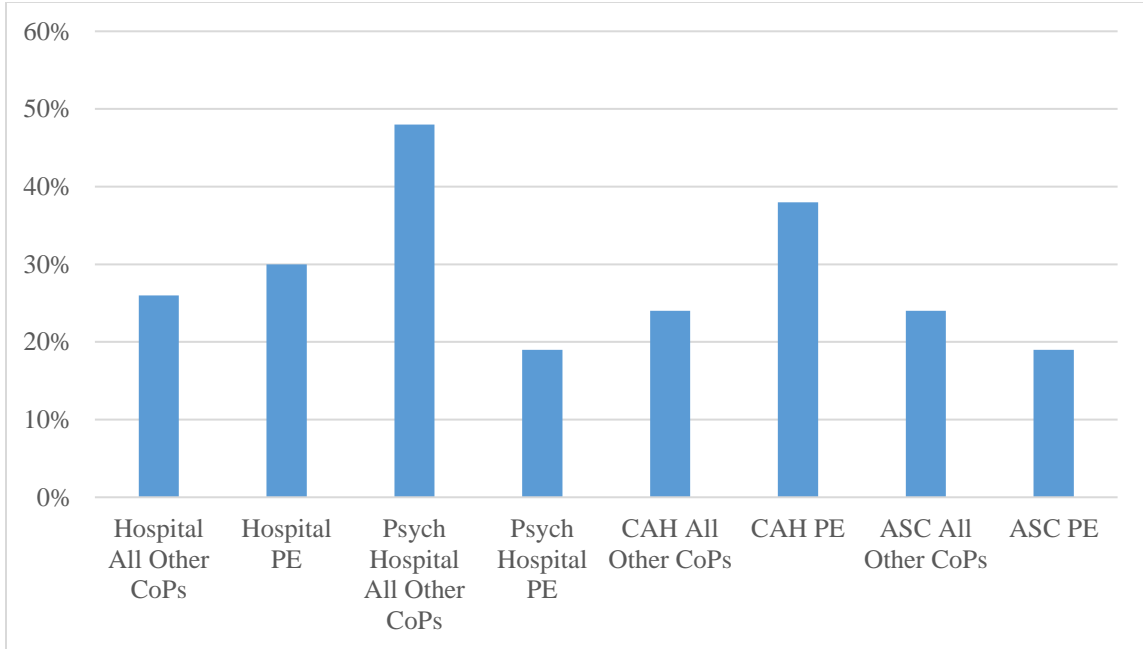
*Acute Care and LTCHs

Table 23
60-Day Validation Survey Results
Comparison between All Other CoPs Cited and
PE for Facility Types with LSC Requirements
FY 2016

	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	28	31	10	4	10	13	19	16
AO Surveys with Missed Comparable Deficiencies	25	29	10	4	8	13	18	14
Disparity Rate	26%	30%	48%	19%	24%	38%	24%	19%

In FY 2016, the PE CoP had a significant impact on the overall disparity rate for both hospitals and CAHs. The disparity rate based on the PE condition for hospitals is only 4 percentage points higher than the disparity rate based on other health and safety conditions. However, the FY 2016 results show that the PE condition is the single largest driver of the disparity rate for CAHs. For CAHs, the disparity rate based on the PE condition is 14 percentage points higher than the disparity rate calculated based on other health and safety conditions. The PE disparity rate for ASCs was 5 percentage points lower than the disparity rate for other health and safety conditions compared to 16 percentage points in FY 2015. In FY 2016, the PE disparity rate for psychiatric hospitals was 29 percentage points lower than the disparity rate for other health and safety conditions. In FY 2015, the PE disparity rate for psychiatric hospitals was 31 percentage points lower than the disparity rate for other health and safety conditions. (See Graph 35.)

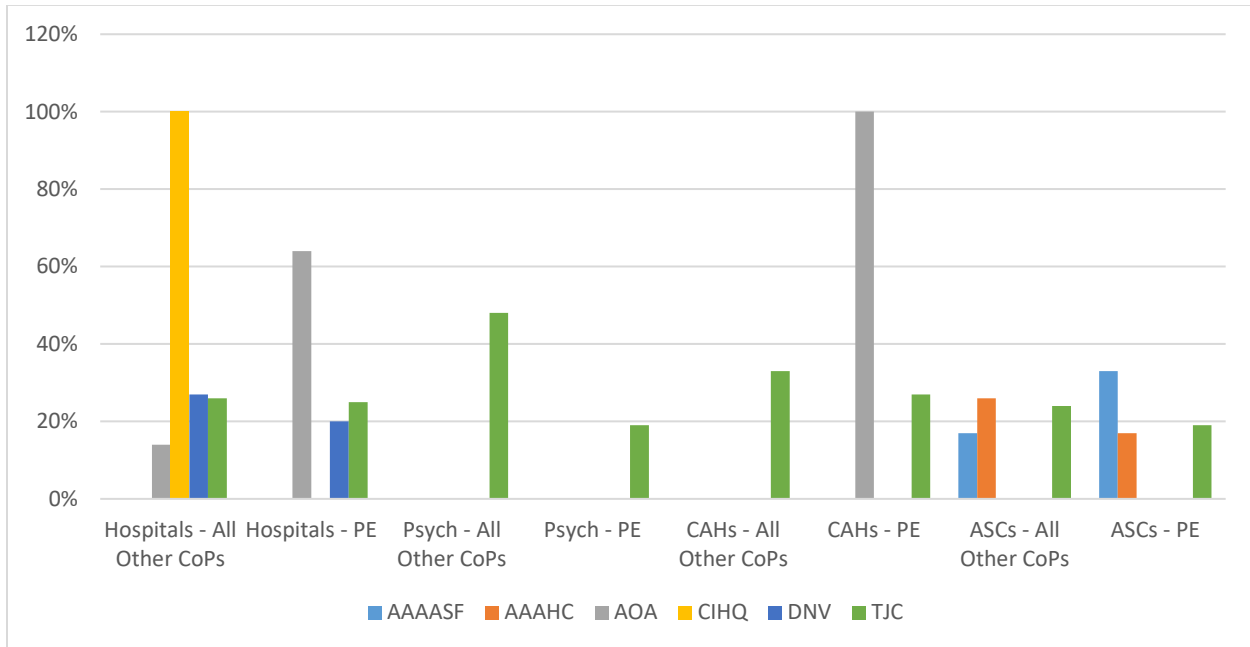
Graph 35
60-Day Validation Survey Disparity Rate Results
Comparison between All Other CoPs Cited and
PE for Facility Types with LSC Requirements
FY 2016



The majority of the PE disparity rates consists of 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 2016. This report is shared with the AOs and 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 2000 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 36.)

Graph 36
60-Day Validation Survey Disparity Rate Results
Comparison between All Other CoPs Cited and
PE for Facility Types with LSC Requirements
by AO
FY 2016



Note: CIHQ had one hospital validation survey for which the health and safety AO findings weren't comparable to the SA findings; therefore, the disparity rate is 100 percent. AOA had two CAH validation surveys for which the PE findings weren't comparable to the SA findings; therefore, the disparity rate is 100 percent.

Comparison of Deficiencies and Disparity Rates for Long-Term Care Hospitals and All Other Hospital Subtypes¹¹

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 24-26 and Graphs 37-41.) CMS attempted to increase the LTCH sample size for 60-day representative sample surveys. However, due to the scheduling of LTCH Medicare accreditation surveys by the AOs and the concentration of

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.

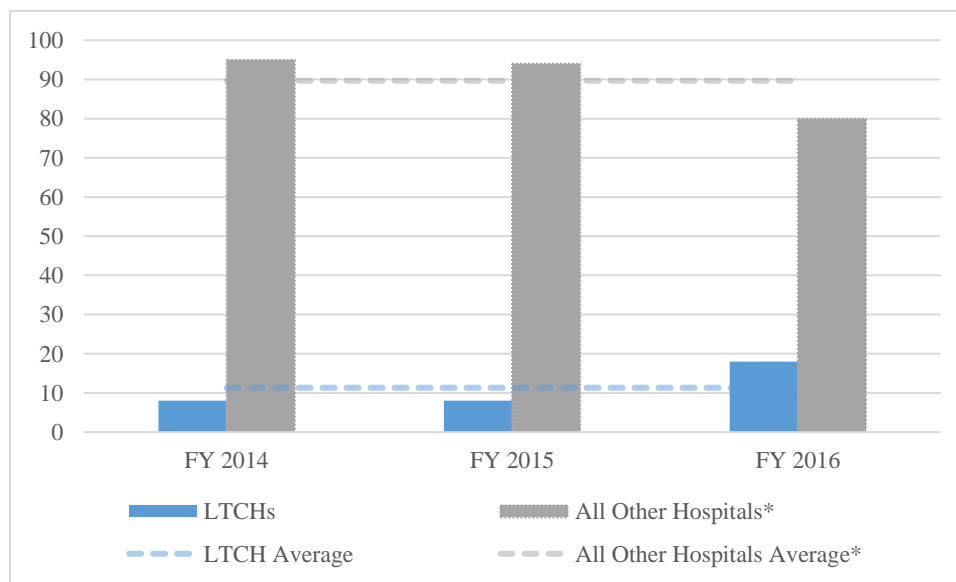
LTCHs in certain states, the ability of CMS to increase the sample size is limited. The need to mobilize a State survey team within 60 days of AO surveys that are not entirely predictable is the main limiting factor, as the fixed surveyor capacity of SAs makes it impractical for SAs in those states to conduct a larger number of validation surveys. In FY 2016, the total number of Medicare-participating LTCHs was 321 and the total number of Medicare-participating hospitals minus the LTCHs was 3,608.

Table 24
Number of 60-Day Validation Surveys and Overall Disparity Rate
LTCHs and All Other Hospital Subtypes
FYs 2014–2016

	LTCHs			All Other Hospitals*			Average LTCHs	Average All Other Hospitals*
	FY 2014	FY 2015	FY 2016	FY 2014	FY 2015	FY 2016	FYs 2014–2016	FYs 2014–2016
60-Day Validation Sample Surveys	8	8	18	95	94	80	11.33	89.67
Overall Disparity Rate	38%	63%	39%	38%	37%	48%	47%	41%

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

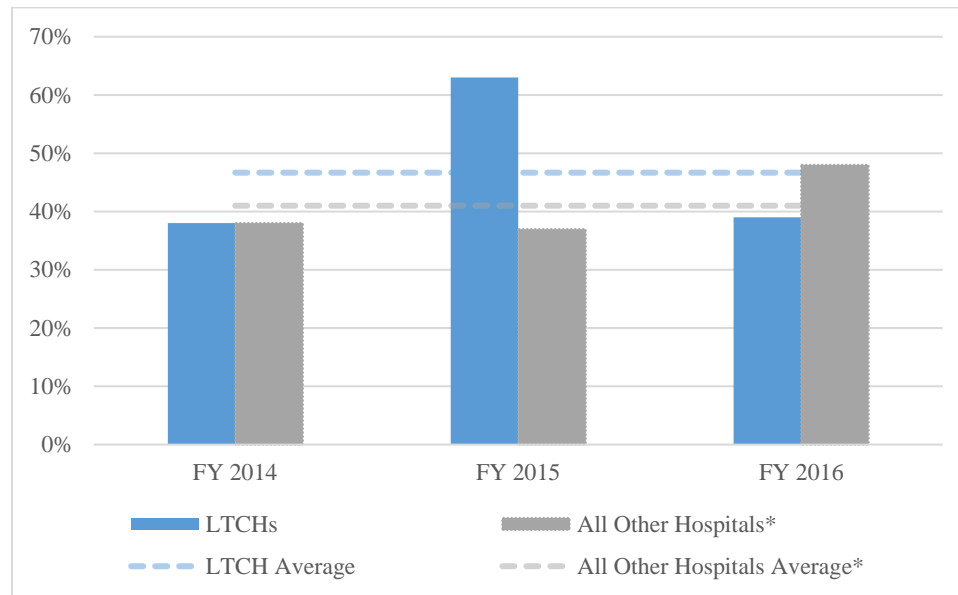
Graph 37
Number of 60-Day Validation Surveys and Averages
LTCHs and All Other Hospital Subtypes
FYs 2014–2016



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

Total number of Medicare-participating LTCHs is 321 and the total number of Medicare-participating hospitals minus the LTCHs is 3,608.

Graph 38
Overall Disparity Rates and Averages LTCHs and All Other Hospital Subtypes
FYs 2014–2016



*All Other Hospital Subtypes are specific to acute care hospitals and do not include Psychiatric Hospitals. Total number of Medicare-participating LTCHs is 321 and the total number of Medicare-participating hospitals minus the LTCHs is 3,608.

Table 25
Comparison of 60-Day Health and PE Validation Survey Results for LTCHs and
All Other Hospital Subtypes
FYs 2014–2016

Validation Survey Analysis	LTCHs - All Other Conditions			LTCHs PE			All Other Hospitals - All Other Conditions			All Other Hospitals PE		
	FY 2014	FY 2015	FY 2016	FY 2014	FY 2015	FY 2016	FY 2014	FY 2015	FY 2016	FY 2014	FY 2015	FY 2016
SA Surveys with Condition-Level Deficiencies	1	3	6	3	3	1	22	22	22	26	24	30
AO Surveys with Missed Comparable Deficiencies	0	2	6	3	3	1	16	14	18	26	24	28
Disparity Rate	0%	25%	33%	38%	38%	6%	17%	15%	23%	27%	26%	35%

Graph 39
Comparison of 60-Day Health and PE Validation Survey Disparity Rate Results for
LTCHs and All Other Hospital Subtypes
FYs 2014–2016

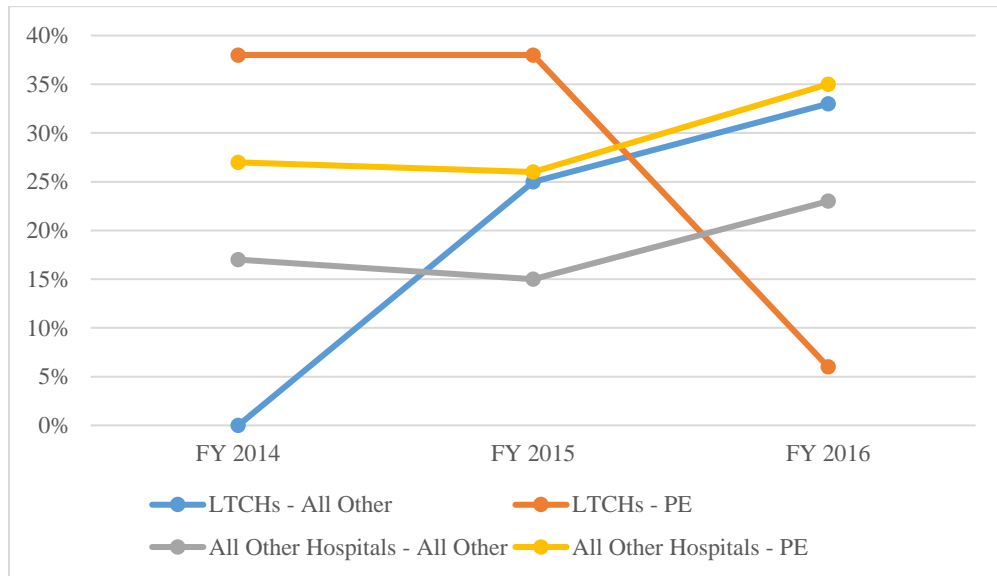
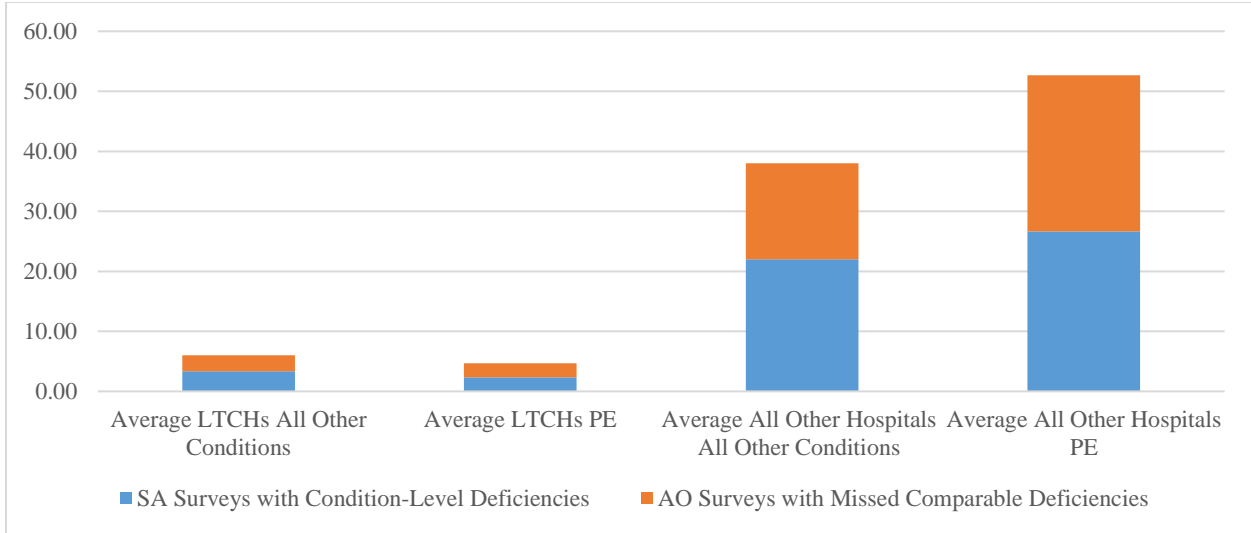


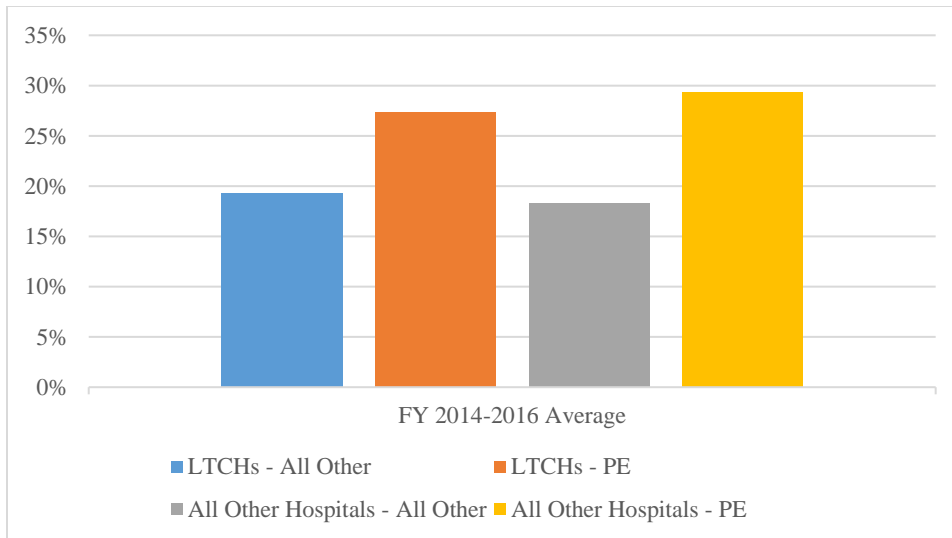
Table 26
Comparison of Averages
60-Day Health and PE Validation Survey Results for LTCHs and
All Other Hospital Subtypes
FYs 2014–2016

	FYs 2014–2016 Average LTCHs All Other Conditions	FYs 2014–2016 Average LTCHs PE	FYs 2014–2016 Average All Other Hospitals All Other Conditions	FYs 2014–2016 Average All Other Hospitals PE
SA Surveys with Condition-Level Deficiencies	3.33	2.33	22.00	26.67
AO Surveys with Missed Comparable Deficiencies	2.67	2.33	16.00	26.00
Disparity Rate	19%	27%	18%	29%

Graph 40
Comparison of Averages
60-Day Health and PE Validation Survey Results for LTCHs and
All Other Hospital Subtypes
FYs 2014–2016



Graph 41
Comparison of Averages
60-Day Health and PE Validation Survey Disparity Rate Results for LTCHs and
All Other Hospital Subtypes
FYs 2014-2016



From FYs 2014–2016, there is an 8-percent difference between the overall average disparity rates in LTCHs’ PE and other condition-level deficiencies, and an 11-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 both LTCHs and all other hospital subtypes. In FY 2016, the PE disparate condition-level deficiencies comprised 6 percent of the disparity

rate while Infection Control became the primary driver for the LTCHs disparity rate which was 22 percent. For all other hospital subtypes, PE is still the primary driver (35 percent) of the disparity rate in FY 2016 with Infection Control and Governing Body conditions comprising 15 percent and 13 percent of the disparity rate respectively.

In FY 2016, the most frequent disparate condition-level deficiencies for all other hospital subtypes and LTCHs were PE, Infection Control, and Governing Body conditions.

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. CMS has also participated in AO surveyor training sessions, delivering analysis findings directly to the AO's survey cadre. And finally, CMS is embarking upon a Validation Program process improvement project, where the entire Validation Program will be evaluated for effectiveness and comparability.

SECTION 5: Life Safety Code and Health & Safety Disparity Rates Analysis

Background and Objectives

As discussed in Section 4 of this report, 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 also identifies the comparable and non-comparable AO deficiency citations. If the AO has comparable findings to all of the identified SA findings, then the survey is determined to be a comparable survey. However, if the AO does not identify a comparable deficiency for all of 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.

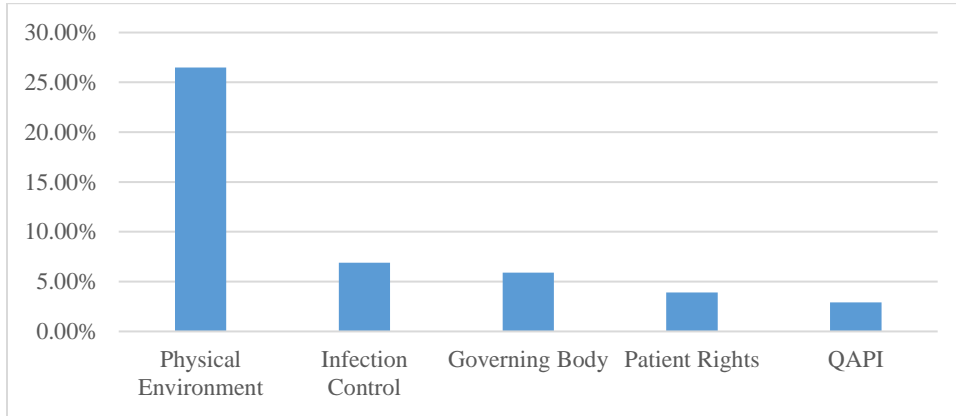
Findings

The PE and Infection Control conditions are the top disparate citations for hospitals, psychiatric hospitals, ASCs, and CAHs. In FY 2015 and FY 2016, the PE condition was found to be in the top three disparate citations for all four of the program types and the Infection Control condition was one of the top five disparate citations for ASCs and hospitals. 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 Doors were the top deficiency citations not cited by AOs, with the Fire/Smoke Barrier noted in all four of the program's top five missed citations for FY 2015 and FY 2016. The other three 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.

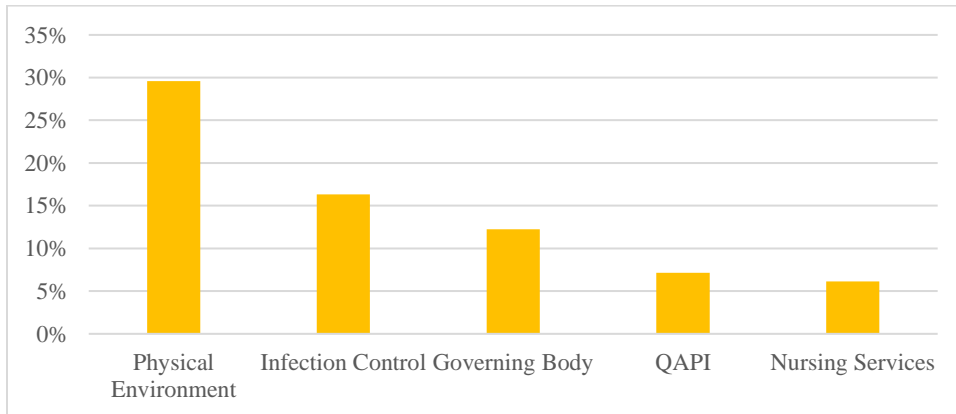
The graphs below discuss, by program type, the top disparate CoPs, the top LSC disparity rates, and an overall depiction of the disparity rates for individual AOs. (See Graphs 42-67.)

Hospital and Long-Term Care Hospital

**Graph 42
Top Five Hospital and LTCH Disparity Rates
FY 2015**

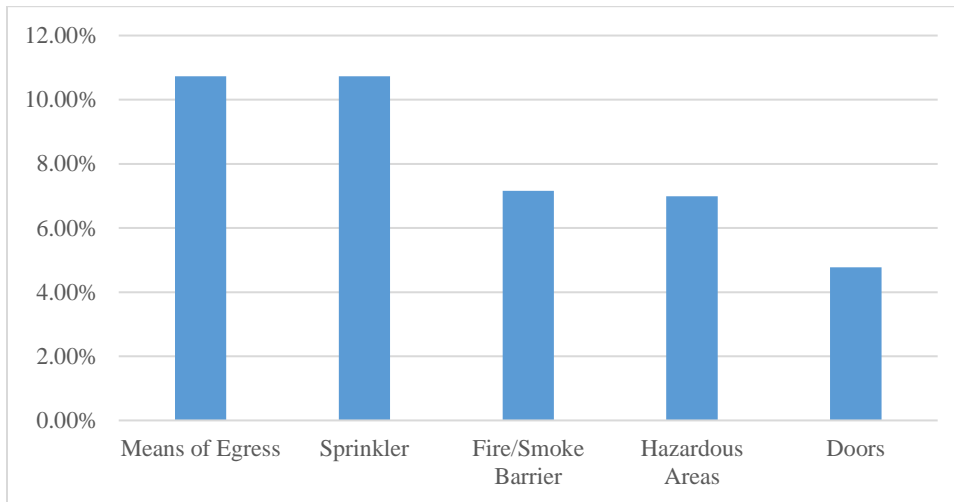


**Graph 43
Top Five Hospital and LTCH Disparity Rates
FY 2016**

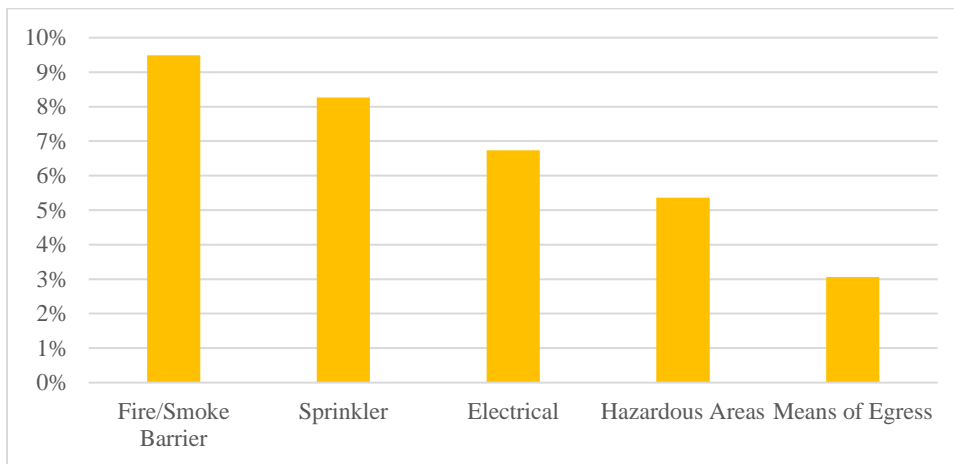


The hospital and LTCH samples consisted of 102 and 98 validation surveys in FYs 2015 and 2016, respectively. PE was identified as the number one disparate CoP and primary driver of the disparity rate for FYs 2015 and 2016. The PE CoP disparity accounted for 48 percent of all disparate findings in FY 2015 and 30 percent of the disparate findings in FY 2016. In FY 2016, the top five disparate CoPs made up 73 percent of all hospital and LTCH disparate findings. The PE, Infection Control, and Governing Body CoPs remained as the top three disparate citations in FY 2016. The overall disparity rate for hospitals and LTCHs was 46 percent in FY 2016, an increase of 7 percentage points from FY 2015.

Graph 44
Top Five Hospital and LTCH
LSC Category Disparity Rates
FY 2015



Graph 45
Top Five Hospital and LTCH
LSC Category Disparity Rates
FY 2016



Out of hospital and LTCH validation surveys, 587 and 653 LSC category citations were cited by the SAs in FYs 2015 and 2016, respectively. The Means of Egress citation disparity rate dropped from 11 percent (63 missed citations) in FY 2015 to 3 percent (20 missed citations) in FY 2016. In FY 2016, the top two most frequently cited LSC categories were Fire/Smoke Barrier, with 103 SA citations, and Sprinkler, with 102 SA citations. The AOs missed 62 comparable citations for Fire/Smoke Barrier (9-percent disparity rate) and 54 comparable citations for Sprinkler (8-percent disparity rate). For FY 2016, a total of 215 missed LSC category citations comprised the top five disparate LSC categories, resulting in 65 percent missed LSC category citations for hospitals and LTCHs.

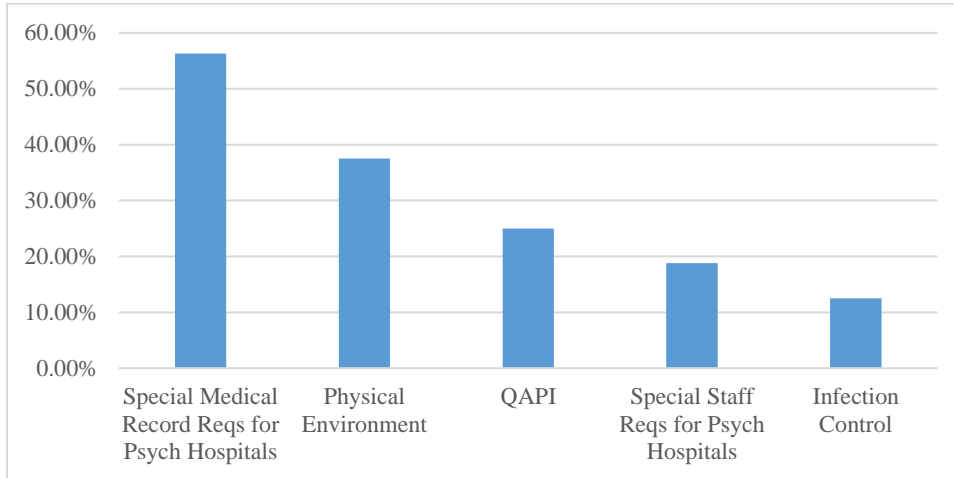
**Graph 46
Hospital and LTCH Disparity Rates
by AO
FYs 2015-2016**



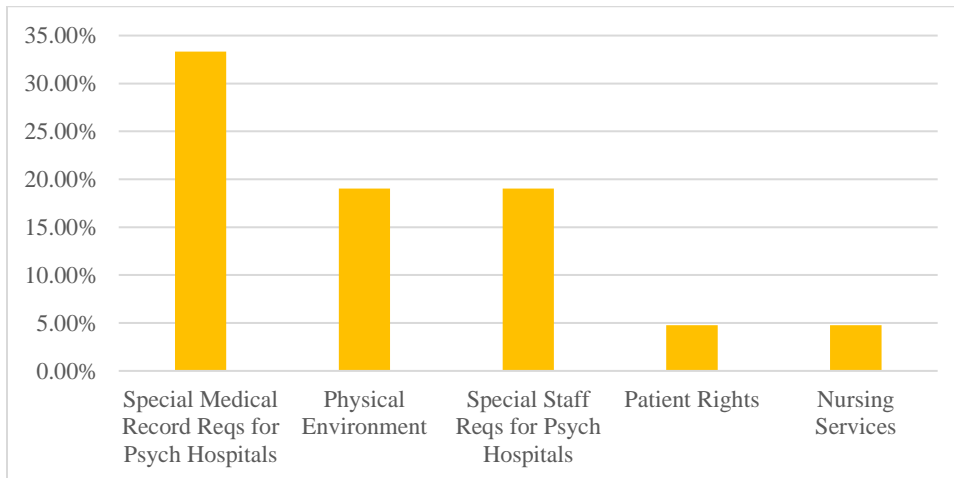
In FY 2015, the SAs didn't cite any health and safety requirements at the condition level for AOA/HFAP. There were also no validation surveys conducted for CIHQ hospitals for which the SAs cited PE requirements at the condition level. Therefore, CIHQ and AOA/HFAP (FY 2015) were not included in this graph due to the limited number of validation surveys performed. AOA/HFAP had 14 validation surveys performed in FY 2016. The overall disparity rate for DNV GL dropped from 50 percent in FY 2015 to 33 percent in FY 2016. The overall disparity rate for TJC increased from 36 percent in FY 2015 to 44 percent in FY 2016.

Psychiatric Hospital

**Graph 47
Top Five Psychiatric Hospital Disparity Rates
FY 2015**

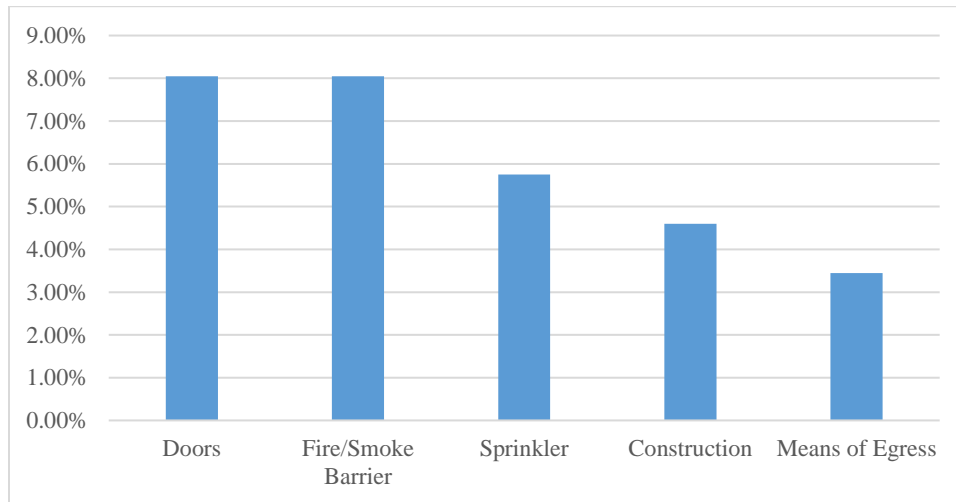


**Graph 48
Top Five Psychiatric Hospital Disparity Rates
FY 2016**

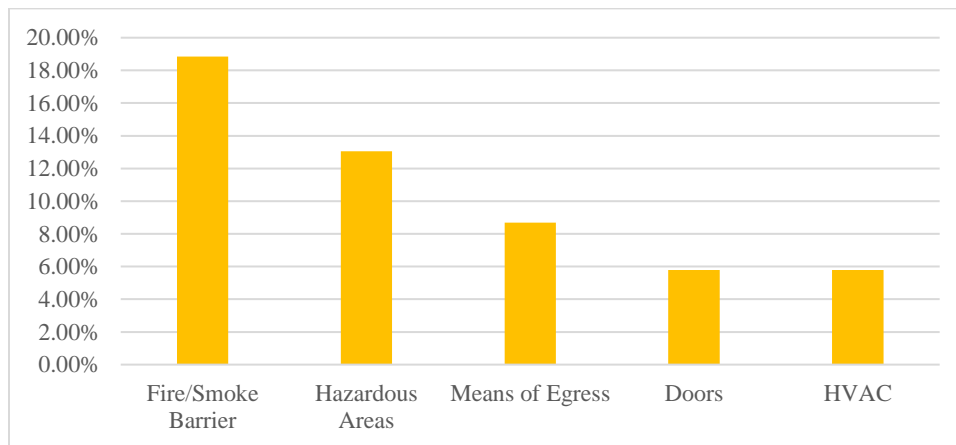


The psychiatric hospital sample consisted of 16 validation surveys in FY 2015 and 21 validation surveys in FY 2016. TJC is the only AO with a CMS-approved psychiatric hospital Medicare accreditation program. Special Medical Record Requirements for psychiatric hospitals was the number one disparate CoP for both years. The SAs cited 14 condition-level citations in FY 2015 and 13 condition-level citations in FY 2016 for this CoP. TJC missed seven comparable deficiencies in FY 2016 resulting in a 33-percent disparity rate. This resulted in a decrease of 23 percentage points in FY 2015 for this particular CoP. PE was the next most frequently cited SA condition with six SA condition-level citations. The SAs cited eight PE condition-level citations for FY 2016 which resulted in a 19-percent citation disparity for PE. This represents a decrease of 18.5 percentage points FY 2015. The overall disparity rate for psychiatric hospitals in FY 2016 was 57 percent. This represents a decrease from the 69-percent disparity rate in FY 2015.

Graph 49
Top Five Psychiatric Hospital
LSC Category Disparity Rates
FY 2015

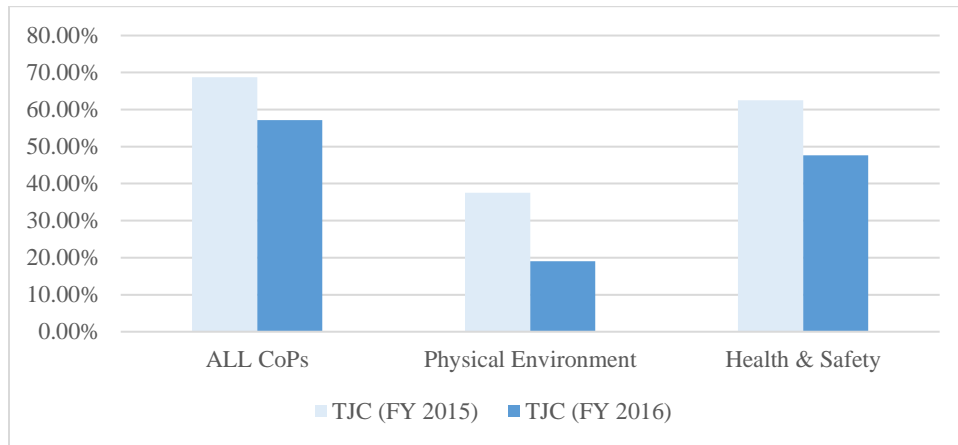


Graph 50
Top Five Psychiatric Hospital
LSC Category Disparity Rates
FY 2016



In FY 2016, 21 psychiatric validation surveys were performed and 69 LSC category citations were cited by the SAs. The top two most frequently cited LSC categories for FY 2016 were Fire/Smoke Barrier with 16 SA citations, and Hazardous Areas with 9 SA citations. TJC missed 13 comparable citations for Fire/Smoke Barrier and 9-comparable citations for Hazardous Areas, resulting in a 19-percent LSC category disparity rate and a 13-percent category disparity rate, respectively. Doors issues were the number one disparate LSC category in FY 2015 with a disparity rate of 8 percent. In FY 2016, the disparity rate for Doors dropped to 6 percent. The number one disparate LSC category in FY 2016 was Fire/Smoke Barrier with a disparity rate of 19 percent. This represents an increase of 11 percentage points from FY 2015. The top five disparate LSC category disparities make up 77 percent of all of the LSC category disparities.

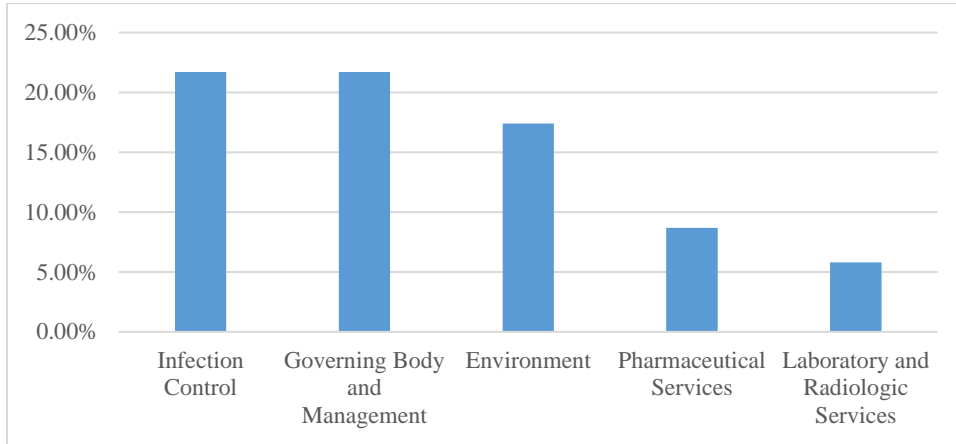
Graph 51
Psychiatric Hospital Disparity Rates
by AO
FYs 2015–2016



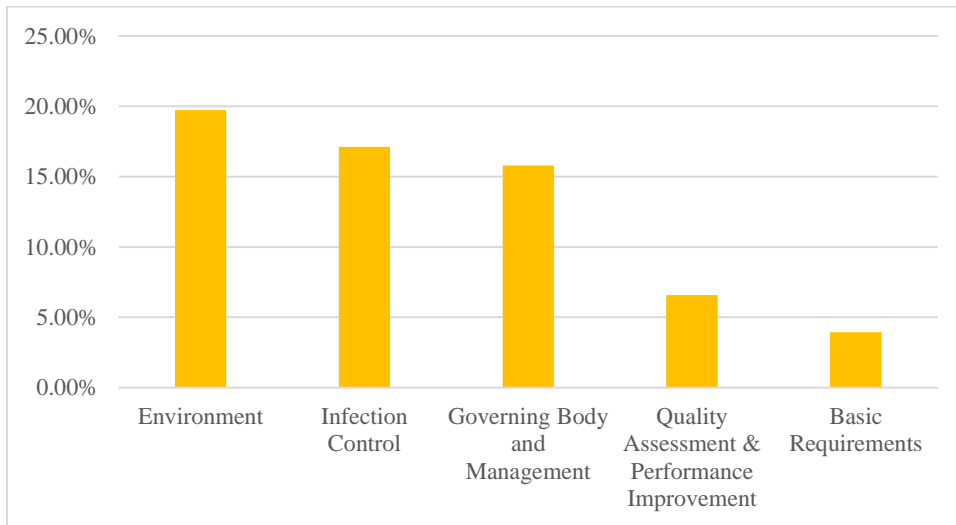
Sixteen psychiatric validation surveys were performed in FY 2015 and 21 in FY 2016. All three disparity rates dropped from FY 2015 to FY 2016. The overall disparity rate for TJC in FY 2016 was 57 percent, down from 69 percent in FY 2015; the PE disparity rate in FY 2016 was 19 percent, down from 37.5 percent in FY 2015; and the health and safety disparity rate for FY 2016 was 48 percent, down from 63 percent in FY 2015 for Psychiatric Hospitals.

Ambulatory Surgery Center

**Graph 52
Top Five ASC Disparity Rates
FY 2015**

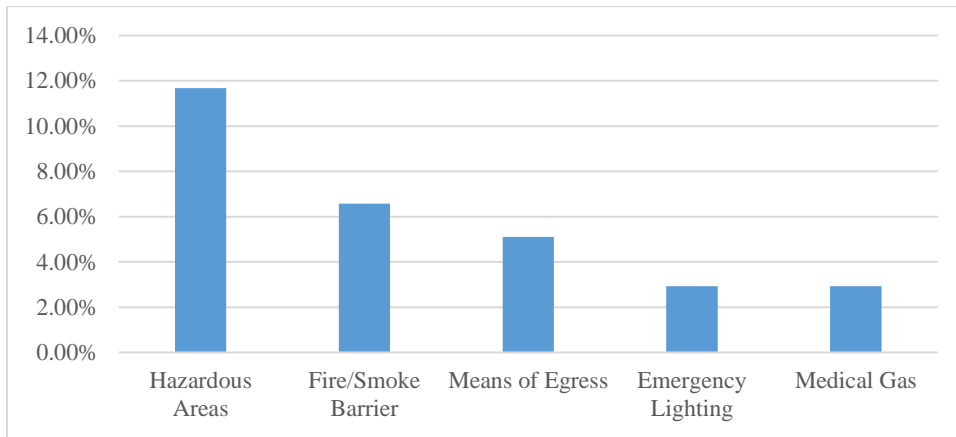


**Graph 53
Top Five ASC Disparity Rates
FY 2016**

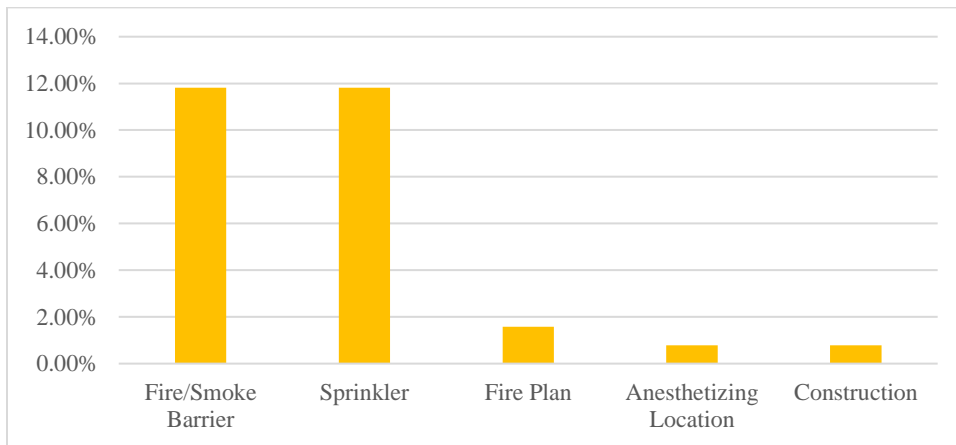


The ASC sample consisted of 69 validation surveys in FY 2015, and 76 validation surveys in FY 2016. Infection Control, Governing Body and Management, and Environment were identified in the top three disparate conditions for both FYs 2015 and 2016. Although the top three disparate conditions remain the same for FY 2015 and FY 2016, the only disparity rate that increased was the Environment condition. This disparity rate increased from 17 percent in FY 2015 to 20 percent in FY 2016. The overall disparity rate for ASCs dropped from 42 percent in FY 2015 to 34 percent in FY 2016. In FY 2016, the top five disparate conditions made up 76 percent of all of the disparate conditions.

**Graph 54
Top Five ASC
LSC Category Disparity Rates
FY 2015**

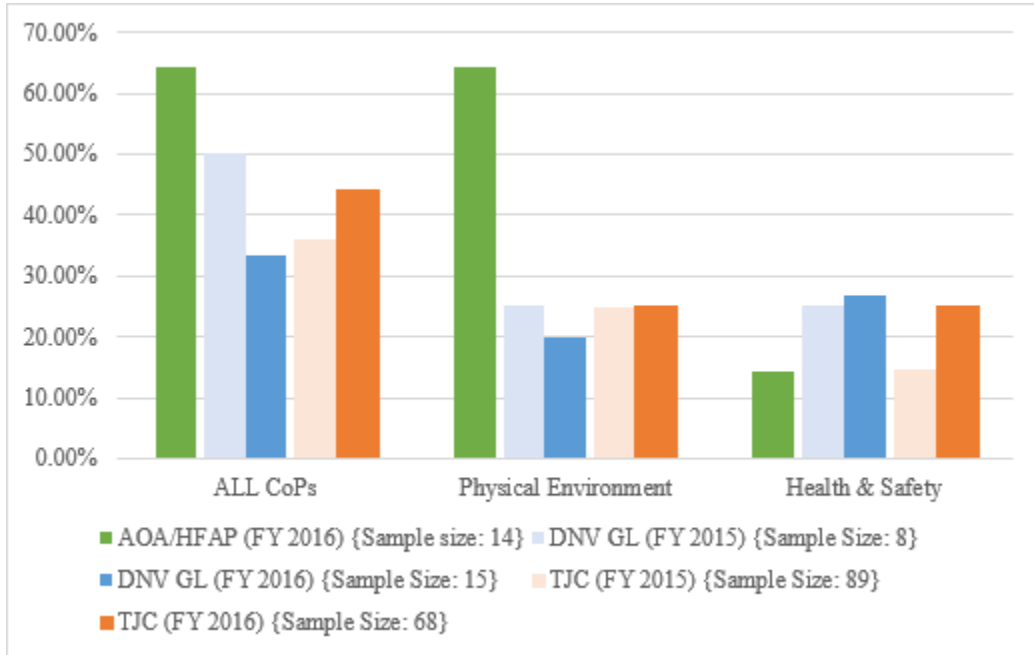


**Graph 55
Top Five ASC
LSC Category Disparity Rates
FY 2016**



Out of 76 ASC validation surveys performed in FY 2016, 127 LSC category citations were cited by the SAs. The most frequently cited LSC category for FY 2015 was Hazardous Areas. The SAs cited this condition 18 times in FY 2015. The SA cited this condition four times in FY 2016; none of the four citations were missed by the AOs. The Fire/Smoke Barrier LSC Category citation was the number one missed citation in FY 2016 with 31 SA citations and 15 missed citations by the AOs. This resulted in a 12-percent disparity rate which is an increase from 7 percent in FY 2015. A total of 34 missed LSC category citations comprised the top 5 disparate LSC categories, resulting in 94 percent missed LSC category citations for ASCs.

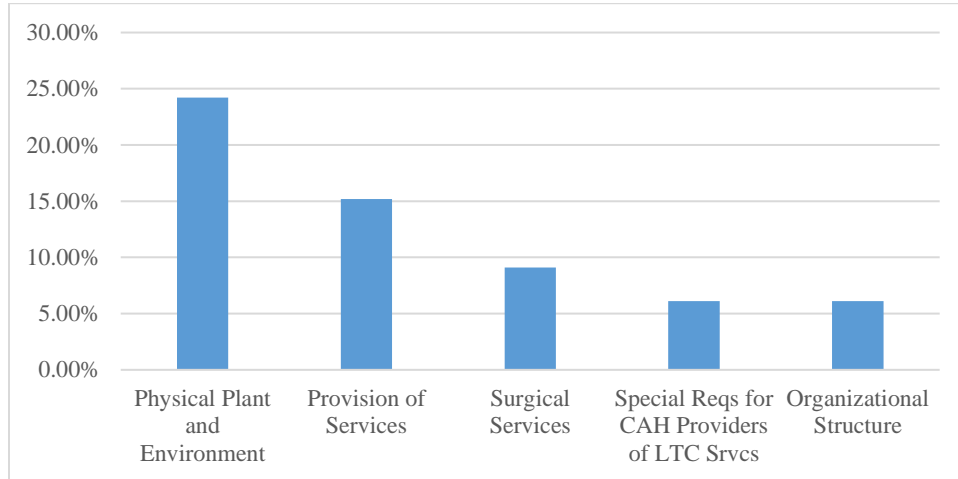
**Graph 56
ASC Disparity Rates
by AO
FYs 2015-2016**



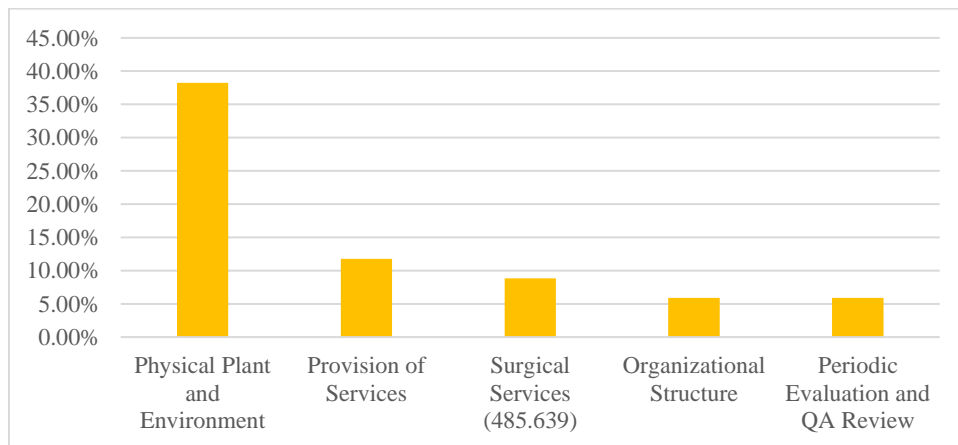
AAAASF, AAAHC, and TJC had validation surveys performed in FY 2015 and FY 2016. All three of the AOs displayed in the graph had a reduction in the overall disparity rate from FY 2015 and FY 2016.

Critical Access Hospital

**Graph 57
Top Five CAH Disparity Rates
FY 2015**

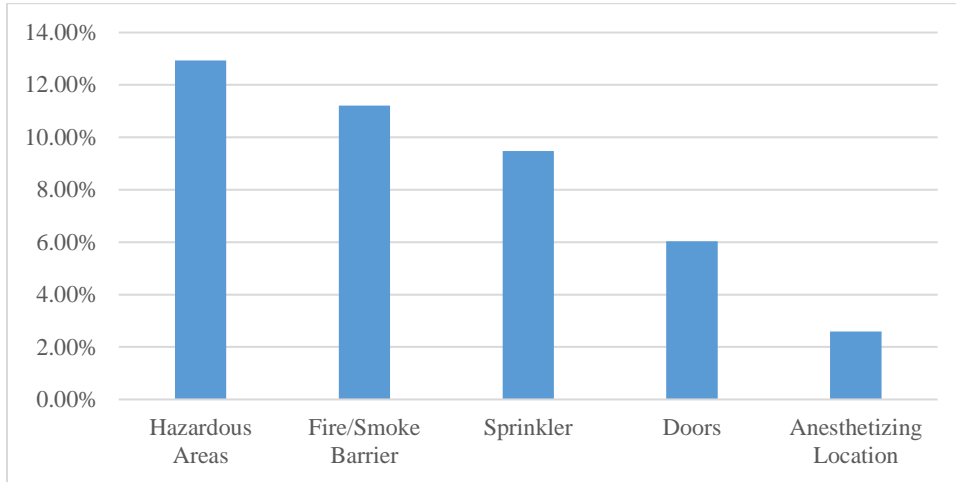


**Graph 58
Top Five CAH Disparity Rates
FY 2016**

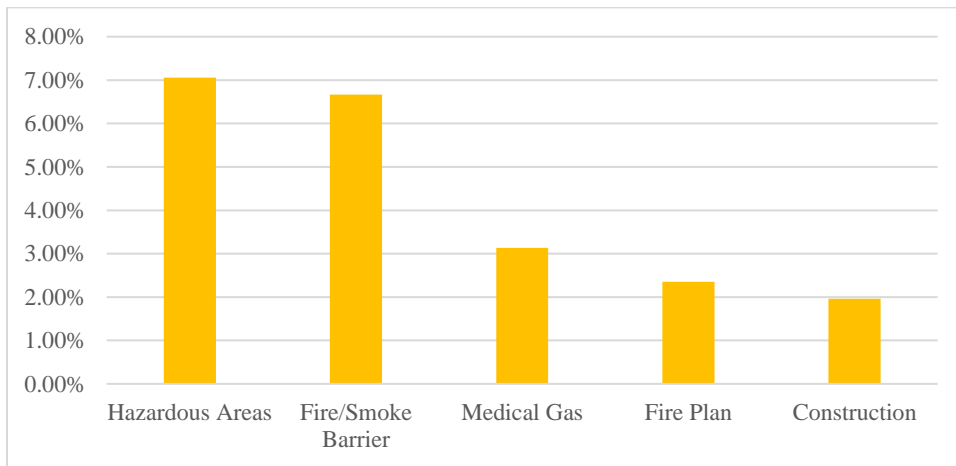


The CAH sample consisted of 33 validation surveys in FY 2015, and 34 validation surveys in FY 2016. Physical Plant and Environment, Provision of Services, and Surgical Servers were identified in the top three disparate CoPs for both FYs 2015 and 2016. Although the top three disparate CoPs remain the same for FY 2015 and FY 2016, the only disparity rate that increased was the Physical Plant and Environment CoP which increased from 24 percent in FY 2015 to 38 percent in FY 2016. The overall disparity rate for HHAs decreased slightly from 45 percent in FY 2015 to 44 percent in FY 2016. In FY 2016, the top five disparate CoPs made up 89 percent of all of the disparate CoPs.

**Graph 59
Top Five CAH
LSC Category Disparity Rates
FY 2015**

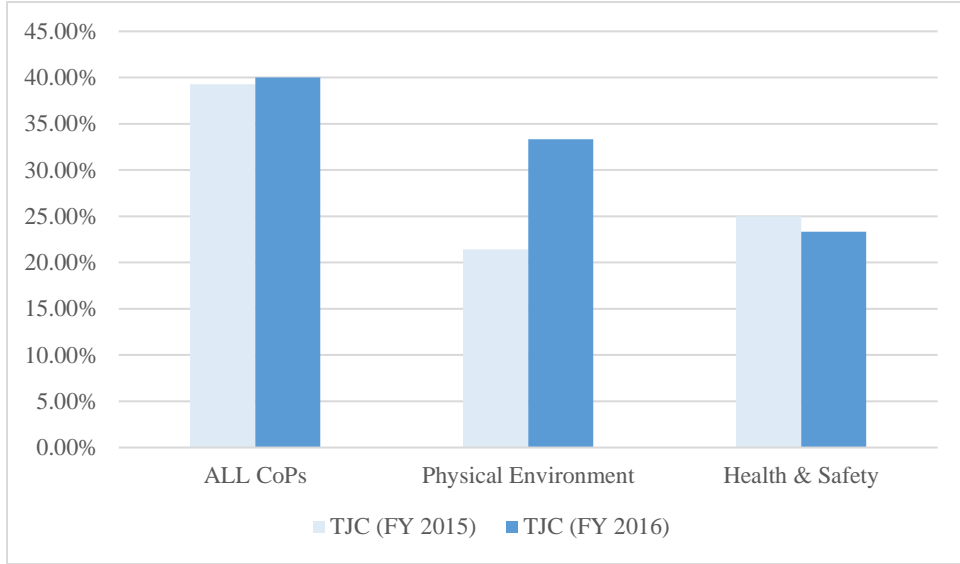


**Graph 60
Top Five CAH
LSC Category Disparity Rates
FY 2016**



Out of 35 CAH validation surveys performed in FY 2016, 255 LSC category citations were cited by the SAs. Hazardous Areas was the most frequently cited LSC category. The SAs cited this condition 15 times in FY 2015 and 28 times in FY 2016. The AOs missed the 15 comparable LSC category citations in FY 2015 and missed 18 LSC category citations in FY 2016. This resulted in a 13-percent disparity rate in FY 2015 and a 7-percent disparity rate in FY 2016. The Fire/Smoke Barrier category was the second highest missed category for the AOs. However, the disparity rate for the LSC Category dropped from 11 percent in FY 2015 to 7 percent in FY 2016. There were a total of 54 missed LSC category citations in the top 5 disparate LSC categories. The top five disparate LSC category citations comprised of 72 percent of all of the missed LSC category citations for CAHs.

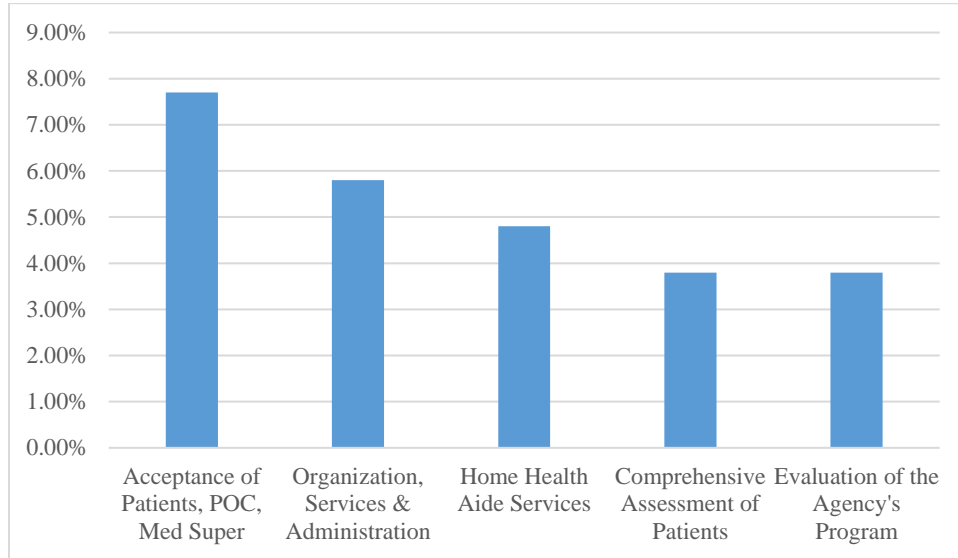
**Graph 61
CAH Disparity Rates
by AO
FYs 2015-2016**



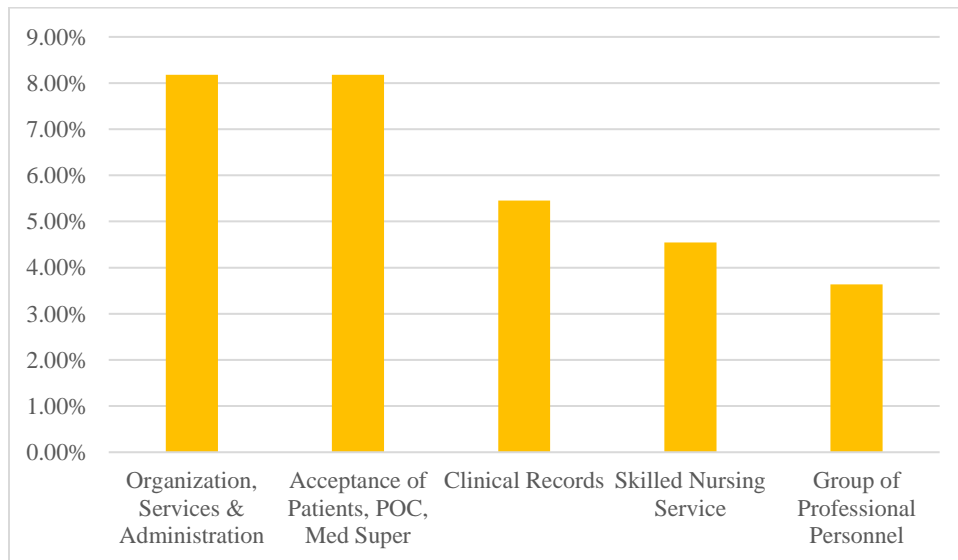
Validation surveys were performed for AOA/HFAP, DNV GL, and TJC in FY 2016, but AOA/HFAP and DNV GL had three or less validation surveys performed in both FYs 2015 and 2016. Therefore, they are not included in this graph. TJC had a slight increase in the overall disparity rate from 39 percent in FY 2015 to 40 percent in FY 2016.

Home Health Agency

**Graph 62
Top Five HHA Disparity Rates
FY 2015**



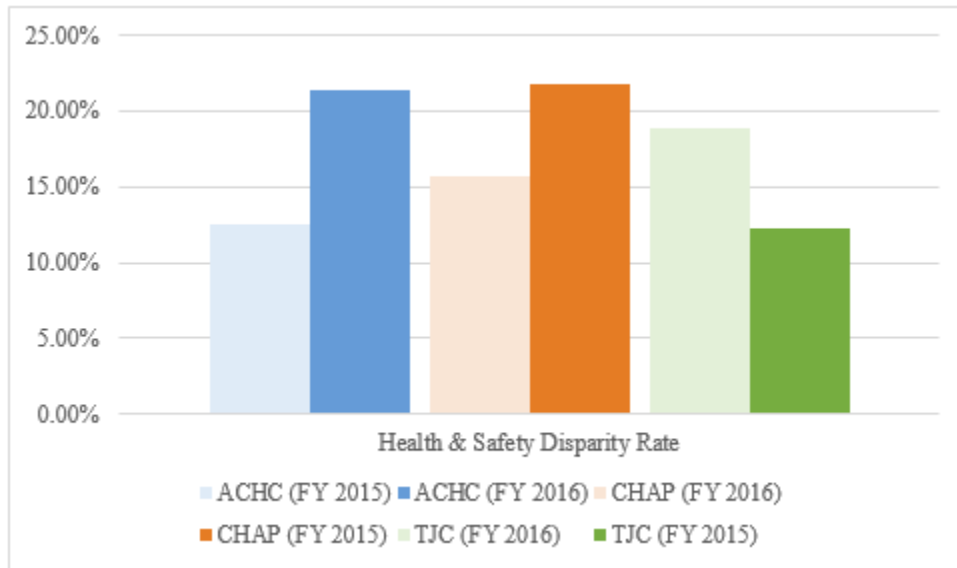
**Graph 63
Top Five HHA Disparity Rates
FY 2016**



The HHA sample consisted of 104 validation surveys in FY 2015 and 110 validation surveys in FY 2016. HHAs do not have any PE or LSC requirements. Acceptance of Patients, Plan of Care and Medical Supervision and Organization, Services & Administration were the top two disparate CoPs identified for HHAs for both FYs 2015 and 2016. The Acceptance of Patients, Plan of Care and Medical Supervision and Organization, Services CoP disparity rate slightly increased from 7.7 percent in FY 2015 to 8.2 percent in FY 2016 while the Organization,

Services & Administration CoP increased from 6 percent in FY 2015 to 8 percent in FY 2016. The overall disparity rate for HHAs increased from 16 percent in FY 2015 to 18 percent in FY 2016. In FY 2016, the top five disparate CoPs made up 70 percent of all of the disparate CoPs.

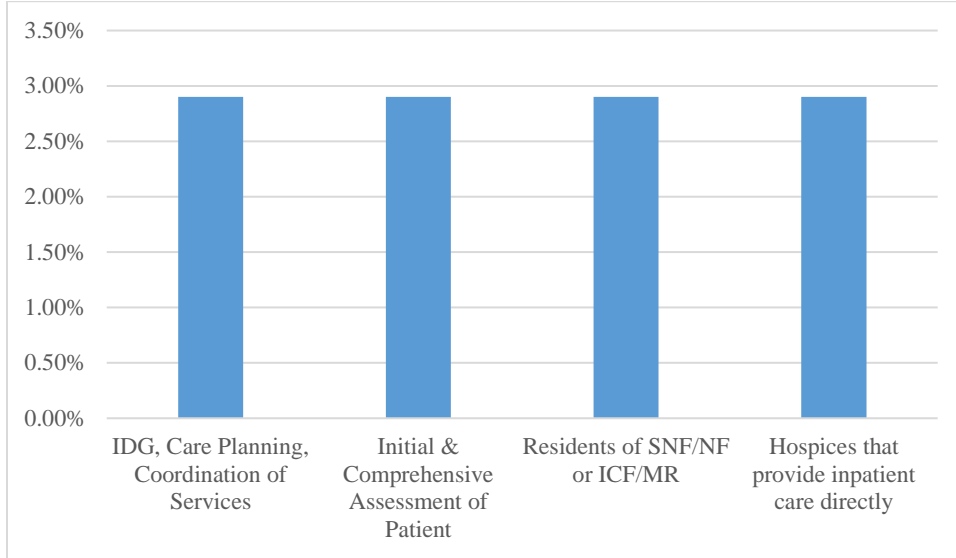
Graph 64
HHA and Safety Disparity Rates
by AO
FYs 2015-2016



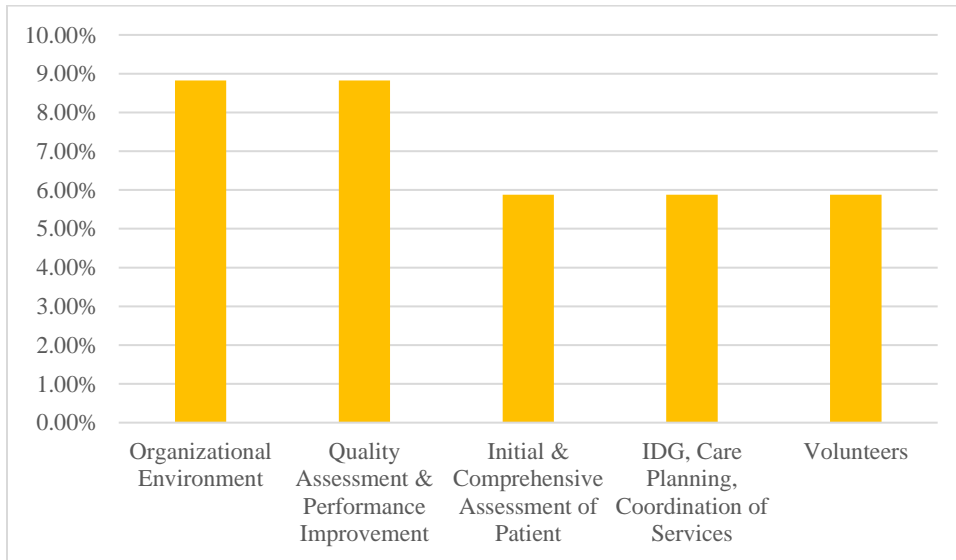
ACHC, CHAP, and TJC had validation surveys performed in FY 2015 and FY 2016 for HHAs. The disparity rate for ACHC increased from 13 percent in FY 2015 to 21 percent in FY 2016, the disparity rate for CHAP increased from 16 percent in FY 2015 to 22 percent in FY 2016, and the disparity rate for TJC dropped from 19 percent in FY 2015 to 12 percent in FY 2016.

Hospice

**Graph 65
Top Four Hospice Disparity Rates
FY 2015**



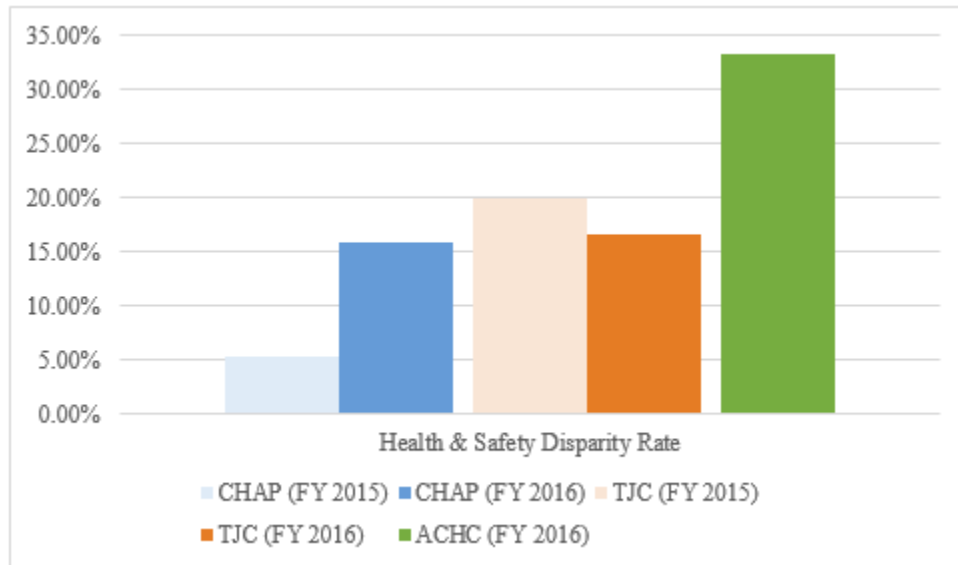
**Graph 66
Top Five Hospice Disparity Rates
FY 2016**



The hospice sample consisted of 34 validation surveys in FY 2015 and FY 2016. Hospice facilities do not have any PE or LSC requirements. In FY 2015, only four facilities were cited at the condition level by the SAs. In FY 2016, six facilities were cited at the condition level by the SAs. In FY 2016, the SA cited a total of 11 condition-level deficiencies; 7 were missed by the AOs. The only two top five citations that were common in FY 2015 and FY 2016 were IDG, Care Planning, Coordination of Services, and Initial & Comprehensive Assessment of Patient.

The individual disparity rates for Initial & Comprehensive Assessment of Patient and IDG, Care, Planning, Coordination of Services conditions increased from 3 percent in FY 2015 to 6 percent in FY 2016. The overall disparity rate for the Hospice program increased from 9 percent in FY 2015 to 18 percent in FY 2016.

Graph 67
Hospice Health and Safety Disparity Rates
by AO
FYs 2015-2016



ACHC, CHAP, and TJC had validation surveys conducted in FYs 2015 and 2016. Disparity rates are not reported for FYs 2015 and 2016. In FY 2015, no SAs cited condition-level findings for any ACHC hospices while conducting validation surveys. Therefore, ACHC has no data displayed in this graph for FY 2015. Only three validation surveys were conducted for ACHC in FY 2016. No disparity rate is reported when the sample size is less than five. CHAP had an increase in the disparity rate from 5 percent in FY 2015 to 16 percent in FY 2016. TJC had a decrease in the disparity from 20 percent in FY 2015 to 17 percent in FY 2016.

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 16 to 48 percent of all disparate surveys in FYs 2015 and 2016 throughout all of the program types with the exception of 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, one of the FY 2015s and 2016 top five disparate LSC categories, is common to each program type with the exception of HHAs and hospices. Means of Egress was the top disparate LSC category for hospitals in FY 2015, but was not in the top five disparate categories in FY 2016. Doors was the top disparate LSC category for psychiatric hospitals in FY 2015, and dropped to the fourth highest disparate finding in FY 2016. The Hazardous Areas category was the number

one disparate finding for CAHs in FYs 2015 and 2016 and ASCs in FY 2015. However, it was not in the top five disparate categories for ASCs in FY 2016. The Infection Control and Governing Body, health and safety conditions are also among the leading disparate conditions across hospitals, including LTCHs and ASCs. Special Medical Record Requirements for Psychiatric Hospitals was the top health and safety disparate condition for Psychiatric Hospitals in FYs 2015 and 2016. The Provision of Services, and Surgical Services, health and safety conditions, were among the top disparate conditions for CAHs in FYs 2015 and 2016.

Among the AOs with a CMS-approved hospital accreditation program and LTCHs, DNV GL has the highest health and safety disparity rate and TJC had the highest overall CoP disparity rate in FY 2016, while AOA/HFAP had the highest PE disparity rate for hospitals. DNV GL also had the highest overall disparity rate and PE disparity rate for CAHs, while TJC had the highest health and safety disparity rate for CAHs in FY 2016. For ASCs, AAAASF had the highest disparity rate for PE, while AAAHC had the highest overall disparity rate and the highest health and safety disparity rate in FY 2016.

Recommendations

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

Each AO needs to develop interventions focusing on their high-volume disparate 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 2016, if the AOs would address the top five disparate CoPs for hospitals, they could potentially eliminate 73 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 2016. Currently, 40 percent (12,495 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 2016, 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)

Centers for Medicare & Medicaid Services/Accrediting Organization Communication and Relationship Building

Communication

CMS continues its periodic meetings with recognized national AOs, including quarterly teleconferences. These meetings serve to foster communication between the AOs and CMS and serve as a forum to: discuss any issues as they arise, communicate and discuss regulatory changes, assure ongoing deemed facility compliance with Medicare conditions, and provide information and education for AO staff. CMS CO, RO staff, and individual AOs communicate on a weekly, if not daily, basis either by email or telephone to address a wide variety of issues, including, but not limited to: specific deemed facility deficiencies, certification issues, program operations, surveys, requirements, interpretation of regulations, and data.

Consultation

CMS increased opportunities for AOs as well as other stakeholders to provide input into the development of sub-regulatory guidance concerning Medicare standards and survey processes. 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. In FY 2016, 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

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 (81 FR 26871), updated 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.

SECTION 7: Clinical Laboratory Improvement Amendments Validation Program

Introduction

CLIA of 1988 expanded survey and certification of clinical laboratories from Medicare-participating and interstate commerce laboratories to all facilities testing human specimens for health purposes, regardless of location. CMS regulates all laboratory testing (whether provided to beneficiaries of CMS programs or to others), including those performed in physicians' offices, for a total of 254,975 facilities at the beginning of calendar year (CY) 2016. 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 18,385 laboratories every 2 years. CMS-approved AOs conduct on-site surveys of an additional 16,441 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) provides research and technical support, and coordinates the Secretary's Clinical Laboratory Improvement Advisory Committee (CLIAC); and (3) the Food and Drug Administration (FDA) performs test categorization.

This report on the Clinical Laboratory Improvement Validation Program covers the evaluations of FY 2016 performance by the seven AOs approved by CMS under CLIA. The seven organizations are:

- AABB
- American Association for Laboratory Accreditation (A2LA)
- AOA/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 as 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, as amended by CLIA, requires any laboratory that performs testing on human specimens for health purposes to meet the requirements established by the CLIA statute and regulations and have in effect an applicable certificate. Section 353 further provides that a laboratory meeting the standards of an approved AO may obtain a CLIA Certificate of Accreditation. Under the CLIA Certificate of Accreditation, 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.

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 “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 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 disparity¹³ 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.

¹³ 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 described in its request for approval. The AO's standards, as a whole, were approved by CMS as being equivalent to or more stringent than the CLIA condition-level requirements.¹⁴ This equivalency is the basis for granting deeming authority.

In evaluating an organization's performance, 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, laboratory practices and outcomes that do not meet their accreditation standards, so that equivalency of the accreditation program is maintained.

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 of 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, 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 16,000 accredited laboratories received a validation survey in 2016. 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, AOA/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. The number of validation surveys performed for each organization is specified below in the summary findings for the organization.

¹⁴ 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.

Results of the Validation Reviews of Each Accrediting Organization

AABB

Rate of disparity: N/A

In FY 2016, approximately 206 laboratories used their AABB accreditation for CLIA program purposes. Validation surveys were conducted in five AABB accredited laboratories. One survey was removed from the pool for administrative reasons. Because the validation sample is only four surveys, no additional data are reported. (See Table 27.)

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 low number of deemed facilities, none of which were due for a biennial survey during the FY 2016 survey cycle. As a result, no CLIA validation surveys were conducted. There is no data to report. (See Table 27.)

American Osteopathic Association/Healthcare Facilities Accreditation Program

Rate of disparity: N/A

For CLIA purposes, approximately 129 laboratories used their AOA/HFAP accreditation. Validation surveys were conducted in three AOA/HFAP-accredited laboratories. No condition-level deficiencies were cited in any of the validation surveys; therefore, no additional data are reported. (See Table 27.)

American Society for Histocompatibility and Immunogenetics

Rate of disparity: N/A

Approximately 110 laboratories used their ASHI accreditation for CLIA purposes. A validation survey was conducted in one ASHI-accredited laboratory and no condition-level deficiencies were cited; therefore, no additional data are reported. (See Table 27.)

COLA

Rate of disparity: 7 percent

In FY 2016, 6,614 laboratories used their COLA accreditation for CLIA program purposes. A total of 202 validation surveys were conducted in COLA-accredited laboratories. Twenty-two laboratories were cited with condition-level deficiencies. In seven of those laboratories, COLA findings were comparable to all of the CLIA condition-level deficiencies cited. In the remaining 15 laboratories, however, COLA noted comparable findings for only some or none of the CLIA condition-level deficiencies cited; thus, there were 15 disparate cases yielding a disparity rate of 7 percent. (See Table 27.)

College of American Pathologists

Rate of disparity: 8 percent

In FY 2016, 6,237 laboratories used their CAP accreditation for CLIA program purposes. A total of 95 validation surveys were conducted in CAP-accredited laboratories. Eleven laboratories were cited with CLIA condition-level deficiencies. In three of those laboratories, CAP findings were comparable to all of the CLIA condition-level deficiencies cited. In eight laboratories, CAP noted comparable findings for only some or none of the CLIA condition-level deficiencies cited; thus, there were eight disparate cases for a disparity rate of 8 percent. (See Table 27.)

The Joint Commission

Rate of disparity: 16 percent

In FY 2016, 2,209 laboratories used their TJC accreditation for CLIA program purposes. During this validation period, a total of 51 validation surveys were conducted in TJC-accredited laboratories. Ten laboratories were cited with CLIA condition-level deficiencies. In two of those laboratories, TJC findings were comparable to all of the CLIA condition-level deficiencies cited. In eight laboratories, TJC noted comparable findings for only some or none of the CLIA condition-level deficiencies cited; thus, there were eight disparate cases yielding a disparity rate of 16 percent. (See Table 27.)

Table 27
Validation Survey Results for Clinical Laboratories
FY 2016

Number of—	AABB	A2LA	AOA	ASHI	CAP	COLA	TJC	Total
Accredited Labs	206	2	129	110	6,237	6,614	2,209	15,507
Validation Surveys	4	0	3	1	95	202	51	356
Surveys with Condition-Level Deficiencies	*N/A	*N/A	*N/A	*N/A	11	22	10	46
Surveys with One or More Condition-Level Deficiencies Missed by AO	*N/A	*N/A	*N/A	*N/A	8	15	8	33
Disparity Rate	*N/A	*N/A	*N/A	*N/A	8.4%	7.4%	15.7%	9.3%

*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, CMS 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
Comparable Measures for FYs 2015-2016**

	AAAASF		AAAHC		ACHC		AOA/HFAP		CHAP		CIHQ		DNV GL		TCT		TJC	
	FY15	FY16	FY15	FY16	FY15	FY16	FY15	FY16	FY15	FY16	FY15	FY16	FY15	FY16	FY15	FY16	FY15	FY16
ASSURE Database																		
Timeliness of facility notification of survey results	NA [†]	99	NA [†]	74	NA [†]	100	NA [†]	100	NA [†]	93	NA [†]	100	NA [†]	100	NA [†]	98	NA [†]	100
Denied initial surveys with condition-level findings	66	100	100	100	100	100	100	**NA	100	100	100	**NA	17	83	67	100	83	68
Timely electronic submission of no-match data follow-up	100	100	75	100	100	100	100	100	100	100	*NA	100	100	100	100	*NA	100	100
Evidence of no-match reconciliation	100	100	100	100	100	100	100	100	100	100	*NA	100	100	100	100	*NA	100	100
Facility Notification Letters																		
Letters submitted with attachments	100	100	100	100	100	100	100	75	100	100	100	95	100	100	100	100	100	96
Notification letters contain all required information	95	98	88	91	100	100	97	100	99	99	100	100	99	100	92	94	98	99
ASSURE is updated consistent with letters	80	92	90	86	98	99	97	100	76	78	96	96	86	96	82	88	79	81

	AAAASF		AAAHC		ACHC		AOA/HFAP		CHAP		CIHQ		DNV GL		TCT		TJC		
	FY15	FY16	FY15	FY16	FY15	FY16	FY15	FY16	FY15	FY16	FY15	FY16	FY15	FY16	FY15	FY16	FY15	FY16	
Survey Schedule																			
AO conducted survey as reported on survey schedule	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	
Number of surveys performed matches number reported in ASSURE	97	99	84	86	100	100	100	100	99	98	100	91	99	100	87	94	98	99	
Formal Correspondence																			
Responses to CMS on or before specified due date	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	**NA	100	100

NA[†]: New measure for FY 2016; not reported in FY 2015.

*NA: No information available for calculation.

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

APPENDIX B: Fiscal Year 2016 Life Safety Code and Health & Safety Disparity Rates

Accrediting Organizations

American Association for Accreditation of Ambulatory Surgery Facilities, Inc.

Ambulatory Surgery Centers

AAAASF (FY 2016 ASC Surveys)	All CoPs	PE	Health & Safety
Number of 60-Day Validation Surveys	6	6	6
Number of Surveys with Conditions Missed by AO	2	2	1
Disparity Rate	33.33%	33.33%	16.67%

**Appendix B Table 1: AAAASF
ASC Disparity Rate
FY 2016**

CoPs	Facilities with CoP(s)	Matching Surveys	Disparate Surveys	Disparity Rate
Environment	2	0	2	33%
Governing Body and Management	2	1	1	17%
Pharmaceutical Services	2	1	1	17%
Infection Control	2	1	1	17%
Medical Records	2	1	1	17%

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

Category	Total Cited by SA	Missed by AO	Disparity Rate
Fire/Smoke Barrier	9	9	69.23%
Generator	2	2	15.38%
Fire Alarm	1	1	7.69%
Sprinkler	1	1	7.69%

**Appendix B Table 3: AAAASF
Missed LSC Citations for ASCs
100 Percent of all Missed Citations**

Accreditation Association for Ambulatory Health Care, Inc

Ambulatory Surgery Centers

AAAHC (FY 2016 ASC Surveys)	All CoPs	PE	Health & Safety
Number of 60-Day Validation Surveys	35	35	35
Number of Surveys with Conditions Missed by AO	13	6	9
Disparity Rate	37.14%	17.14%	25.71%

**Appendix B Table 4: AAAHC
ASC Disparity Rate
FY 2016**

CoPs	Facilities with CoP(s)	Matching Surveys	Disparate Surveys	Disparity Rate
Environment	14	7	7	20%
Infection Control	9	2	7	20%
Governing Body and Management	4	0	4	11%
Patient Admission, Assessment and Discharge	2	0	2	6%
Pharmaceutical Services	2	1	1	3%

**Appendix B Table 5: AAAHC
Top Five Disparate CoPs for ASCs
88 Percent of all Disparate Surveys**

Category	Total Cited by SA	Missed by AO	Disparity Rate
Sprinkler	12	7	10%
Fire/Smoke Barrier	14	5	7%
Fire Plan	5	3	4%
Fire Extinguisher	2	2	3%
Anesthetizing Location	1	1	1%
Doors	1	1	1%
Fire Drill	4	1	1%
Generator	12	1	1%

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

Accreditation Commission for Health Care

Home Health Agency

ACHC (FY 2016 HHA Surveys)	All CoPs	Health & Safety
Number of 60-Day Validation Surveys	14	14
Number of Surveys with Conditions Missed by AO	3	3
Disparity Rate	21.43%	21.43%

**Appendix B Table 7: AAAHC
HHA Disparity Rate
FY 2016**

CoPs	Facilities with CoP(s)	Matching Surveys	Disparate Surveys	Disparity Rate
Acceptance of Patients, POC, Med Super	5	3	2	15%
Organization, Services & Administration	4	2	2	15%
Clinical Records	3	1	2	15%
Skilled Nursing Service	3	2	1	8%
Group of Professional Personnel	1	0	1	8%

**Appendix B Table 8: AAAHC
Top Five Disparate CoPs for HHAs
80 Percent of all Disparate Surveys**

Hospice

ACHC (FY 2016 Hospice Surveys)	All CoPs	Health & Safety
Number of 60-Day Validation Surveys	3	3
Number of Surveys with Conditions Missed by AO	1	1
Disparity Rate	33.33%	33.33%

**Appendix B Table 9: AAAHC
HHA Disparity Rate
FY 2016**

CoPs	Facilities with CoP(s)	Matching Surveys	Disparate Surveys	Disparity Rate
Short-Term Inpatient Care	1	0	1	33%
Initial & Comprehensive Assessment of Patient	1	0	1	33%
Quality Assessment & Performance Improvement	1	0	1	33%

**Appendix B Table 10: AAAHC
Top Five Disparate CoPs for Hospice
100 Percent of all Disparate Surveys**

American Osteopathic Association/Healthcare Facilities Accreditation Program

Hospitals

AOA/HFAP (FY 2016 Hospital Surveys)	All CoPs	PE	Health & Safety
Number of 60-Day Validation Surveys	14	14	14
Number of Surveys with Conditions Missed by AO	9	9	2
Disparity Rate	64.29%	64.29%	14.29%

**Appendix B Table 11: AOA/HFAP
Hospital Disparity Rate
FY 2016**

CoP	Facilities with CoP	Matching Surveys	Disparate Surveys	Disparity Rate
Physical Environment	19	10	9	64%
Patient Rights	1	0	1	7%
Pharmaceutical Services	1	0	1	7%
Surgical Services	1	0	1	7%

**Appendix B Table 12: AOA/HFAP
Disparate CoPs for Hospitals
100 Percent of all Disparate Surveys**

Category	Total Cited by SA	Missed by AO	Disparity Rate
Fire/Smoke Barrier	29	20	11%
Hazardous Areas	19	12	7%
Sprinkler	23	6	3%
Cooking Facility	7	4	2%
Fire Plan	5	4	2%
Electrical	6	3	2%
Elevators	3	3	2%
Emergency Lighting	3	3	2%
Fire Drill	6	3	2%
Means of Egress	27	3	2%

**Appendix B Table 13: AOA/HFAP
Missed LSC Citations for Hospitals
87 Percent of all Missed Citations**

Critical Access Hospitals

AOA/HFAP (FY 2016 CAH Surveys)	All CoPs	PE	Health & Safety
Number of 60-Day Validation Surveys	2	2	2
Number of Surveys with Conditions Missed by AO	2	2	0
Disparity Rate	100.00%	100.00%	0.00%

**Appendix B Table 14: AOA/HFAP
CAH Disparity Rate
FY 2016**

CoP	Facilities with CoP	Matching Surveys	Disparate Surveys	Disparity Rate
Physical Plant and Environment	4	2	2	100%

**Appendix B Table 15: AOA/HFAP
Disparate CoPs for CAHs
100 Percent of all Disparate Surveys**

Category	Total Cited by SA	Missed by AO	Disparity Rate
Hazardous Areas	5	3	8%
Emergency Lighting	2	2	5%
Elevators	1	1	3%
Essential Electrical System (EES)	1	1	3%
Fire/Smoke Barrier	5	1	3%
HVAC	1	1	3%

**Appendix B Table 16: AOA/HFAP
Missed LSC Citations for CAHs
100 Percent of all Missed Citations**

Community Health Accreditation Partner

Home Health Agency

CHAP (FY 2016 HHA Surveys)	All CoPs	Health & Safety
Number of 60-Day Validation Surveys	55	55
Number of Surveys with Conditions Missed by AO	12	12
Disparity Rate	21.82%	21.82%

**Appendix B Table 17: CHAP
HHA Disparity Rate
FY 2016**

CoPs	Facilities with CoPs	Matching Surveys	Disparate Surveys	Disparity Rate
Acceptance of Patients, POC, Med Super	10	4	6	11%
Organization, Services & Administration	7	3	4	7%
Skilled Nursing Service	4	1	3	5%
Clinical Records	4	1	3	5%
Home Health Aide Services	3	1	2	4%

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

Hospice

CHAP (FY 2016 Hospice Surveys)	All CoPs	Health & Safety
Number of 60-Day Validation Surveys	19	19
Number of Surveys with Conditions Missed by AO	3	3
Disparity Rate	15.79%	15.79%

**Appendix B Table 19: CHAP
Hospice Disparity Rate
FY 2016**

CoPs	Facilities with CoP(s)	Matching Surveys	Disparate Surveys	Disparity Rate
IDG, Care Planning, Coordination of Services	4	2	2	11%

CoPs	Facilities with CoP(s)	Matching Surveys	Disparate Surveys	Disparity Rate
Organizational Environment	2	0	2	11%
Quality Assessment & Performance Improvement	2	1	1	5%
Initial & Comprehensive Assessment of Patient	2	1	1	5%
Residents of SNF/NF or ICF/MR	1	0	1	5%

**Appendix B Table 20: CHAP
Disparate CoPs for Hospice
78 Percent of all Disparate Surveys**

Center for Improvement in Healthcare Quality

Hospitals

CIHQ (FY 2016 Hospital Surveys)	All CoPs	PE	Health & Safety
Number of 60-Day Validation Surveys	1	1	1
Number of Surveys with Conditions Missed by AO	1	0	1
Disparity Rate	100.00%	0.00%	100.00%

**Appendix B Table 21: CIHQ
Hospital Disparity Rate
FY 2016**

CoP	Facilities with CoP	Matching Surveys	Disparate Surveys	Disparity Rate
QAPI	1	0	1	100%
Infection Control	1	0	1	100%

**Appendix B Table 22: CIHQ
Disparate CoPs for Hospitals
100 Percent of all Disparate Surveys**

DNV GL-Healthcare

Hospitals

DNV GL (FY 2016 Hospital Surveys)	All CoPs	PE	Health & Safety
Number of 60-Day Validation Surveys	15	15	15
Number of Surveys with Conditions Missed by AO	5	3	4
Disparity Rate	33.33%	20.00%	26.67%

**Appendix B Table 23: DNV GL-Healthcare
Hospital Disparity Rate
FY 2016**

CoPs	Facilities with CoP(s)	Matching Surveys	Disparate Surveys	Disparity Rate
Infection Control	5	1	4	27%
Governing Body	4	0	4	27%
Physical Environment	6	3	3	20%
QAPI	3	0	3	20%
Pharmaceutical Services	2	1	1	7%

**Appendix B Table 24: DNV GL-Healthcare
Disparate CoPs for Hospitals
75 Percent of all Disparate Surveys**

Category	Total Cited by SA	Missed by AO	Disparity Rate
Doors	11	11	12%
Means of Egress	12	10	11%
Fire/Smoke Barrier	16	9	10%
Electrical	12	8	9%
Sprinkler	10	7	8%
Emergency Lighting	4	4	4%
Fire Alarm	5	4	4%
Fire Plan	3	3	3%
Fire Drill	3	3	3%
Fire Extinguisher	3	3	3%

**Appendix B Table 25: DNV GL-Healthcare
Top 10 Missed LSC Citations for Hospitals
90 Percent of all Missed Citations**

Critical Access Hospitals

DNV GL (FY 2016 CAHs)	All CoPs	PE	Health & Safety
Number of 60-Day Validation Surveys	2	2	2
Number of Surveys with Conditions Missed by AO	1	1	1
Disparity Rate	50.00%	50.00%	50.00%

**Appendix B Table 26: DNV GL-Healthcare
CAHs Disparity Rate
FY 2016**

CoP	Facilities with CoP	Matching Surveys	Disparate Surveys	Disparity Rate
Physical Plant and Environment	2	1	1	50%
Provision of Services	2	1	1	50%

**Appendix B Table 27: DNV GL-Healthcare
Disparate CoPs for CAHs
100 Percent of all Disparate Surveys**

Category	Total Cited by SA	Missed by AO	Disparity Rate
Medical Gas	5	5	24%
Doors	3	3	14%
Electrical	3	3	14%
Hazardous Areas	3	3	14%
Fire Drill	1	1	5%
Fire Extinguisher	1	1	5%
Fire/Smoke Barrier	2	1	5%
Sprinkler	1	1	5%

**Appendix B Table 28: DNV GL-Healthcare
Missed LSC Citations for CAHs
100 Percent of all Missed Citations**

The Joint Commission

Hospitals

TJC (FY 2016 Hospital and LTCH Surveys)	All CoPs	PE	Health & Safety
Number of 60-Day Validation Surveys	68	68	68
Number of Surveys with Conditions Missed by AO	30	17	17
Disparity Rate	44.12%	25.00%	25.00%

**Appendix B Table 29: TJC
Hospital and LTCH Disparity Rate
FY 2016**

CoPs	Facilities with CoPs	Matching Surveys	Disparate Surveys	Disparity Rate
Physical Environment	31	14	17	25%
Infection Control	15	4	11	16%
Governing Body	13	5	8	12%
Nursing Services	7	2	5	7%
Radiologic Services	4	0	4	6%

**Appendix B Table 30: TJC
Top Five Disparate CoPs for Hospitals
73 Percent of all Disparate Surveys**

Category	Total Cited by SA	Missed by AO	Disparity Rate
Sprinkler	69	41	11%
Electrical	41	33	9%
Fire/Smoke Barrier	58	33	9%
Hazardous Areas	34	22	6%
Doors	34	20	5%
Emergency Lighting	10	10	3%
Fire Alarm	17	9	2%
Flammable & Combustible Storage	13	9	2%
Construction	8	7	2%
Generator	10	7	2%

**Appendix B Table 31: TJC
Top 10 Missed LSC Citations for Hospital
88 Percent of all Missed Citations**

Psychiatric Hospitals

TJC (FY 2016 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	12	4	10
Disparity Rate	57.14%	19.05%	47.62%

**Appendix B Table 32: TJC
Psychiatric Hospital Disparity Rate
FY 2016**

CoPs	Facilities with CoPs	Matching Surveys	Disparate Surveys	Disparity Rate
Special Medical Record Reqs for Psych Hospitals	13	6	7	33%
Physical Environment	8	4	4	19%
Special Staff Reqs for Psych Hospitals	8	4	4	19%
Patient Rights	2	1	1	5%
Nursing Services	2	1	1	5%

**Appendix B Table 33: TJC
Top Five Disparate CoPs for Psychiatric Hospitals
85 Percent of all Disparate Surveys**

Category	Total Cited by SA	Missed by AO	Disparity Rate
Fire/Smoke Barrier	16	13	19%
Hazardous Areas	9	9	13%
Means of Egress	10	6	9%
Doors	6	4	6%
HVAC	5	4	6%
Fire Plan	3	3	4%
Generator	3	3	4%
Fire Alarm	5	2	3%
Electrical	5	1	1%
EES	1	1	1%

**Appendix B Table 34: TJC
Top 10 Missed LSC Citations for Psychiatric Hospitals
98 Percent of all Missed Citations**

Ambulatory Surgery Center

TJC (FY 2016 ASC Surveys)	All CoPs	PE	Health & Safety
Number of 60-Day Validation Surveys	34	34	34
Number of Surveys with Conditions Missed by AO	9	6	8
Disparity Rate	26.47%	17.65%	23.53%

**Appendix B Table 35: TJC
ASC Disparity Rate
FY 2016**

CoPs	Facilities with CoPs	Matching Surveys	Disparate Surveys	Disparity Rate
Governing Body and Management	11	4	7	21%
Environment	10	4	6	18%
Infection Control	7	2	5	15%
Quality Assessment & Performance Improvement	5	2	3	9%
Basic Requirements	3	0	3	9%

**Appendix B Table 36: TJC
Top Five Disparate CoPs for ASCs
80 Percent of all Disparate Surveys**

Category	Total Cited by SA	Missed by AO	Disparity Rate
Sprinkler	10	7	16%
Electrical	8	5	12%
Means of Egress	3	3	7%
Construction	1	1	2%
Fire/Smoke Barrier	8	1	2%
Flammable & Combustible Storage	1	1	2%

**Appendix B Table 37: TJC
Top 10 Missed LSC Citations for ASCs
100 Percent of all Missed Citations**

Home Health Agency

TJC (FY 2016 HHA Surveys)	All CoPs	Health & Safety
Number of 60-Day Validation Surveys	41	41
Number of Surveys with Conditions Missed by AO	5	5
Disparity Rate	12.20%	12.20%

**Appendix B Table 38: TJC
HHA Disparity Rate
FY 2016**

CoPs	Facilities with CoPs	Matching Surveys	Disparate Surveys	Disparity Rate
Organization, Services & Administration	4	1	3	7%
Acceptance of Patients, POC, Med Super	2	1	1	2%
Skilled Nursing Service	2	1	1	2%
Clinical Records	2	1	1	2%
Evaluation of the Agency's Program	1	0	1	2%

**Appendix B Table 39: TJC
Top Five Disparate CoPs for HHAs
64 Percent of all Disparate Surveys**

Hospice

TJC (FY 2016 Hospice 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 40: TJC
Hospice Disparity Rate
FY 2016**

CoPs	Facilities with CoP	Matching Surveys	Disparate Surveys	Disparity Rate
Quality Assessment & Performance Improvement	2	1	1	8%
Volunteers	2	1	1	8%
Infection Control	1	0	1	8%
Patient Rights	1	0	1	8%
Organizational Environment	1	0	1	8%

**Appendix B Table 41: TJC
Disparate CoPs for Hospice
83 Percent of all Disparate Surveys**

Critical Access Hospital

TJC (FY 2016 CAH Surveys)	All CoPs	PE	Health & Safety
Number of 60-Day Validation Surveys	30	30	30
Number of Surveys with Conditions Missed by AO	12	10	7
Disparity Rate	40.00%	33.33%	23.33%

**Appendix B Table 42: TJC
CAH Disparity Rate
FY 2016**

CoPs	Facilities with CoPs	Matching Surveys	Disparate Surveys	Disparity Rate
Physical Plant and Environment	20	10	10	33%
Surgical Services	5	2	3	10%
Provision of Services	5	2	3	10%
Organization Structure	2	0	2	7%
Periodic Evaluation and QA Review	2	0	2	7%

**Appendix B Table 43: TJC
Top Five Disparate CoPs for CAHs
91 Percent of all Disparate Surveys**

Category	Total Cited by SA	Missed by AO	Disparity Rate
Fire/Smoke Barrier	35	15	8%
Hazardous Areas	20	12	6%
Doors	18	11	6%
Construction	8	7	4%
Fire Plan	9	7	4%
Sprinkler	22	6	3%
HVAC	11	4	2%
Emergency Lighting	6	3	2%
Fire Extinguisher	6	3	2%
Means of Egress	19	3	2%

**Appendix B Table 44: TJC
Missed LSC Citations for CAHs
89 Percent of all Missed Citations**

Program Types

Hospital

ALL AOs (FY 2016 Hospital and LTCH Surveys)	All CoPs	PE	Health & Safety
Number of 60-Day Validation Surveys	98	98	98
Number of Surveys with Conditions Missed by AO	45	29	24
Disparity Rate	45.92%	29.59%	24.49%

Appendix B Table 45: Hospital Disparities FY 2016

CoPs	Facilities with CoPs	Matching Surveys	Disparate Surveys	Disparity Rate
Physical Environment	56	27	29	30%
Infection Control	22	6	16	16%
Governing Body	18	6	12	12%
QAPI	9	2	7	7%
Nursing Services	8	2	6	6%

**Appendix B Table 46: Top Five Disparate CoPs for Hospitals
73 Percent of all Disparate Surveys**

Category	Total Cited by SA	Missed by AO	Disparity Rate
Fire/Smoke Barrier	91	62	10%
Sprinkler	94	54	9%
Electrical	54	44	7%
Hazardous Areas	50	35	6%
Doors	47	20	3%
Means of Egress	69	20	3%
Emergency Lighting	15	17	3%
Flammable & Combustible Storage	17	14	2%
Fire Plan	14	11	2%
Fire Drill	16	11	2%

**Appendix B Table 47: Top 10 Missed LSC Citations for Hospitals
87 Percent of all Missed Citations**

Psychiatric Hospital

ALL AOs (FY 2016 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	12	4	10
Disparity Rate	57.14%	19.05%	47.62%

Appendix B Table 48: Psychiatric Hospital Disparities FY 2016

CoPs	Facilities with CoPs	Matching Surveys	Disparate Surveys	Disparity Rate
Special Medical Record Reqs for Psych Hospitals	13	6	7	33%
Physical Environment	8	4	4	19%
Special Staff Reqs for Psych Hospitals	8	4	4	19%
Patient Rights	2	1	1	5%
Nursing Services	2	1	1	5%

**Appendix B Table 49: Top Five Disparate CoPs for Psychiatric Hospitals
85 Percent of all Disparate Surveys**

Category	Total Cited by SA	Missed by AO	Disparity Rate
Fire/Smoke Barrier	16	13	19%
Hazardous Areas	9	9	13%
Means of Egress	10	6	9%
Doors	6	4	6%
HVAC	5	4	6%
Fire Plan	3	3	4%
Generator	3	3	4%
Fire Alarm	5	2	3%
Electrical	5	1	1%
EES	1	1	1%

**Appendix B Table 50: Top 10 Missed LSC Citations for Psychiatric Hospitals
98 Percent of all Missed Citations**

Ambulatory Surgery Center

ALL AOs (FY 2016 ASC Surveys)	All CoPs	PE	Health & Safety
Number of 60-Day Validation Surveys	76	76	76
Number of Surveys with Conditions Missed by AO	26	14	18
Disparity Rate	34.21%	18.42%	23.68%

Appendix B Table 51: ASC Disparities FY 2016

CoPs	Facilities with CoPs	Matching Surveys	Disparate Surveys	Disparity Rate
Environment	26	11	15	20%
Infection Control	18	5	13	17%
Governing Body and Management	17	5	12	16%
Quality Assessment & Performance Improvement	7	2	5	7%
Pharmaceutical Services	5	2	3	4%

**Appendix B Table 52: Top Five Disparate CoPs for ASCs
66 Percent of all Disparate Surveys**

Category	Total Cited by SA	Missed by AO	Disparity Rate
Fire/Smoke Barrier	31	15	12%
Sprinkler	23	15	12%
Fire Plan	5	2	2%
Anesthetizing Location	1	1	1%
Construction	1	1	1%
Doors	2	1	1%
Fire Extinguisher	2	1	1%

**Appendix B Table 53: Top 10 Missed LSC Citations for ASCs
100 Percent of all Missed Citations**

Critical Access Hospital

ALL AOs (FY 2016 CAH Surveys)	All CoPs	PE	Health & Safety
Number of 60-Day Validation Surveys	34	34	34
Number of Surveys with Conditions Missed by AO	15	13	9
Disparity Rate	44.12%	38.24%	26.47%

Appendix B Table 54: CAH Disparities FY 2016

CoPs	Facilities with CoPs	Matching Surveys	Disparate Surveys	Disparity Rate
Physical Plant and Environment	26	13	13	38%
Provision of Services	7	3	4	12%
Surgical Services	5	2	3	9%
Organization Structure	2	0	2	6%
Periodic Evaluation and QA Review	2	0	2	6%

**Appendix B Table 55: Top Five Disparate CoPs for CAHs
92 Percent of all Disparate Surveys**

Category	Total Cited by SA	Missed by AO	Disparity Rate
Hazardous Areas	28	18	7%
Fire/Smoke Barrier	42	17	7%
Medical Gas	19	8	3%
Fire Plan	9	6	2%
Construction	9	5	2%
Emergency Lighting	8	5	2%
HVAC	12	5	2%
Sprinkler	28	4	2%
Fire Drill	6	3	1%
EES	3	2	1%

**Appendix B Table 56: Top 10 Missed LSC Citations for CAHs
97 Percent of all Missed Citations**

Hospice

ALL AOs (FY 2016 Hospice Surveys)	All CoPs	Health & Safety
Number of 60-Day Validation Surveys	34	34
Number of Surveys with Conditions Missed by AO	6	6
Disparity Rate	17.65%	17.65%

Appendix B Table 57: Hospice Disparities FY 2016

CoPs	Facilities with CoP(s)	Matching Surveys	Disparate Surveys	Disparity Rate
Quality Assessment & Performance Improvement	5	2	3	9%
Organizational Environment	3	0	3	9%
IDG, Care Planning, Coordination of Services	4	2	2	6%
Volunteers	3	1	2	6%

**Appendix B Table 58: Disparate CoPs for Hospice Facilities
67 Percent of all Disparate Surveys**

Home Health Agency

ALL AOs (FY 2016 HHA Surveys)	All CoPs	Health & Safety
Number of 60-Day Validation Surveys	110	110
Number of Surveys with Conditions Missed by AO	20	20
Disparity Rate	18.18%	18.18%

Appendix B Table 59: HHA Disparities FY 2016

CoPs	Facilities with CoPs	Matching Surveys	Disparate Surveys	Disparity Rate
Acceptance of Patients, POC, Med Super	17	8	9	8%
Organization, Services & Administration	15	6	9	8%
Clinical Records	9	3	6	6%
Skilled Nursing Service	9	4	5	5%
Group of Professional Personnel	5	1	4	4%

**Appendix B Table 60: Top Five Disparate CoPs for HHAs
70 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 also to minimize disruption within the internal wiring system.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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