DEPARTMENT OF HEALTH & HUMAN SERVICES

OFFICE OF THE SECRETARY

Assistant Secretary for Legislation
Washington, DC 20201

August 21, 2025

The Honorable JD Vance
President of the Senate
Washington, DC 20510

Dear Mr. President:

I respectfully submit the enclosed report, "Fiscal Year (FY) 2022 Report to Congress: Review of Medicare's Program for Oversight of Accrediting Organizations (AOs) and the Clinical Laboratory Improvement Validation Program."

This annual report contains the Centers for Medicare & Medicaid Services' (CMS) review of the Medicare Program's oversight of AOs and the Clinical Laboratory Improvement Amendments of 1988 (CLIA) Validation Program during the prior fiscal year covering the period October 1, 2020, through September 30, 2021 (FY 2021). Section 1875(b) of the Social Security Act requires the Secretary to submit an annual report to Congress on its oversight of all CMS-approved AO accreditation programs. Section 353(e)(3) of the Public Health Service Act requires the Secretary to submit an annual report of CLIA's validation program results.

I am also sending a copy of this report to the Speaker of the House of Representatives. Please do not hesitate to contact me at 202-690-7627 if you have questions or concerns.

Sincerely,

Gary Andres
Assistant Secretary for Legislation

Enclosure

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DEPARTMENT OF HEALTH & HUMAN SERVICES

OFFICE OF THE SECRETARY

Assistant Secretary for Legislation
Washington, DC 20201

August 21, 2025

The Honorable Mike Johnson
Speaker of the House of Representatives
Washington, DC 20515

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Sincerely,

Gary Andres
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Enclosure

U.S. Department of Health and Human Services
Centers for Medicare & Medicaid Services

REPORT TO CONGRESS

Fiscal Year 2022
Review of Medicare's Program for Oversight of Accrediting Organizations and the Clinical Laboratory Improvement Validation Program

August 2025

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Review of Medicare's Program for Oversight of Accrediting Organizations

Introduction

Per the statute, 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. Section 1875 of the Act requires the Secretary to provide an annual report on its oversight of all CMS-approved AO accreditation programs. Each year's annual report provides a data analysis for the prior fiscal year. This report addresses AO activity in fiscal year (FY) 2021 (October 1, 2020 – September 30, 2021), only as it relates to CMS- approved Medicare accreditation programs.

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

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

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

[3] CoPs apply to providers; CfCs apply to suppliers; 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 conditions 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 is referred to as having deemed status.[5]

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

Currently, CMS has approved accreditation programs under 42 CFR Part 488 for the following facility types: hospitals, psychiatric hospitals, critical access hospitals (CAHs), home health agencies (HHAs), hospices, ambulatory surgery centers (ASCs), outpatient physical therapy and speech-language pathology services (OPTs), rural health clinics (RHCs), and End-Stage Renal Disease (ESRD) facilities.[6] CMS maintains a comprehensive AO Medicare accreditation oversight program and continually strives to strengthen and enhance its ongoing oversight. The program includes:

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

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

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

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

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

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

[6] 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 non-listed facility types. CMS also accredits suppliers of Durable Medical Equipment, Prosthetics, Orthotics and Supplies and the technical component of Advanced Diagnostic Imaging under other accreditation statutes.

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

Validation redesign program (VRP) pilot – CMS has developed a pilot that utilizes the SAs in an observational capacity to observe and evaluate the ability of the AO surveyors to survey for compliance with CMS regulations rather than conducting a second survey of the facility. The VRP pilot was placed on hold in August 2019 to make enhancements based on lessons learned. The VRP pilot resumed in FY 2024. After completion of the surveys and analysis of the findings, future reports will discuss outcomes.

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

During FY 2021, in response to the COVID-19 Public Health Emergency (PHE), CMS limited health care facility and clinical laboratory survey activity to allow focus on the most serious health and safety threats. As a result, non-emergency surveys (i.e., validation surveys) were suspended. This report reviews AO validation survey activity prior to this suspension and SA complaint survey activities in FYs 2019, 2020, and 2021, compares this activity to past years, discusses the impact of suspended and prioritized surveys, and outlines the current CMS oversight of approved Medicare accreditation programs in the following sections:

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

Section 2 – Scope of Accrediting Organization Medicare Accreditation Programs
The current number of deemed status and non-deemed Medicare-certified facilities by program type; the growth in deemed status facilities within the Medicare program since FY 2008; the effect of COVID-19 as it relates to FY 2021 deemed status facilities; and the overall Medicare accreditation survey activities of each AO in FY 2021, including the number of initial and renewal accreditation surveys performed, the number of facilities denied, and the number of voluntary withdrawals.

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; FY 2020 (ending July 1, 2020) and FY 2021 AO performance measure changes.

Section 4 – Validation of Accrediting Organization Surveys
This section includes 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 highlights the

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

impact of the COVID-19 public health emergency (PHE) in relation to the decreased representative validation survey sample size and disparity rates in FY 2020, for which data is only available from October 1, 2019, to March 4, 2020, and continued suspension of validation surveys throughout FY 2021. Further, we describe the comparative analysis process conducted for the 60-day validation surveys to assess the ability of each AO Program to evaluate and ensure compliance with the applicable Medicare conditions. The validation performance results for FYs 2019–2020 are presented by facility type for each AO. The FY 2019 and FY 2020 (ending March 4, 2020) 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) during that same time.

PLEASE NOTE for Section 4:

Validation surveys for psychiatric hospitals were significantly impacted by the PHE, with only five surveys performed in FY 2020 before the suspension beginning March 4, 2020, representing one percent of the total number of deemed psychiatric hospitals and only five percent of the total number of psychiatric hospital surveys conducted by the single Psychiatric Hospital AO program during this reporting period (there are now two CMS-approved Psychiatric Hospital AO programs). As a result, the small validation sample used to determine the disparity rate from October 1, 2019, to March 4, 2020, increased the margin of error in the calculation, thus affecting the potential usefulness of this number and the extent to which it accurately represents the effectiveness of an AO's survey activities.

Additionally, we found that the disparities cited were less likely to be related to major patient safety deficiencies, such as infection prevention and control and medical staff requirements and were more likely to be centered around documentation and communication deficiencies, such as those in the medical records and patient's rights requirements.

In the small validation sample of psychiatric hospital surveys described and occurring in this report from October 1, 2019, to March 4, 2020, examples of documentation and communication requirement deficiencies where disparities were cited for the AO include:

- The Special Medical Record Requirements for Psychiatric Hospitals, which were cited six times by SAs (and missed three of those times by the AO) for facilities that failed to ensure staff adequately documented various details and elements related to some patient master treatment plans; and
- The Patient's Rights requirements, which were cited five times by SAs (and missed three of those times by the AO) for facilities that failed to ensure all patients were—
    - Provided the Important Message from Medicare notice;
    - Provided written notice that a doctor of medicine or osteopathy was not present in the facility or on-call for the facility, 24 hours per day, seven days per week;
    - Informed of their rights in advance of the hospital discontinuing patient care; and
    - Provided written notice of grievance decisions, including name of the hospital contact person, steps taken on behalf of the patient to investigate the grievance, grievance decision, and completion date.

Section 5 – Life Safety Code, Health & Safety Disparity Rates Analysis and Complaint Survey

Citations
The most frequently disparate 60-day validation survey condition-level deficiencies, the top five disparate 60-day validation survey Life Safety Code (LSC) categories and disparity rates by program type; the top five complaint survey condition-level deficiencies by program type; the impact of the COVID-19 PHE; the limitations surrounding the disparity rates; and conclusion 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 2021.

Section 7 – Clinical Laboratory Improvement Amendments Validation Program
Clinical Laboratory Improvement Amendments of 1988 (CLIA) includes statutory requirements for deeming by AOs, for conducting AO validation reviews, and the impact from COVID-19 on both.

Appendix A – Fiscal Years 2019-2020 State Agency and Accrediting Organization Comparison of Condition-Level Deficiency Findings

Appendix B – Fiscal Years 2019-2020 Top Five Missed LSC Categories by Program Type

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. 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's 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 the Secretary 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 the date of 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 approved for 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 may be 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. Applications submitted to CMS during the COVID-19 PHE resulted in reduced terms of approvals for 4 years or shorter.

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's administrative requirements that facilitate ongoing oversight of the AO's CMS-approved accreditation program(s). CMS's evaluation process includes, but is not limited to, the following components:

- Onsite survey observations are conducted to ensure that the accreditation program is fully implemented and operational as described in the written application.

- Inspection of the AO's operations to verify and assess compliance with its own policies and procedures; review of survey reports and complaint files; reviews of the accreditation process and the accreditation decision-making process, and interviews with the organization's staff.

- 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 information, 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: CMS Review of AO Medicare Accreditation Programs
FYs 2011–2021

Type of Review and CMS Decision	FY 2011	FY 2012	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017	FY 2018	FY 2019	FY 2020	FY 2021
Initial Applications											
Decision: Full approval	3	1	1	1	0	1	0	2	0	1	0
Decision: Denied	0	0	0	0	0	0	0	0	0	0	0
Incomplete application	0	2	0	0	1	1	0	1	3	0	0
Application withdrawn	1	1	1	0	0	0	0	0	0	1	0
Renewal Applications											
Decision: Full approval	0	3	6	4	6	1	5	8	1	6	3
Decision: Denied	0	0	0	0	0	0	0	0	0	0	0
Decision: Conditional approval	0	0	0	0	0	0	0	0	0	0	0
Decision: Final approval removing conditional status	0	0	0	0	0	0	0	0	0	0	0
Total Reviews of Initial and Renewal Applications	**4**	**7**	**8**	**5**	**7**	**3**	**5**	**11**	**4**	**8**	**3**
Focused Reviews											
Standards review*	18	20	3	25	12	23	78	32	16	27	29
Survey process review	10	5	0	1	5	5	18	3	18	18	29
Issue review and resolution	44	22	41	11	3	16	9	2	1	0	4
Performance review	3	3	0	4	3	1	2	1	0	0	0
Total Focused Reviews	**75**	**50**	**44**	**41**	**23**	**45**	**107**	**38**	**35**	**45**	**62**

* In FY 2020, CMS's increase in focused standard reviews was due to additional regulatory changes (e.g., Program Efficiency, Transparency, and Burden Reduction Final Rule; Requirements for Discharge Planning for Hospitals Final Rule).

From FY 2011 through FY 2021, CMS completed 65 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 565 focused reviews. In total, 630 comprehensive reviews were completed.

Approved Accrediting Organization Medicare Accreditation Programs

CMS reviews and approves separately, each provider or supplier Medicare accreditation program for which an AO seeks CMS approval. AOs currently have CMS approval for nine provider or supplier program types: hospital, psychiatric hospital, CAH, HHA, hospice, ASC, OPT, RHC and ESRD facilities. As of September 30, 2021, there were nine national AOs with 24 approved Medicare accreditation programs. (See Tables 2 and 3.)

Table 2: AOs with Approved Medicare Accreditation Programs FY 2021

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
CHAP	Community Health Accreditation Partner
CIHQ	Center for Improvement in Healthcare Quality
DNV	DNV Healthcare USA Inc.
NDAC	National Dialysis Accreditation Commission
TCT	The Compliance Team
TJC	The Joint Commission

*On September 24, 2020, AAHHS/HFAP underwent a change in ownership (CHOW). CMS approved ACHC's request to transfer the existing CMS approval for AAHHS/HFAP's CAH, ASC and acute care hospital accreditation programs to ACHC. AAHHS/HFAP's program types and their existing CMS terms of approval are outlined in the Approval of Medicare Accreditation Programs subsection.

Table 3: Approved Medicare Accreditation Programs by AO FY 2021

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

The number of CMS-approved Medicare accreditation programs has grown steadily over the past several years resulting in 24 approved programs in FY 2021.

Approval of Medicare Accreditation Programs as of September 30, 2021

American Association for Accreditation of Ambulatory Surgery Facilities, Inc.

Ambulatory Surgery Center

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

Outpatient Physical Therapy and Speech-Language Pathology Services

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

Rural Health Clinic

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

Note: In FY 2022, AAAASF rebranded and is now doing business as (DBA) QUAD A.

Accreditation Association for Ambulatory Health Care, Inc.

Ambulatory Surgery Center

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

Accreditation Commission for Health Care (ACHC)

Hospital

AAHHS/HFAP has had an approved hospital Medicare accreditation program since February 22, 2000. In late 2020, AAHHS/HFAP merged with the Accreditation Commission for Health Care (ACHC). ACHC's current term of approval is effective September 25, 2019, through September 25, 2023. The final notice announcing this decision was published in the *Federal Register* (84 FR 9799) (March 18, 2019), and can be accessed at https://www.govinfo.gov/content/pkg/FR-

2019-03-18/pdf/2019-05037.pdf.

End Stage Renal Disease

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

Home Health Agency

ACHC's HHA Medicare accreditation program was initially approved February 24, 2006. ACHC's current term of approval is effective February 24, 2021, through February 24, 2025. The final notice announcing this decision was published in the *Federal Register* (86 FR 12005) (March 1, 2021), and can be accessed at https://www.govinfo.gov/content/pkg/FR-2021-03-01/pdf/2021-04169.pdf.

Hospice

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

Critical Access Hospital

AAHHS/HFAP's CAH Medicare accreditation program was initially approved December 27, 2001. In late 2020, AAHHS/HFAP merged with the Accreditation Commission for Health Care (ACHC). ACHC's current term of approval is effective December 27, 2019, through December 27, 2025. The final notice announcing this decision was published in the *Federal Register* (84 FR 70975) (December 26, 2019), and can be accessed at https://www.govinfo.gov/content/pkg/FR-2019-12-26/pdf/2019-27836.pdf.

Ambulatory Surgery Center

AAHHS/HFAP's ASC Medicare accreditation program was initially approved January 30, 2003. In late 2020, AAHHS/HFAP merged with the Accreditation Commission for Health Care (ACHC).ACHC's current term of approval is effective September 22, 2017, through September 22, 2023. The final notice announcing this approval was published in the *Federal Register* (82 FR 44414) (September 22, 2017), and can be accessed at https://www.govinfo.gov/content/pkg/FR-2017-09-22/pdf/2017-20281.pdf.

Community Health Accreditation Partner

Home Health Agency

CHAP's HHA Medicare accreditation program was initially approved August 27, 1992. CHAP's current term of approval is effective March 31, 2018, through March 31, 2024. The

final notice announcing this decision was published in the *Federal Register* (83 FR 12769) (March 23, 2018), and can be accessed at https://www.govinfo.gov/content/pkg/FR-2018-03-23/pdf/2018-05891.pdf.

Hospice

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

Center for Improvement in Healthcare Quality

Hospital

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

DNV-Healthcare

Hospital

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

Critical Access Hospital

DNV's CAH Medicare accreditation program was initially approved December 23, 2010. DNV's current term of approval is effective December 23, 2020, through December 23, 2024. The final notice announcing this decision was published in the *Federal Register* (85 FR 65812) (October 16, 2020), and can be accessed at https://www.govinfo.gov/content/pkg/FR-2020-10-16/pdf/2020-22883.pdf.

Psychiatric Hospital

DNV's psychiatric hospital Medicare accreditation program was initially approved July 30, 2020. DNV's current term of approval is effective through July 30, 2024. The final notice announcing this decision was published in the Federal Register (85 FR 45639) (July 29, 2020), and can be accessed at 2020-16453.pdf (govinfo.gov).

National Dialysis Accreditation Commission

End Stage Renal Disease

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

The Compliance Team

Rural Health Clinics

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

The Joint Commission

Hospital

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

Psychiatric Hospital

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

Critical Access Hospital

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

Home Health Agency

TJC's HHA Medicare accreditation program was initially approved September 28, 1993. TJC's current term of approval is effective March 31, 2020, through March 31, 2026. The final notice

announcing this decision was published in the *Federal Register* (85 FR 18245) (April 1, 2020), and can be accessed at https://www.govinfo.gov/content/pkg/FR-2020-04-01/pdf/2020-06792.pdf.

Hospice

TJC's hospice Medicare accreditation program was initially approved June 18, 1999. TJC's current term of approval is effective June 18, 2021, through June 18, 2025. The final notice announcing this decision was published in the *Federal Register* (86 FR 16373) (March 29, 2021), and can be accessed at https://www.govinfo.gov/content/pkg/FR-2021-03-29/pdf/2021-06413.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, 2020, through December 20, 2024. The final notice announcing this decision was published in the *Federal Register* (85 FR 66989) (October 21, 2020), and can be accessed at https://www.govinfo.gov/content/pkg/FR-2020-10-21/pdf/2020-23230.pdf.

SECTION 2: Scope of Accrediting Organization Medicare Accreditation Programs

Medicare-Participating Facilities by Program Type:

In FY 2021, AOs were responsible for ensuring compliance with Medicare conditions for 34 percent (15,143) of all Medicare-participating facilities in the nine program types for which there was a CMS-approved AO Medicare accreditation program. (See Table 4 and Graph 1.)

Table 4: Deemed & Non-Deemed Medicare-Participating Facilities and Program Types with a Medicare Accreditation Program Option FY 2021

Program Type	Deemed* (percentage)	Non-Deemed** (percentage)	Total***
Hospital	3,503 (82)	769 (18)	4,272
Psychiatric Hospital	545 (87)	84 (13)	629
CAH	446 (33)	914 (67)	1,360
HHA	4,172 (36)	7,334 (64)	11,506
Hospice	3,112 (51)	3,002 (49)	6,114
ASC	1,692 (28)	4,396 (72)	6,088
ESRD****	386 (5)	7,473 (95)	7,859
OPT	269 (14)	1,712 (86)	1,981
RHC	1,018 (20)	4,148 (80)	5,166
Total	15,143 (34)	29,832 (66)	44,975

Note: The total number of deemed facilities represents the number of deemed surveys performed. The term "facilities" include clinics, rehabilitation agencies, and public health agencies as providers of outpatient physical therapy and speech language pathology services, referred to as OPTs.

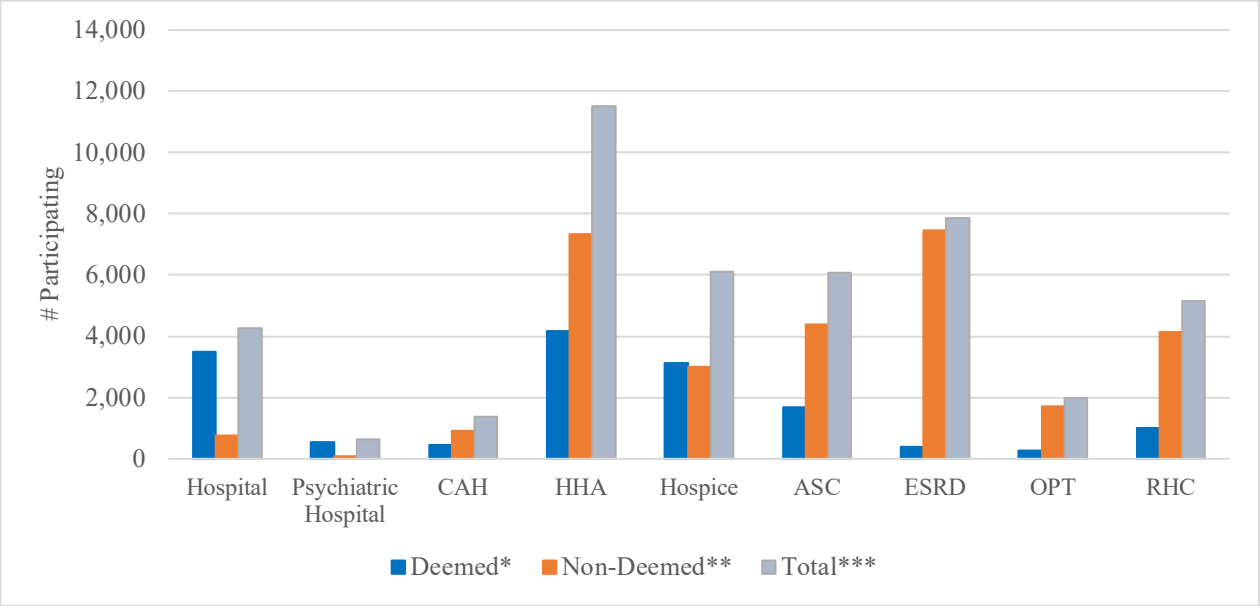
*Providers that are deemed and surveyed by AOs for compliance with Medicare conditions. Data reported by AOs.

** Providers that are certified and surveyed by a SA for compliance with Medicare conditions.

***As reported in the Quality Improvement Evaluation System (QIES)/Certification and Survey Provider Enhanced Reports (CASPER) and QIES/Accrediting Organization System for Storing User Recorded Experiences (ASSURE) 9/29/2022.

****Historically, section 1865(a)(1) of the Act previously excluded dialysis facilities from participating in Medicare via a CMS-approved accreditation program; however, section 50403 of the Bipartisan Budget Act of 2018 (Pub. L. No. 115-123, § 50403, 132 Stat. 64, (2018)) amended the Act to include accreditation of renal dialysis facilities.

Graph 1: Deemed & Non-Deemed Medicare-Participating Facilities and Program Types with a Medicare Accreditation Program Option FY 2021



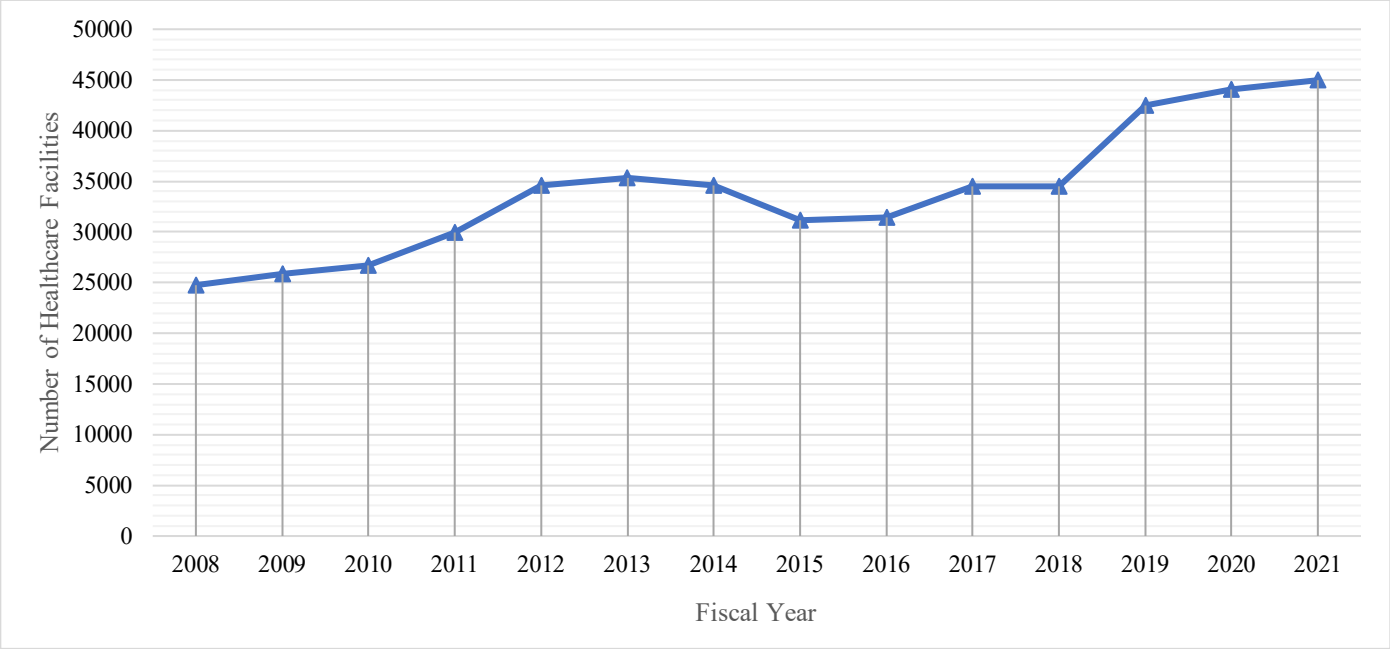
*As reported by AOs.
**Surveyed by an SA for compliance with Medicare conditions.
***As reported in QIES/CASPER and QIES/ASSURE 9/29/2022.

In FY 2021, the AOs with CMS-approved Medicare accreditation programs were responsible for monitoring compliance with health and safety standards for varying percentages of the total number of Medicare-participating facilities for each program type. This percentage ranges from a high of 82 percent for hospitals to a low of 5 percent for ESRD facilities.

Growth in Medicare Deemed Facilities

The total number of Medicare-participating health care facilities (among those that have the option of being certified via a CMS-approved accreditation program) has increased 6 percent from 42,459 in FY 2019 to 44,975 in FY 2021. (See Graph 2.) The number of deemed health care facilities participating via a Medicare accreditation program option increased 11 percent, from 13,608 in FY 2019 to 15,143 in FY 2021.

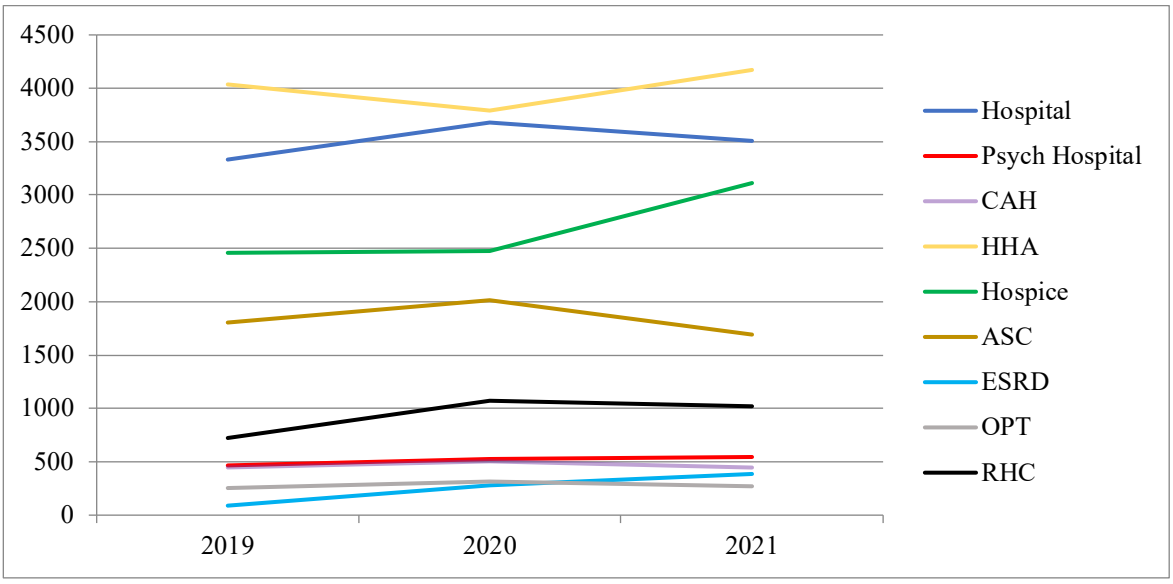
Graph 2: Medicare-Participating Health Care Facilities FYs 2008–2021



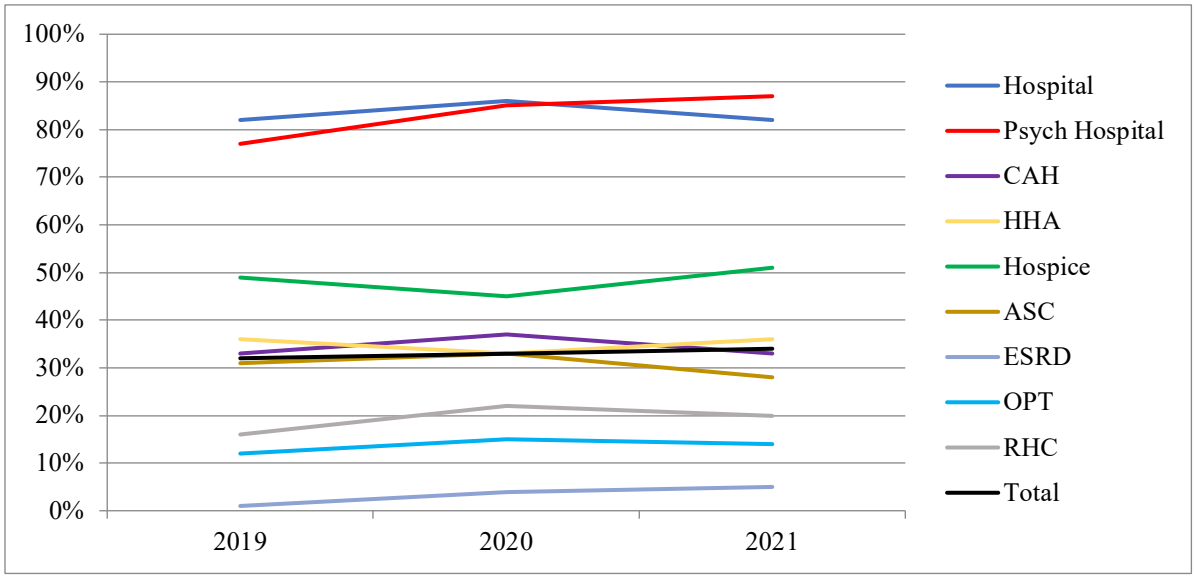
The growth in the number of deemed facilities is likely attributable, in part, to CMS's workload priorities for SAs. The long-standing CMS policy for SAs has been that initial surveys for newly enrolling facilities with an approved accreditation option have a lower priority as compared to: statutorily 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 from FY 2019 through FY 2021 by CMS by virtue of a CMS-approved Medicare accreditation program, and the percentage of all Medicare-certified facilities that these deemed facilities represent. These graphs represent the nine program types for which there is currently more than 1 year of data.

Graph 3: Number of Deemed Facilities by Program Type FYs 2019–2021



Graph 4: Deemed Facilities as Percentage of Medicare-Participating Facilities by Program Type FYs 2019-2021



While the total number of deemed facilities increased from FY 2020 through FY 2021, five of the nine program types experienced decreases in their number of deemed facilities. These decreases can be attributed to voluntary withdrawals by the facilities and the COVID-19 PHE. During this time, the AO's ability to conduct onsite surveys was impacted by CMS's suspension of non-emergency surveys and limitations related to location-specific COVID-19 restrictions, resulting in a number of delayed surveys. These overdue surveys were tracked and reported to CMS as backlogged surveys by the AOs. The AOs reported their backlogged surveys to CMS monthly according to the following survey types: initial, initial virtual, reaccreditation, complaint, follow-up, and extension. The data for accredited facilities, including the number of withdrawals and the total number of backlogged surveys, is discussed in detail below by program type.

- **Total:** From FY 2019 to FY 2021, the total number of Medicare-participating facilities (among those with an accreditation option) increased from 42,459 to 44,975, a 6 percent increase. During that same time, the growth in the number of facilities accredited by a CMS-approved Medicare accreditation program increased from 13,608 to 15,143, an 11 percent increase.
  - From FY 2019 to FY 2020, the number of facilities participating in Medicare via deemed status increased from 13,608 to 14,651, an 8 percent increase.
  - From FY 2020 to FY 2021, the number of facilities participating in Medicare via deemed status increased from 14,651 to 15,143, a 3 percent increase.
  - By the end of FY 2021, there were 1,426 backlogged surveys reported by the AOs.
  - In FY 2021, the AOs reported 904 withdrawals. (See Table 5.)
  - While the SAs continue to survey and monitor the majority of Medicare-participating facilities, in FY 2021, 15,143 (34 percent) facilities participated in Medicare via their accreditation from a CMS-approved Medicare accreditation program.
- **Hospital:** The hospital, psychiatric hospital, and hospice programs are the only categories of providers in which the majority of facilities participate in Medicare by virtue of accreditation under an approved Medicare accreditation program. The number of Medicare-certified hospitals increased from 4,072 in FY 2019 to 4,272 in FY 2021, a 5 percent increase.
  - From FY 2019 to FY 2020, the number of deemed hospitals increased from 3,332 to 3,679, an increase of 10 percent.
  - From FY 2020 to FY 2021, the number of deemed hospitals decreased slightly from 3,679 to 3,503, a 5 percent decrease.
  - By the end of FY 2021, there were 602 backlogged surveys reported by the AOs.
  - In FY 2021, the AOs reported 69 withdrawals. (See Table 5.)
  - The proportion of all Medicare-participating hospitals that were deemed in FY 2019 and FY 2021 was 82 percent.
- **Psychiatric Hospital:** The number of Medicare-certified psychiatric hospitals increased slightly from 609 in FY 2019 to 629 in FY 2021, a 3 percent increase.
  - From FY 2019 to FY 2020, the number of deemed psychiatric hospitals increased from 466 to 524, a 12 percent increase.
  - From FY 2020 to FY 2021, the number of deemed psychiatric hospitals increased from 524 to 545, a 4 percent increase.

- By the end of FY 2021, there were 55 backlogged surveys reported by TJC.
- In FY 2021, TJC reported nine withdrawals. (See Table 5.)
- The proportion of all Medicare-participating psychiatric hospitals that were deemed increased from 77 percent in FY 2019 to 87 percent in FY 2021.

- **CAH:** The number of Medicare-certified CAHs increased very slightly from 1,354 in FY 2019 to 1,360 in FY 2021, a less than 1 percent increase.
  - From FY 2019 to FY 2020, the number of deemed CAHs increased from 449 to 504, a 12 percent increase.
  - From FY 2020 to FY 2021, the number of deemed CAHs decreased from 504 to 446, a 12 percent decrease.
  - By the end of FY 2021, there were 81 backlogged surveys reported by the AOs.
  - In FY 2021, the AOs reported four withdrawals. (See Table 5.)
  - The proportion of all Medicare-participating CAHs that were deemed in FY 2019 and FY 2021 was 33 percent.

- **HHA:** The number of Medicare-certified HHAs increased slightly from 11,315 in FY 2019 to 11,506 in FY 2021, a 2 percent increase.
  - From FY 2019 to FY 2020, the number of deemed HHAs decreased from 4,034 to 3,791, a 6 percent decrease.
  - From FY 2020 to FY 2021, the number of deemed HHAs increased from 3,791 to 4,172, a 10 percent increase.
  - By the end of FY 2021, there were 314 backlogged surveys reported by the AOs.
  - In FY 2021, the AOs reported 376 withdrawals. (See Table 5.)
  - The proportion of all Medicare-participating HHAs that were deemed in FY 2019 and FY 2021was 36 percent.

- **Hospice:** The number of Medicare-certified hospices increased from 5,007 in FY 2019 to 6,114 in FY 2021, a 22 percent increase.
  - From FY 2019 to FY 2020, the number of deemed hospices increased very slightly from 2,458 to 2,473, a 1 percent increase.
  - From FY 2020 to FY 2021, the number of deemed hospices increased from 2,473 to 3,112, a 26 percent increase.
  - By the end of FY 2021, there were 247 backlogged surveys reported by the AOs.
  - In FY 2021, the AOs reported 212 withdrawals. (See Table 5.)
  - The proportion of all Medicare-participating hospices that were deemed increased from 49 percent in FY 2019 to 51 percent in FY 2021.
- **ASC:** The number of Medicare-certified ASCs increased from 5,841 in FY 2019 to 6,088 in FY 2021, a 4 percent increase.
  - From FY 2019 to FY 2020, the number of deemed ASCs increased from 1,803 to 2,014, a 12 percent increase.
  - From FY 2020 to FY 2021, the number of deemed ASCs decreased from 2,014 to 1,692, a 16 percent decrease.
  - By the end of FY 2021, there were 125 backlogged surveys reported by the AOs.
  - In FY 2021, the AOs reported 144 withdrawals. (See Table 5.)

- The proportion of all Medicare-participating ASCs that were deemed decreased from 31 percent in FY 2019 to 28 percent in FY 2021.

- **OPT:** The number of Medicare-certified OPTs decreased from 2,056 in FY 2019 to 1,981 in FY 2021, a 4 percent decrease. Note, for the purposes of this report, CMS includes clinics, rehabilitation agencies, and public health agencies as providers of outpatient physical therapy and speech language pathology services, referred to as OPTs, in the term "facilities."
  - From FY 2019 to FY 2020, the number of deemed OPTs increased from 254 to 315, a 24 percent increase.
  - From FY 2020 to FY 2021, the number of deemed OPTs decreased from 315 to 269, a 15 percent decrease.
  - By the end of FY 2021, there were zero backlogged surveys reported by AAAASF.
  - In FY 2021, there were 20 withdrawals reported by AAAASF. (See Table 5.)
  - The proportion of all Medicare-participating OPTs that were deemed increased from 12 percent in FY 2019 to 14 percent in FY 2021.

- **RHC:** The number of Medicare-certified RHCs increased from 4,538 in FY 2019 to 5,166 in FY 2021, a 14 percent increase.
  - From FY 2019 to FY 2020, the number of deemed RHCs increased from 723 to 1,072, a 48 percent increase.
  - From FY 2020 to FY 2021, the number of deemed RHCs decreased from 1,072 to 1,018, a 5 percent decrease.
  - By the end of FY 2021, there were zero backlogged surveys reported by the AOs.
  - In FY 2021, the AOs reported 69 withdrawals. (See Table 5.)
  - The proportion of all Medicare-participating RHCs that were deemed increased from 16 percent in FY 2019 to 20 percent in FY 2021.

- **ESRD:** The number of Medicare-certified ESRD facilities increased slightly from 7,667 in FY 2019 to 7,859 in FY 2021, a 3 percent increase.
  - From FY 2019 to FY 2020, the number of deemed ESRD facilities increased from 89 to 279, a 213 percent increase. This large percentage increase is due to the relatively recent availability of an accreditation option for ESRD facilities. CMS approved the first Medicare ESRD accreditation program in January 2019; therefore, there was a low number of deemed ESRD facilities in FY 2019.
  - From FY 2020 to FY 2021, the number of deemed ESRD facilities increased from 279 to 386, a 38 percent increase.
  - By the end of FY 2021, there were 2 backlogged surveys reported by the AOs.
  - In FY 2021, there was one withdrawal reported. (See Table 5.)
  - The proportion of all Medicare-participating ESRD facilities that were deemed increased from 1 percent in FY 2019 to 5 percent in FY 2021.

Medicare Accreditation Program Survey Activity

An AO with a CMS-approved 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 CoPs or CfCs. The evaluation

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

In addition, facilities seeking initial deemed status with an AO must be found to be in compliance with *all* conditions through the on-site survey activity. "Condition-level" deficiencies are the most serious type of deficiency cited, indicating a provider or supplier is not in compliance with an entire CoP or CfC. A "standard-level" deficiency means that the provider or supplier may be out of compliance with one aspect of a CoP or CfC 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 "plan of correction" (POC) and subsequently 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 Locations include Survey & Operations Group (SOG) Location staff who 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, CMS Locations have 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 ensure the health and safety of patients receiving care in Medicare facilities.

In FY 2021, the AOs reported having performed 2,822 initial surveys and 4,334 renewal surveys. The total number of deemed-status facilities including dually accredited facilities in FY 2021 was 15,181. The total number of facilities denied was 295. The number of voluntary withdrawals was 904. (See Table 5.)

Table 5: Total Number of Deemed Facilities/Initial Surveys and Renewal Surveys/Denials and Withdrawals by AO Accreditation Program FY 2021

Program Type/AOs	Total Deemed Facilities	Initial Surveys	Renewal Surveys	Denials	Withdraws
Hospital					
ACHC**	80	2	36	0	3
CIHQ	115	14	54	4	2
DNV	392	42	125	13	5
TJC	2,922	35	878	4	59
Hospital Total	**3,509**	**93**	**1,093**	**21**	**69**
Psychiatric Hospital					
TJC	545	20	168	3	9
Psychiatric Hospital Total	**545**	**20**	**168**	**3**	**9**
CAH					
ACHC**	20	1	11	0	0
DNV	125	14	50	6	1
TJC	302	4	96	1	3
CAH Total	**447**	**19**	**157**	**7**	**4**
HHA					
ACHC	1,401	431	308	39	70
CHAP	1,252	203	453	21	204
TJC	1,531	138	482	21	102
HHA Total	**4,184**	**772**	**1,243**	**81**	**376**
Hospice					
ACHC	1,109	554	174	43	31
CHAP	854	236	246	14	93
TJC	1,166	170	297	15	88
Hospice Total	**3,129**	**960**	**717**	**72**	**212**
ASC					
AAAASF	169	45	76	10	16
AAAHC	858	196	242	59	73
ACHC**	48	23	10	1	4
TJC	618	83	197	5	51
ASC Total	**1,693**	**347**	**525**	**75**	**144**
ESRD*					
ACHC	31	18	0	1	0
NDAC	355	142	0	9	1
ESRD Total	**386**	**160**	**0**	**10**	**1**

Program Type/AOs	Total Deemed Facilities	Initial Surveys	Renewal Surveys	Denials	Withdraws
OPT					
AAAASF	269	66	123	1	20
OPT Total	**269**	**66**	**123**	**1**	**20**
RHC					
AAAASF	258	58	117	3	28
TCT	761	327	191	22	41
RHC Total	**1,019**	**385**	**308**	**25**	**69**
Total	15,181	2,822	4,334	295	904

Source: As reported by the AOs.
*The NDAC and ACHC ESRD accreditation programs received initial approval in FY 2019. Therefore, no renewal surveys were due to be conducted.
**Prior to the change in ownership, ACHC's hospital, CAH, and ASC programs were AAHHS/HFAP accredited programs.
Note: The total number of deemed facilities represents the number of deemed surveys performed. The total number of deemed facilities in this table includes 38 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's 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 to enable CMS to take appropriate follow-up enforcement action. It was also essential for CMS to have information concerning planned AO survey schedules to effectively implement the validation program once re-instituted following the COVID-19 PHE suspension. To this end, AOs are required to submit the following to CMS:

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

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

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

- Information on the essential elements that should be included in an AO facility notification letter regarding a facility's Medicare accreditation status, which facilitates AO communication with CMS;
- Dedicated Central Office (CO) and CMS Location 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's national Medicare certification database.

Accrediting Organization Performance Measures and Scoring

In FY 2009, CMS instituted performance measures for AOs. 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. Annual scores are the average of all four quarterly scores. Measures are scored as a percentage of correct submissions for a specific month/quarter.

Prior to the COVID-19 PHE, the performance measures were reviewed and updated annually.

Significant Changes for Fiscal Years 2020 and 2021 Accrediting Organization Performance Measures

Retired Fiscal Year 2020 Performance Measures

Performance measures are retired when CMS observes consistently high scoring by the AOs. In FY 2020, CMS retired five of the FY 2019 performance measures in three key performance focus areas based on quarterly average scores for each of the AOs from FYs 2017-2019.

ASSURE Database:
AOs use the ASSURE electronic database to record all AO Medicare accreditation program activity, including enforcement activity, and to submit a quarterly export file of this ASSURE data to CMS. Performance in this area was based on:

- The facilities with condition-level findings denied on initial surveys* – From FYs 2017 – 2019, the AOs' quarterly averages ranged from 95 percent to 99 percent.
- The timeliness of notifying facilities of survey results – From FYs 2017 – 2019, the AOs' quarterly averages ranged from 94 percent to 97 percent.

Facility Notification Letters:
AOs should electronically submit facility notification letters to CMS for all Medicare accreditation program actions in CMS-approved programs. Performance in this area was based on:

- The notification letters contain all required information – From FYs 2017 – 2019, the AOs' quarterly averages ranged from 92 percent to 97 percent.
- The data in ASSURE is being updated consistent with the letters – From FYs 2017 – 2019, the AOs' quarterly averages ranged from 85 percent to 91 percent.

Survey Schedule:
AOs should submit a monthly schedule which documents surveys completed in the past month as well as scheduled surveys for the current and next 2 months. Performance in this area is based on:

- The accuracy of the data in ASSURE regarding the number of surveys reported as completed for the quarter and the number of surveys actually completed each quarter** - From FYs 2017 – 2019, the AOs' quarterly averages ranged from 95 percent to 99 percent.

*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.
**The survey schedule measure quarterly score is calculated based on monthly scores.

On July 1, 2020, based on the average scores for three quarters, CMS retired the only remaining reportable performance measure "CMS notified timely of withdrawals" from the ASSURE Database key performance focus area.

In FY 2020, CMS recognized that the measures were administrative in nature and did not assess the performance of the AOs' evaluation of regulatory compliance through survey activities. In FY 2021, no performance measures were implemented due to the PHE. CMS is in the process of revising the methodology to capture AO performance as part of CMS' CMS's continued assessment and oversight of the AOs.

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 as 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, deemed status facilities may be subject to validation surveys authorized by CMS and generally conducted by a SA.

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

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

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

Note: On March 4, 2020, CMS suspended all non-emergency surveys including the validation surveys of facilities participating in Medicare via accreditation, allowing surveyors to focus on potentially emergent concerns related to the COVID-19 PHE.[8]

This section discusses the methodology for and results of CMS validation of the AOs' Medicare accreditation programs, based only upon analysis of the 60-day representative sample validation surveys. These validation surveys were completed before March 4, 2020. Therefore, FY 2020 validation survey findings refer to data from October 1, 2019, to March 4, 2020, throughout this section. No validation surveys were conducted in FY 2021 due to the COVID-19 PHE.

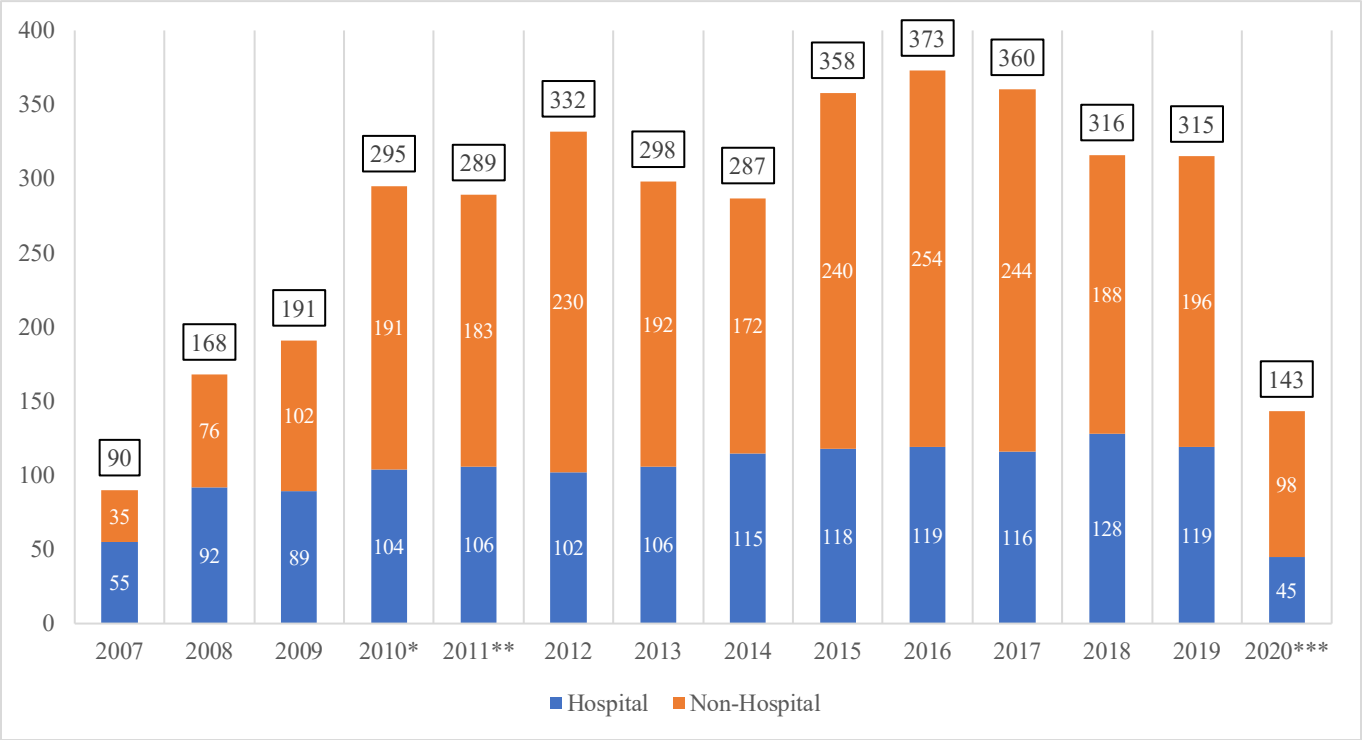
In 1972, Section 1875 of the Act was amended to require the Health Care Finance Administration (HCFA) (now CMS) to validate TJC survey process for hospitals and report the results to Congress annually.[9] In FY 2007, CMS began conducting 60-day validation surveys for selected non-hospital facility types (CAHs, HHAs, and ASCs), in addition to those already being performed for deemed status hospitals. In FY 2010, hospice 60-day validation surveys were added, and in FY 2011, psychiatric hospital 60-day validation surveys were added. In FY 2020, OPT and RHC 60-day validation surveys were added. In FY 2020, CMS conducted a total of

[8] QSO-20-12-All - Suspension of Survey Activities, March 4, 2020

[9] Section 125(b)(4) of P.L. 110-275 (2008) revised this provision to apply to all AOs.

143 representative sample 60-day validation surveys for 8 facility types across AOs.[10] This total comprised 45 hospital surveys (including 5 psychiatric hospitals) and 98 non-hospital validation surveys. In FY 2021, CMS did not conduct 60-day validation surveys due to the COVID-19 PHE. (See Graph 5.)

Graph 5: Number of Representative Sample Validation Surveys for Both Hospital and Non-Hospital Facilities FYs 2007-2020



*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.
***Validation surveys completed October 1, 2019 - March 4, 2020.

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

- 2015: 118 hospital, including 16 psychiatric hospital, and 240 non-hospital surveys totaling 358 surveys.
- 2016: 119 hospital, including 21 psychiatric hospital, and 254 non-hospital surveys totaling 373 surveys.
- 2017: 116 hospital, including 21 psychiatric hospital, and 244 non-hospital surveys totaling 360 surveys.
- 2018: 128 hospital, including 21 psychiatric hospital, and 188 non-hospital surveys totaling 316 surveys.
- 2019: 119 hospital, including 20 psychiatric hospital, and 196 non-hospital surveys totaling 315 surveys

[10] ESRD providers are not included in the validation sample.

- 2020: 45 hospital, including 5 psychiatric hospital, and 98 non-hospital surveys totaling 143 surveys.
- 2021: No validation surveys were conducted due to the COVID-19 PHE

In FY 2020, the COVID-19 PHE significantly impacted the validation survey sample size due to CMS suspending all non-emergency surveys on March 4, 2020, including the validation surveys of facilities participating in Medicare via accreditation. From FY 2019 to FY 2020, the overall number of validation surveys conducted decreased from 315 surveys to 143 surveys, a 55 percent decrease. During the same period, the number of non-hospital validation surveys conducted decreased from 196 in FY 2019 to 98 in FY 2020, a 50 percent decrease. The number of hospital surveys conducted decreased by 62 percent, from 119 surveys in FY 2019 to 45 surveys in FY 2020.

Prior to FY 2020, these numbers represent a 250 percent increase in the overall number of validation surveys conducted, from 90 in FY 2007 to 315 in FY 2019. During the same time period, the number of non-hospital validation surveys conducted increased by 460 percent, from 35 surveys in FY 2007 to 196 surveys in FY 2019. The number of hospital validation surveys conducted increased by 116 percent, from 55 surveys in FY 2007 to 119 surveys in FY 2019. In FY 2021, the validation surveys remained suspended. No hospital or non-hospital validation surveys were conducted.

60-Day Validation Surveys

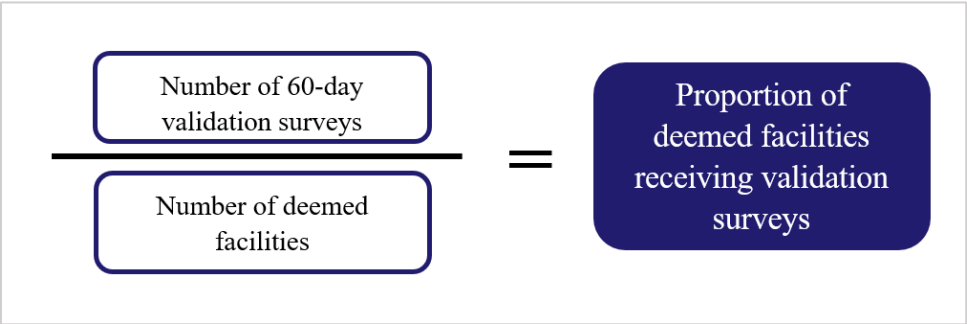
The purpose of 60-day validation surveys is to assess the AO's ability to ensure compliance with Medicare conditions. These validation surveys are on-site full surveys completed by SA surveyors no later than 60 days after the end date of an AO's Medicare accreditation program full survey. The SA performs 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 FY 2020 and FY 2021, the COVID-19 PHE was the primary driver impacting CMS's ability to build 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



In FY 2020, a small sample of validation surveys was conducted prior to suspension of the program, allowing the proportion of deemed facilities receiving validation surveys to be calculated and reported. The validation survey suspension remained in effect throughout FY 2021 due to the COVID-19 PHE.

Validation Analysis

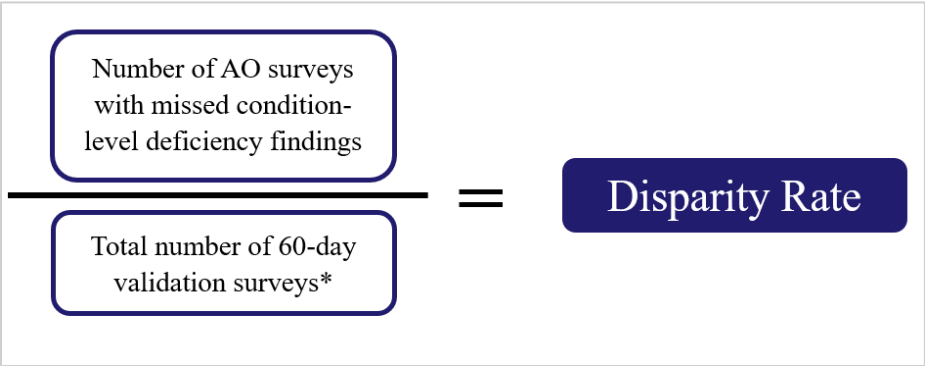
Condition-Level Deficiencies and Disparity Rate

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

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

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

Figure 2: Disparity Rate Calculation



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

The methodology for calculating the disparity rate is set by regulation at 42 CFR § 488.1, in the definition for "rate of disparity." 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 facilities' condition-level deficiencies cited by the SA, the disparity rate would be 16 percent (12 divided by 77).

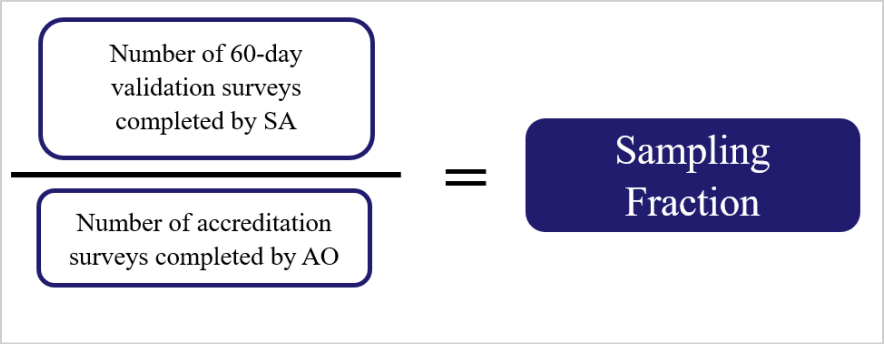
There are, however, limitations when discussing disparity rates. The disparity rate does not solely measure the AO's performance. Additionally, a high AO disparity rate does not necessarily indicate unsatisfactory performance by the AO. (See Section 5.) AO program types having smaller sample sizes may result in higher AO disparity rates. For example, if 38 validation surveys are conducted, half the number of surveys conducted in the first example, and the AO missed 12 condition-level deficiencies, the disparity rate would be 32 percent (12 divided by 38). When the number of validation surveys completed is less than five, the data is considered statistically invalid, and the disparity rate is not reported.

In FY 2020, due to the COVID-19 PHE, there were significant decreases in the number of validation surveys completed across all program types for the majority of AOs. In many instances, these decreases resulted in higher than usual AO disparity rates. In FY 2021, there were no AO disparity rates to report due to the continued suspension of the validation surveys.

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. Prior to the COVID-19 PHE, CMS has worked to increase this sampling fraction for each AO and to include a minimum of five 60-day validation surveys per year for each AO program, to the extent possible.

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

Validation Performance Results: Each Facility Type

The table below presents the results of the 60-day validation surveys for all AOs from FY 2019 through FY 2021 by facility type. (See Table 6.)

Table 6: 60-Day Validation Survey Results for Each Facility Type FYs 2019–2021

	FY 2019	FY 2020*	FY 2021**
HOSPITAL			
60-Day Validation Sample Surveys	99	40	-
SA Surveys with Condition-Level Deficiencies	48	19	-
AO Surveys with Missed Comparable Deficiencies	42	18	-
Disparity Rate	**42%**	**45%**	-
Sampling Fraction	.07	.05	-
PSYCHIATRIC HOSPITAL			
60-Day Validation Sample Surveys	20	5	-
SA Surveys with Condition-Level Deficiencies	12	5	-

	FY 2019	FY 2020*	FY 2021**
AO Surveys with Missed Comparable Deficiencies	9	5	-
Disparity Rate	**45%**	**100%******	-
Sampling Fraction	.09	.05	-
CRITICAL ACCESS HOSPITAL			
60-Day Validation Sample Surveys	13	12	-
SA Surveys with Condition-Level Deficiencies	7	5	-
AO Surveys with Missed Comparable Deficiencies	6	5	-
Disparity Rate	**46%**	**42%**	-
Sampling Fraction	.09	.09	-
HOME HEALTH AGENCY			
60-Day Validation Sample Surveys	84	33	-
SA Surveys with Condition-Level Deficiencies	8	5	-
AO Surveys with Missed Comparable Deficiencies	7	4	-
Disparity Rate	**8%**	**12%**	-
Sampling Fraction	.05	.02	-
HOSPICE			
60-Day Validation Sample Surveys	32	15	-
SA Surveys with Condition-Level Deficiencies	6	3	-
AO Surveys with Missed Comparable Deficiencies	6	3	-
Disparity Rate	**19%**	**20%**	-
Sampling Fraction	.03	.02	-
AMBULATORY SURGERY CENTER			
60-Day Validation Sample Surveys	67	28	-
SA Surveys with Condition-Level Deficiencies	26	5	-
AO Surveys with Missed Comparable Deficiencies	23	5	-
Disparity Rate	**34%**	**18%**	-
Sampling Fraction	.08	.05	-
RURAL HEALTH CLINIC			

	FY 2019	FY 2020*	FY 2021**
60-Day Validation Sample Surveys***	-	8	-
SA Surveys with Condition-Level Deficiencies	-	0	-
AO Surveys with Missed Comparable Deficiencies	-	0	-
Disparity Rate	-	**0%**	-
Sampling Fraction	-	.02	-
OUTPATIENT PHYSCIAL THERAPY AND SPEECH LANGUAGE PATHOLOGY SERVICES			
60-Day Validation Sample Surveys***	-	2	-
SA Surveys with Condition-Level Deficiencies	-	0	-
AO Surveys with Missed Comparable Deficiencies	-	0	-
Disparity Rate	-	**0%**	-
Sampling Fraction	-	.02	-

* Due to the suspension of validation surveys related to the PHE, the number of validation surveys completed from October 1, 2019 – March 4, 2020, were smaller compared to FY 2019.
**In FY 2021, no validation surveys were conducted due to the PHE.
***Validation survey sample did not include RHCs or OPTs in FY 2019.
****The small number of surveys increases the margin of error, potentially affecting the validity of the overall disparity rate calculation. Please see further discussion in the Psychiatric Hospital heading beginning at page 46.

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 2019–2020. This lower deficiency rate is primarily due to these facility types not having deficiencies related to physical environment (PE) conditions, which has historically been the primary driver for cited deficiencies in other program types. There is no PE condition for HHAs since these services are provided in the patient's home. Although hospices do have a PE Condition for inpatient hospices, most hospice services are provided in the patient's home as well. The goal of hospice care is to help terminally ill individuals continue life with minimal disruption to normal activities while remaining primarily in the home environment.[11]

From FY 2019 to FY 2020, CAHs and ASCs had the only decreases in disparity rates of all the program types, with a 4 percent and 16 percent decrease, respectively. The disparity rates for hospitals increased by 3 percent from FYs 2019 to 2020. The disparity rates for psychiatric hospitals increased by 55 percent from FY 2019 to FY 2020 (Please see Psychiatric Hospital Section and Table 11, both beginning on p. 45, for further discussion). The disparity rates for HHAs and hospices increased by 4 percent and 1 percent respectively from FY 2019 to FY 2020. In FY 2020, the OPT and RHC surveys did not have condition-level deficiencies cited by the

[11] https://www.federalregister.gov/d/2021-16311/p-20

SAs. OPTs and RHCs are not subject to a life safety code survey.

In FYs 2019 and 2020, the last traditional validation surveys were completed and are summarized in Sections 4 and 5. Future reports will present changes to the validation survey process.

Validation Performance Results: Individual Accrediting Organizations

Each AO receives feedback on the results of CMS's 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 2019 to 2021. (See Tables 7-14)

When the number of 60-day validation surveys completed by the SA is less than five surveys, the disparity rate is not calculated. The small 60-day validation sample sizes limited the analysis of some AO programs. Since 2008, CMS has tried to significantly increase the number of 60-day validation samples. With minimal exception, the sample size for every AO program was either maintained or increased from FYs 2011 to 2012. In FY 2013, the sample size decreased for each program type, except for psychiatric hospitals and CAHs. In FY 2014, the number of validation surveys for CAHs, HHAs, hospices and ASCs decreased. In FYs 2015 and 2016, the number of validation surveys for these same program types increased except for hospices which remained the same. Only hospitals showed a decrease in the number of surveys performed from FY 2014 to FY 2017. In FY 2017, the sample size decreased for each program type except for psychiatric hospitals and hospices. The number of validation surveys for psychiatric hospitals and hospices remained the same from FY 2016 to FY 2017. From FYs 2017 to 2018, the number of validation surveys decreased for CAHs, HHAs, hospices and ASCs. Hospital was the only program type to increase the number of validation surveys performed during that same time while psychiatric hospitals remained the same. From FYs 2018 to 2019, the number of validation surveys decreased for hospitals, psychiatric hospitals and CAHs. During that same time, the number of validation surveys increased for HHAs and ASCs while hospices remained the same. From FY 2019 to FY 2020, the number of validation surveys decreased for each facility type due to the COVID-19 PHE.

The presentation of validation results over several time periods provides a more complete examination of the consistency of individual AO performance, except for FY 2020. During this time, many of the AOs sustained higher than usual disparity rates and statistically invalid data due to the reduced number of validation surveys completed. For FY 2021, no data is available due to the continued suspension of the validation surveys. The results for the FYs 2019–2021 60-day validation surveys for individual AOs are outlined in the tables below by program type. Additionally, in past reports, discussion following each table compared the current fiscal year to the last fiscal year in the look back period. Because there aren't any FY 2021 data to report, discussion pertains to FYs 2019 and 2020 for validation survey sample sizes five or more.

Hospital

The AOs with hospital programs in FY 2021 were ACHC, CIHQ, DNV, and TJC. (See Table 7.)

Table 7: Hospital 60-Day Validation Survey Results by AO FYs 2019–2021

	ACHC			CIHQ			DNV			TJC			Totals
	FY 2019	FY 2020	FY 2021	FY 2019	FY 2020	FY 2021	FY 2019	FY 2020	FY 2021	FY 2019	FY 2020	FY 2021	FYs 2019–2021
60-Day Validation Sample Surveys	3	2	0	1	3	0	7	9	0	88	26	0	139
SA Surveys with Condition-Level Deficiencies	*N/A	*N/A	*N/A	*N/A	*N/A	*N/A	3	6	*N/A	43	11	*N/A	63
AO Surveys with Missed Comparable Deficiencies	*N/A	*N/A	*N/A	*N/A	*N/A	*N/A	3	6	*N/A	37	10	*N/A	56
Overall Disparity Rate	***N/A**	***N/A**	***N/A**	***N/A**	***N/A**	***N/A**	**43%**	**67%**	***N/A**	**42%**	**38%**	***N/A**	**40%**
Health and Safety Disparity Rate	***N/A**	***N/A**	***N/A**	***N/A**	***N/A**	***N/A**	**43%**	**11%**	***N/A**	**31%**	**8%**	***N/A**	**25%**
Physical Environment Disparity Rate	***N/A**	***N/A**	***N/A**	***N/A**	***N/A**	***N/A**	**29%**	**67%**	***N/A**	**23%**	**35%**	***N/A**	**27%**
Sampling Fraction	*N/A	*N/A	*N/A	*N/A	*N/A	*N/A	.05	.08	*N/A	.08	.04	*N/A	.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.
Note: FY 2020 includes validation surveys completed from October 1, 2019 – March 4, 2020.

- **ACHC:** In FY 2019, due to the low number of deemed hospitals for resurvey, only three validation surveys were conducted**.** In FY 2020, due to the low number of deemed hospitals due for resurvey and the suspension of the validation surveys due to the COVID-19 PHE, only two validation surveys were conducted. Therefore, no additional data is reported. Suspension of the validation surveys remained in effect throughout FY 2021.
- **CIHQ:** The validation survey sample sizes were less than five. Therefore, there are no data to report.
- **DNV:** In FY 2020, the overall hospital disparity rate was 67 percent based on the completion of nine validation surveys. The number of validation surveys conducted represents an 8 percent sample of the surveys conducted by DNV. The FY 2020 overall disparity rate is 24 percent higher than the overall disparity rate for FY 2019. The FY 2019 overall disparity rate was based on a 5 percent sample of the surveys conducted during that period. In FY 2020, DNV's PE disparity rate was 56 percentage points higher than the health and safety disparity rate. The SAs cited PE at the condition level 11 times. DNV missed six comparable deficiencies resulting in a 67 percent disparity rate. The FY 2020 PE disparity rate is 38 percentage points higher than the FY 2019 PE disparity rate.
- **TJC:** In FY 2020, the hospital overall disparity rate was 38 percent based on the completion of 26 validation surveys. The number of validation surveys conducted represents a 4 percent sample of the surveys conducted by TJC. The FY 2020 overall disparity rate is 4 percentage points lower than the overall disparity rate for FY 2019. The FY 2019 overall disparity rate was based on an 8 percent sample of the surveys conducted during that period. In FY 2020, TJC's PE disparity rate was 27 percentage points higher than the health and safety disparity rate. The SAs cited PE at the condition level 18 times. TJC missed nine comparable deficiencies resulting in a 35 percent disparity rate. The FY 2020 PE disparity rate is 12 percentage points higher than the FY 2019 PE disparity rate.

Psychiatric Hospital

TJC was the only AO with a CMS-approved psychiatric hospital Medicare accreditation program in FY 2021. The psychiatric hospital program was initially approved by CMS in FY 2011. (See Table 8.)

Table 8: Psychiatric Hospital 60-Day Validation Survey Results by AO FYs 2019–2021

	FY 2019	FY 2020	FY 2021	Total FYs 2019 - 2021
60-Day Validation Sample Surveys	20	5	0	25
SA Surveys with Condition-Level Deficiencies	12	5	*N/A	17
AO Surveys with Missed Comparable Deficiencies	9	5	*N/A	14
Overall Disparity Rate	**45%**	**100%**	***N/A**	**56%**
Health and Safety Disparity Rate	**30%**	**100%**	***N/A**	**44%**
Physical Environment Disparity Rate	**20%**	**60%**	***N/A**	**28%**
Sampling Fraction	.09	.05	*N/A	.05

Note: FY 2020 includes validation surveys completed from October 1, 2019 – March 4, 2020.

TJC: In FY 2020, due to the suspension of validation surveys related to the PHE, only five validation surveys were performed for psychiatric hospitals, representing 1 percent of the total number of deemed psychiatric hospitals and only 5 percent of the total number of psychiatric hospital surveys conducted by TJC during this same period. The FY 2020 overall disparity was 100 percent, which is 55 percent higher than the overall disparity rate for FY 2019. It is important to note that TJC had some findings comparable to those of the SA for all five validation surveys. However, in calculating disparity rates, the AOs are not given partial credit in these instances. Unless the AO cites comparable findings, whether at the standard level or condition level, for each SA condition-level finding, the survey is considered disparate. In addition to this "all-or-nothing rule," the suspension of validation surveys related to the PHE resulted in fewer psychiatric hospital validation surveys completed compared to previous years. In FY 2019, for example, the disparity rate was based on a 9 percent sample of the surveys conducted during that period. As a result, the small sample of only five validation surveys used to determine a disparity rate in FY 2020 increased the margin of error in the calculation of the disparity rate, thus affecting the validity of this number and the extent to which it accurately represents the effectiveness of TJC's survey activities.

In FY 2020, TJC's health and safety disparity rate was 40 percentage points higher than the PE disparity rate and was 70 percentage points higher than the FY 2019 health and safety disparity rate. In FY 2020, the primary drivers of TJC's health and safety disparity rate were as follows: Patient's Rights; Special Medical Record Requirements for Psychiatric Hospitals; Special Staff Requirements for Psychiatric Hospitals; and Governing Body.

The SA cited the Patient's Rights requirement at the condition level five times. TJC missed three comparable deficiencies. The SA cited the Special Medical Record Requirements for Psychiatric Hospitals six times. TJC missed three comparable deficiencies. Both conditions yielded a 60 percent disparity rate. The SA cited the Special Staff Requirements for Psychiatric Hospitals requirement at the condition level two times. TJC missed both comparable deficiencies. The SA cited the Governing Body at the condition level three times. TJC missed two comparable deficiencies. Both conditions yielded a 40 percent disparity rate.

As noted on page 8 of this report, CMS's validation program and AO performance measures were suspended on March 4, 2020, and July 1, 2020, respectively as CMS focused on access to care and survey flexibilities to safeguard patient safety. During the extended period when overall rates of COVID-19 cases and COVID-19- related hospitalizations were at their highest nationwide, CMS allowed AOs (including TJC) to modify their on-site survey activities and to instead use virtual survey processes to ensure that facilities were still being surveyed while also minimizing the risk of transmission of the SARS- CoV-2 virus among AO surveyors and facility staff, patients, and residents.

We also note that in FY 2022, TJC's Psychiatric Hospital deeming program was evaluated by CMS to determine whether it would be granted continued recognition as a CMS-approved accreditation program with deeming authority. During the entire observation and review of TJC's psychiatric hospital deeming program, CMS found only minimal areas of concern that were addressed and corrected by TJC. As part of its evaluation, the CMS team also conducted an onsite survey observation of TJC's psychiatric hospital program at a psychiatric hospital in the Washington, DC area.

CMS plans to reengage with all AOs, including TJC's psychiatric hospital deeming program, regarding AO performance after the conclusion of the PHE. CMS will continue to monitor AO certification of psychiatric hospitals to determine the accuracy with which they are citing deficiencies and completing certification responsibilities. Please see Section 6 for additional details and further discussion regarding CMS monitoring and oversight of AO performance and activities.

Critical Access Hospital

The AOs with CAH accreditation programs in FY 2021 were ACHC, DNV, and TJC. (See Table 9.)

Table 9: CAH 60-Day Validation Survey Results by AO FYs 2019–2021

	ACHC			DNV			TJC			Total
	FY 2019	FY 2020	FY 2021	FY 2019	FY 2020	FY 2021	FY 2019	FY 2020	FY 2021	FYs 2019 -2021
60-Day Validation Sample Surveys	0	0	0	4	1	0	9	11	0	25
SA Surveys with Condition-Level Deficiencies	*N/A	*N/A	*N/A	*N/A	*N/A	*N/A	7	5	*N/A	12
AO Surveys with Missed Comparable Deficiencies	*N/A	*N/A	*N/A	*N/A	*N/A	*N/A	6	5	*N/A	11
Overall Disparity Rate	***N/A**	***N/A**	***N/A**	***N/A**	***N/A**	***N/A**	**67%**	**45%**	***N/A**	**44%**
Health and Safety Disparity Rate	***N/A**	***N/A**	***N/A**	***N/A**	***N/A**	***N/A**	**22%**	**9%**	***N/A**	**15%**
Physical Environment Disparity Rate	***N/A**	***N/A**	***N/A**	***N/A**	***N/A**	**N/A**	**56%**	**36%**	***N/A**	**45%**
Sampling Fraction	*N/A	*N/A	*N/A	*N/A	*N/A	*N/A	.08	.13	*N/A	.06

*N/A: When a minimum sample size of five is not achieved for an AO, no data is reported given the lack of statistical significance.
Note: FY 2020 includes validation surveys completed from October 1, 2019 – March 4, 2020.

- **ACHC:** In FYs 2019-2021, the State Agency did not conduct any validation surveys for ACHC CAHs. Therefore, no additional data is reported.

- **DNV:** In FY 2019, due to the low number of deemed hospitals for resurvey, only four validation surveys were conducted**.** In FY 2020, due to the low number of deemed CAHs due for resurvey and the suspension of validation surveys due to the COVID-19 PHE, only one validation survey was conducted. Therefore, no additional data are reported. Suspension of the validation surveys remained in effect throughout FY 2021.

- **TJC:** In FY 2020, the CAH overall disparity rate was 45 percent based on the completion of 11 validation surveys. The number of surveys conducted represents a 13 percent sample of the surveys conducted by TJC. The FY 2020 overall disparity rate is 22 percent lower than the FY 2019 overall disparity rate. The FY 2019 disparity rate was based on an 8 percent sample of the surveys conducted during that period. In FY 2020, the PE disparity rate was 27 percentage points higher than the health and safety disparity rate. The SA cited PE at the condition level seven times. TJC missed four comparable deficiencies resulting in a 36 percent disparity rate. The FY 2020 PE disparity rate is 20 percentage points lower than the FY 2019 PE disparity rate.

Home Health Agency

The AOs with HHA accreditation programs in FY 2021 were ACHC, CHAP, and TJC. (See Table 10.)

Table 10: HHA 60-Day Validation Survey
Results by AO FYs 2019–2021

	ACHC			CHAP			TJC			Total
	FY 2019	FY 2020	FY 2021	FY 2019	FY 2020	FY 2021	FY 2019	FY 2020	FY 2021	2019 - 2021
60-Day Validation Sample Surveys	17	10	0	36	19	0	31	4	0	117
SA Surveys with Condition-Level Deficiencies	0	2	*N/A	6	3	*N/A	2	*N/A	*N/A	13
AO Surveys with Missed Comparable Deficiencies	0	1	*N/A	5	3	*N/A	2	*N/A	*N/A	11
Overall Disparity Rate	**0%**	**10%**	***N/A**	**14%**	**16%**	***N/A**	**6%**	***N/A**	***N/A**	**9%**
Sampling Fraction	.04	.02	*N/A	.06	.03	*N/A	.04	*N/A	*N/A	.02

*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: FY 2020 includes validation surveys completed from October 1, 2019 – March 4, 2020.

- **ACHC**: In FY 2020, the HHA overall disparity rate was 10 percent based on the completion of 10 validation surveys. The number of validation surveys completed represents a 2 percent sample of the surveys conducted by ACHC. The FY 2020 overall disparity rate is 10 percentage points higher than the overall disparity rate for FY 2019. The overall disparity rate for FY 2019 was based on a 4 percent sample of the surveys conducted during that period. In FY 2020, the primary drivers of ACHC's overall disparity rate were Clinical Records; and Quality Assessment/Performance Improvement. The SAs cited the Clinical Records requirement two times. The SAs cited the Quality Assessment/Performance Improvement requirement one time. In both instances, ACHC missed one comparable. Both conditions yielded a 10 percent disparity rate.

- **CHAP**: In FY 2020, the HHA overall disparity rate was 16 percent based on the completion of 19 validation surveys. The number of validation surveys completed represents a 3 percent sample of the surveys conducted by CHAP. The FY 2020 overall disparity rate is 2 percentage points higher than the overall disparity rate for FY 2019. The overall disparity rate for FY 2019 was based on a 6 percent sample of surveys conducted during that period. In FY 2020, the primary driver of CHAP's overall disparity rate was Skilled Professional Services. The SAs cited Skilled Professional Services at the condition level two times. CHAP missed two comparable deficiencies resulting in an 11 percent disparity rate.

- **TJC**: In FY 2019, the HHA overall disparity rate was based on the completion of 31 validation surveys. The number of validation surveys completed represents a 4 percent sample of the surveys conducted by TJC. In FY 2020, due to the suspension of validation surveys related to the COVID-19 PHE, only four validation surveys were conducted. Therefore, no additional data is reported. Suspension of the validation surveys remained in effect throughout FY 2021.

Hospice

The AOs with hospice accreditation programs in FY 2021 were ACHC, CHAP and TJC. (See Table 11.)

Table 11: Hospice 60-Day Validation Survey Results by AO FYs 2019–2021

	ACHC			CHAP			TJC			Total
	FY 2019	FY 2020	FY 2021	FY 2019	FY 2020	FY 2021	FY 2019	FY 2020	FY 2021	2019 - 2021
60-Day Validation Sample Surveys	8	3	0	11	7	0	13	5	0	47
SA Surveys with Condition-Level Deficiencies	2	*N/A	*N/A	1	2	*N/A	3	1	*N/A	9
AO Surveys with Missed Comparable Deficiencies	2	*N/A	*N/A	1	2	*N/A	3	1	*N/A	9
Overall Disparity Rate	**25%**	***N/A**	***N/A**	**9%**	**29%**	***N/A**	**23%**	**20%**	***N/A**	**19%**
Sampling Fraction	.03	*N/A	*N/A	.03	.02	*N/A	.03	.02	*N/A	.01

*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: FY 2020 includes validation surveys completed from October 1, 2019 – March 4, 2020.

- **ACHC:** In FY 2019, the hospice overall disparity rate was based on the completion of eight validation surveys. The number of validation surveys completed represents a 3 percent sample of the surveys conducted by ACHC. In FY 2020, due to the suspension of validation surveys related to the COVID-19 PHE, only four validation surveys were conducted. Therefore, no additional data is reported. Suspension of the validation surveys remained in effect throughout FY 2021.

- **CHAP:** In FY 2020, the hospice overall disparity rate was 29 percent based on the completion of seven validation surveys. The number of validation surveys completed represents a 2 percent sample of the surveys conducted by CHAP. The FY 2020 overall disparity rate is 20 percentage points higher than the overall disparity rate for FY 2019. The overall disparity rate for FY 2019 was based on a 3 percent sample of surveys conducted during that period. In FY 2020, the primary drivers of CHAP's overall disparity rate were Core Services; Furnishing of Non-Core Services; and Volunteers. The SAs cited the Core Services and Furnishing of Non-Core Services requirements once. In both instances, CHAP missed comparable deficiencies. The SAs cited the Volunteers requirement two times. CHAP missed one comparable deficiency. Each condition yielded a 14 percent disparity rate.

- **TJC:** In FY 2020, the hospice overall disparity rate was 20 percent based on the completion of five validation surveys. The number of validation surveys completed represents a 2 percent sample of the survey conducted by TJC. The FY 2020 overall disparity rate is 3 percentage points lower than the overall disparity rate in FY 2019. The overall disparity rate for FY 2019 was based on a 3 percent sample of the surveys conducted during that period. In FY 2020, the primary driver of TJC's overall disparity rate was the Hospices that Provide Inpatient Care Directly requirement. The SAs cited the condition two times. TJC missed one comparable condition resulting in a 20 percent disparity rate.

Ambulatory Surgery Center

The AOs with ASC accreditation programs in FY 2021 were AAAASF, AAAHC, ACHC, and TJC. (See Table 12.)

Table 12: ASC 60-Day Validation Survey Results by AO FYs 2019–2021

	AAAASF			AAAHC			ACHC **			TJC			Total
	FY 2019	FY 2020	FY 2021	FY 2019	FY 2020	FY 2021	FY 2019	FY 2020	FY 2021	FY 2019	FY 2020	FY 2021	FYs 2019–2021
60-Day Validation Sample Surveys	6	8	0	39	10	0	1	0	0	21	10	0	95
SA Surveys with Condition-Level Deficiencies	3	1	*N/A	16	2	*N/A	*N/A	*N/A	*N/A	6	2	*N/A	30
AO Surveys with Missed Comparable Deficiencies	3	1	*N/A	15	2	*N/A	*N/A	*N/A	*N/A	4	2	*N/A	27
Overall Disparity Rate	**50%**	**13%**	***N/A**	**38%**	**20%**	***N/A**	***N/A**	***N/A**	***N/A**	**19%**	**20%**	***N/A**	**28%**
Health and Safety Disparity Rate	**33%**	**0%**	***N/A**	**31%**	**10%**	***N/A**	***N/A**	***N/A**	***N/A**	**14%**	**0%**	***N/A**	**19%**
Physical Environment Disparity Rate	**33%**	**13%**	***N/A**	**13%**	**10%**	***N/A**	***N/A**	***N/A**	***N/A**	**10%**	**20%**	***N/A**	**14%**
Sampling Fraction	.06	.12	*N/A	.10	.03	*N/A	*N/A	*N/A	*N/A	.07	.07	*N/A	.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.
**ACHC was formerly known as AAHHS/HFAP. Very few ACHC ASC validation survey selections have been made since FY 2012 due to the low numbers of deemed ASCs.
Note: FY 2020 includes validation surveys completed from October 1, 2019 – March 4, 2020.

- **AAAASF:** In FY 2020, the ASC overall disparity rate was 13 percent, based on the completion of eight validation surveys. The number of validation surveys completed represents a 12 percent sample of the surveys performed by AAAASF. The FY 2020 overall disparity rate is 37 percent lower than the overall disparity rate for FY 2019. The overall disparity rate for FY 2019 was based on a 6 percent sample of the surveys conducted during that period. In FY 2020, the SAs did not cite any health and safety requirements at the condition level. In FY 2020, AAAASF's PE disparity rate was 13 percent. The SA cited PE at the condition level one time. AAAASF missed the comparable deficiency. The FY 2020 PE disparity rate is 20 percentage points lower than the FY 2019 PE disparity rate.

- **AAAHC:** In FY 2020, the ASC overall disparity rate was 20 percent based on the completion of 10 validation surveys. The number of validation surveys completed represents a 3 percent sample of the surveys conducted by AAAHC. The FY 2020 overall disparity rate is 18 percentage points lower than the overall disparity rate for FY 2019. The overall disparity rate for FY 2019 was based on a 10 percent sample of the surveys conducted during that period. In FY 2020, AAAHC's health and safety and PE disparity rates were 10 percent. In FY 2020, the primary drivers of AAAHC's health and safety disparity rate were the following: Governing Body and Management; Nursing Services; Pharmaceutical Services; Laboratory and Radiologic Services; and Infection Control. The SAs cited the Governing Body and Management and the Laboratory and Radiologic Services requirements requirement one time. In both instances, AAAHC missed the comparable deficiency. The SAs cited the Nursing Services, Pharmaceutical Services and Infection Control requirements two times. In each instance AAAHC missed one comparable. Each condition yielded a 10 percent disparity rate. The SAs cited the PE requirement at the condition level two times. AAAHC missed one comparable deficiency resulting in a 10 percent disparity rate. The FY 2020 health and safety disparity rate is 21 percentage points lower than the FY 2019 health and safety disparity rate. The FY 2020 PE disparity rate is 3 percentage points lower than the FY 2019 PE disparity rate.

- **ACHC:** In FY 2019, due to the low number of deemed hospitals due for resurvey, only one ASC validation survey was conducted**.** Due to the consistently low number of deemed ACHC ASCs, and the COVID-19 PHE survey suspension, no validation surveys were conducted in FY 2020. Therefore, no additional data is reported. Suspension of the validation surveys remained in effect throughout FY 2021.

- **TJC:** In FY 2020, the ASC overall disparity rate was 20 percent, based on the completion of 10 validation surveys. The number of validation surveys completed represents a 7 percent sample of the surveys conducted by TJC. The FY 2020 overall disparity rate is 1 percentage point higher than the overall disparity rate for FY 2019. The disparity rate for FY 2019 was based on a 7 percent sample of surveys conducted during that period. In FY 2020, TJC's health and safety disparity rate was 0 percent. The SA cited Infection Control at the condition level 1 time. TJC matched the comparable deficiency. In FY 2020, TJC's PE disparity rate was 20 percent. The SAs cited the PE requirement at the condition level three times. TJC missed two comparable deficiencies. The FY 2020 PE disparity rate is 10 percentage points higher than the FY 2019 PE disparity rate.

Rural Health Clinic

The AOs with RHC accreditation programs in FY 2021 were AAAASF and TCT. AAAASF's and TCT's RHC Medicare accreditation programs were initially approved by CMS in FY 2012 and FY 2014 respectively. The RHC programs were not selected by CMS to participate in the validation surveys prior to FY 2020. (See Table 13.)

Table 13: RHC 60-Day Validation Survey Results by AO FYs 2020-2021

	AAAASF FY 2020	AAAASF FY 2021	TCT FY 2020	TCT FY 2021	Total FYs 2020-2021
60-Day Validation Sample Surveys**	5	0	3	0	8
SA Surveys with Condition-Level Deficiencies	0	*N/A	*N/A	*N/A	0
AO Surveys with Missed Comparable Deficiencies	0	*N/A	*N/A	*N/A	0
Overall Disparity Rate	**0%**	***N/A**	***N/A**	***N/A**	**0%**
Sampling Fraction	.04	*N/A	*N/A	*N/A	.01

*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.
**CMS's validation program did not include RHCs in FY 2019.
Note: FY 2020 includes validation surveys completed from October 1, 2019 – March 4, 2020.

- **AAAASF:** In FY 2020, five RHC validation surveys were completed. The number of validation surveys conducted represents a 4 percent sample of the surveys conducted by AAAASF. There is no data available for FY 2021. No validation surveys were conducted due to the PHE.

- **TCT:** In FY 2020, due to the low number of deemed TCT RHCs and the suspension of validation surveys related to COVID-19, only three validation surveys were conducted. Therefore, no additional data is reported. Suspension of the validation surveys remained in effect throughout FY 2021.

Outpatient Physical Therapy and Speech-language Pathology

AAAASF was the only AO with a CMS-approved OPT Medicare accreditation program in FYs 2020 and 2021. The OPT program was initially approved by CMS in FY 2011. The OPT programs were not selected by CMS to participate in the validation surveys prior to FY 2020. (See Table 14.)

Table 14: OPT 60-Day Validation Survey Results by AO FYs 2020-2021

	FY 2020	FY 2021	Total FYs 2020-2021
60-Day Validation Sample Surveys**	2	0	2
SA Surveys with Condition-Level Deficiencies	*N/A	*N/A	*N/A
AO Surveys with Missed Comparable Deficiencies	*N/A	*N/A	*N/A
Overall Disparity Rate	***N/A**	***N/A**	***N/A**
Health and Safety Disparity Rate	***N/A**	***N/A**	***N/A**
Physical Environment Disparity Rate	***N/A**	***N/A**	***N/A**
Sampling Fraction	*N/A	*N/A	*N/A

*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.
**CMS's validation program did not include OPTs in FY 2019.
Note: FY 2020 includes validation surveys completed from October 1, 2019 – March 4, 2020.

- **AAAASF:** In FY 2020, due to the low number of deemed AAAASF OPTs and the suspension of validation surveys related to COVID-19, only two validation surveys were conducted. Therefore, no additional data is reported. Suspension of the validation surveys remained in effect throughout FY 2021.

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 - 2018 and FY 2020, the SAs identified more health and safety condition-level deficiencies than PE condition-level deficiencies for one or more program type. Those program types are outlined below by FY:

- FY 2014: Psychiatric hospitals
- FY 2015: Psychiatric hospitals and ASCs

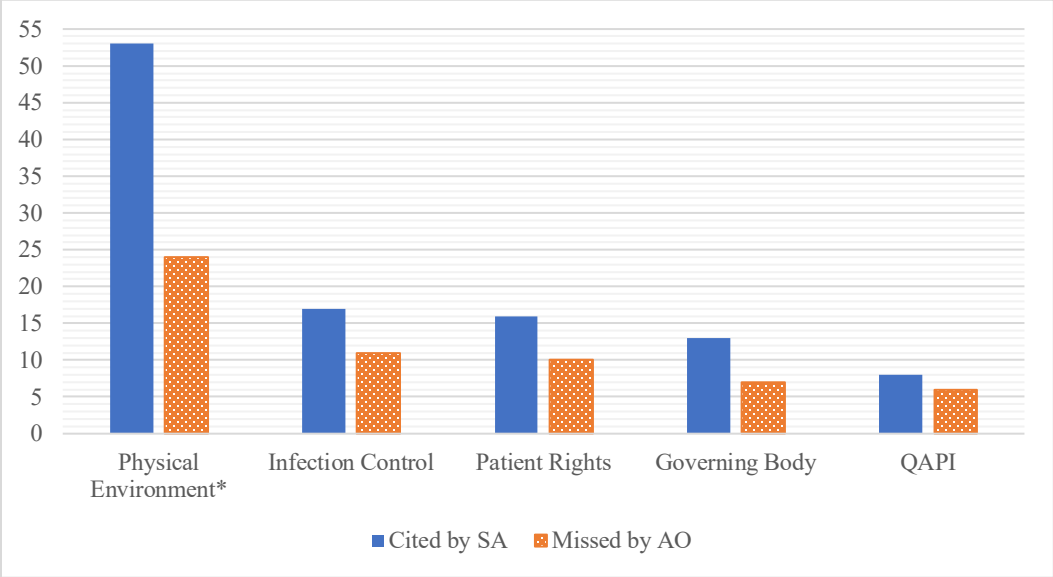
- FY 2016: Psychiatric hospitals
- FY 2017: Hospitals
- FY 2018: Psychiatric hospitals
- FY 2020: Psychiatric hospitals

In FY 2019, the SAs identified more PE condition-level deficiencies than health and safety condition-level deficiencies for hospitals, psychiatric hospitals, CAHs, and ASCs.

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

The first analysis yields the number of facilities cited by SAs for specific condition-level deficiencies and the number of surveys where the AOs missed citing comparable deficiencies. This analysis includes findings from the most recent validation surveys completed pre-COVID in FY 2019, and validation surveys completed in FY 2020 prior to CMS suspension related to the PHE. The top 5 findings are discussed below by each specific facility type and fiscal year. (See Graphs 6-25.) A complete listing of SA cited condition-level citation findings and missed AO comparable deficiencies for FY 2019 and FY 2020 are outlined in Appendix A.

Graph 6: Top Five Condition-Level Deficiencies Most Frequently Cited on 60-Day Validation Surveys Hospitals FY 2019



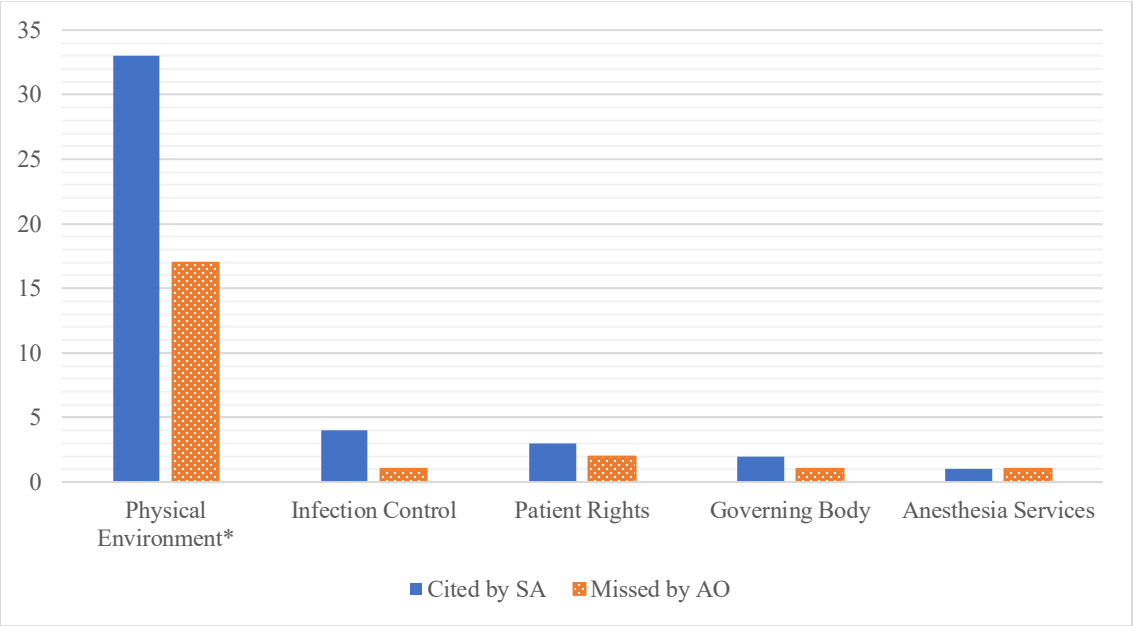
*Most frequently cited deficiency.
Note: The PE condition includes the National Fire Protection Association (NFPA) 2012 edition of the LSC requirements that CMS has adopted as part of its health and safety standards.

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

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

SAs, and missed 10 times by the AOs; and Governing Body, cited 13 times by the SAs, and missed seven times by the AOs.

Graph 7: Top Five Condition-Level Deficiencies Most Frequently Cited on 60-Day Validation Surveys Hospitals FY 2020



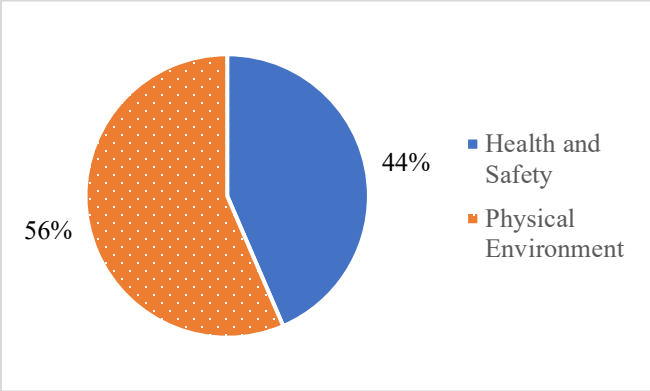
*Most frequently cited deficiency.
Note: FY 2020 includes validation surveys completed from October 1, 2019 – March 4, 2020.

In FY 2020, the hospital sample consisted of 40 validation surveys. In this sample, the SAs cited condition-level deficiencies in 19 facilities. The PE requirement was cited at the condition level by the SAs 33 times. The AOs missed 17 comparable deficiencies for PE. From FYs 2012-2019, the findings were similar.

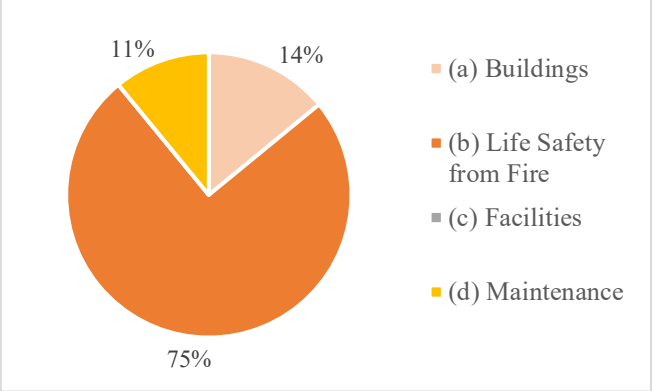
In FY 2020, the next most frequently SA-cited conditions were as follows: Infection Control, cited four times by the SAs, and missed one time by the AOs; Patient Rights, cited three times by the SAs, and missed two times by the AOs; and Governing Body, cited two times by the SAs, and missed one time by the AOs.

In FY 2021, the validation surveys remained suspended due to the ongoing COVID-19 PHE.

Graph 8: Percentage of Health and Safety vs PE Condition-Level Deficiencies Cited on 60- Day Validation Surveys Hospitals FYs 2019–2020



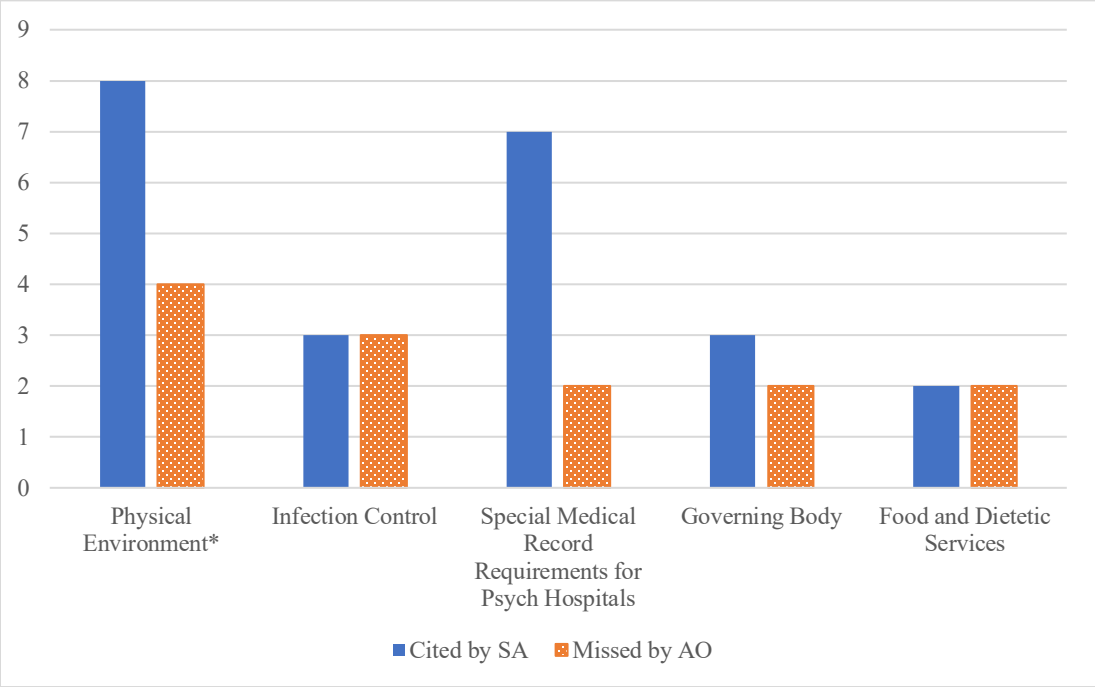
Graph 9: Percentage of PE Standards Cited on 60- Day Validation Surveys Hospitals FYs 2019–2020



Note: FY 2020 includes validation surveys completed from October 1, 2019 – March 4, 2020.

From FY 2019 to FY 2020, there were 67 validation surveys cited with condition-level deficiencies for hospitals. Of the 67 surveys, 37 of the surveys had health and safety citations, 48 of the surveys had PE citations, and 18 of the surveys were cited with both. For hospitals, the PE condition consists of four standards: (a) Buildings, (b) Life Safety from Fire, (c) Facilities, and (d) Maintenance. There were 64 standards cited for the PE condition and 48 of these standards were related to Life Safety from Fire.

Graph 10: Top Five Condition-Level Deficiencies Most Frequently Cited on 60-Day Validation Surveys Psychiatric Hospitals FY 2019

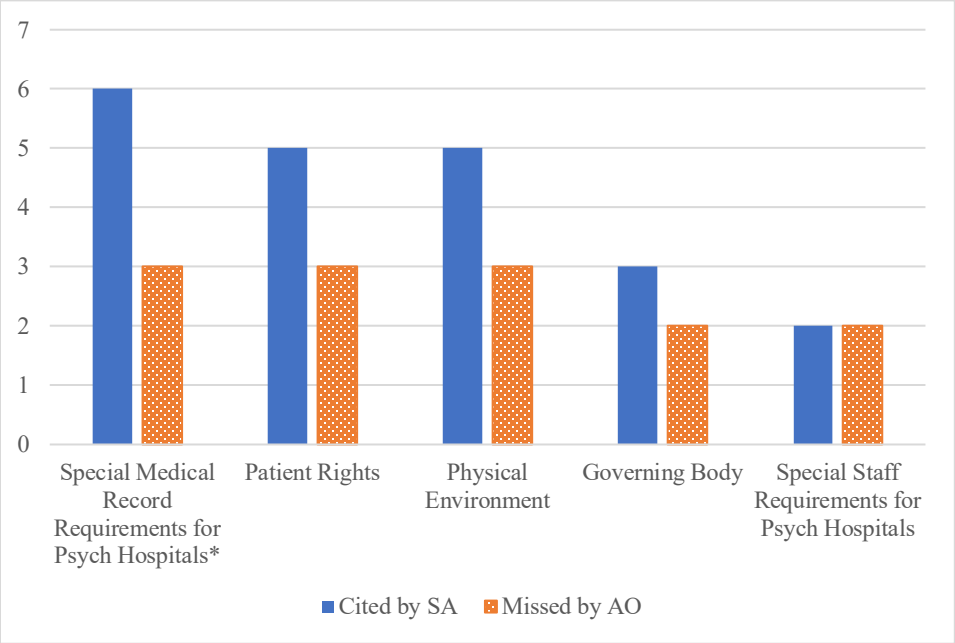


*Most frequently cited deficiency

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

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

Graph 11: Top Five Condition-Level Deficiencies Most Frequently Cited on 60-Day Validation Surveys Psychiatric Hospitals FY 2020



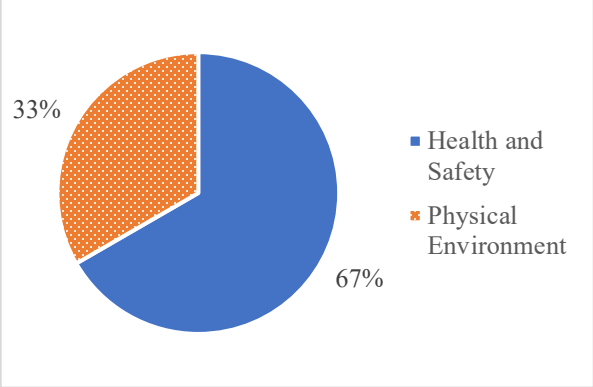
*Most frequently cited deficiency
Note: FY 2020 includes validation surveys completed from October 1, 2019 – March 4, 2020.

In FY 2020, the psychiatric hospital sample consisted of five validation surveys. In this sample, the SAs cited five facilities at the condition level. The Special Medical Record Requirements for Psychiatric Hospitals requirement was cited at the condition level by the SAs six times. The AOs missed three comparable deficiencies for Special Medical Record Requirements for Psychiatric Hospitals. In FY 2019, the PE requirement was cited most frequently at the condition level by the SAs for psychiatric hospitals. In FY 2018, the following requirements were cited most frequently by the SAs at the condition level for psychiatric hospitals: PE and Special Medical Record Requirements for Psychiatric Hospitals.

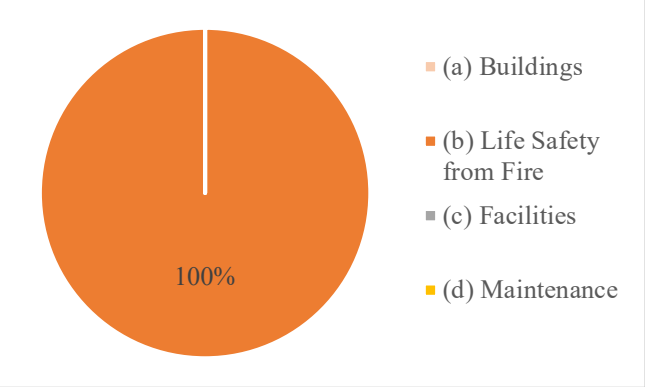
In FY 2020, the next most frequently SA-cited conditions were Patient Rights and PE, both cited five times by the SAs, and missed three times by the AOs; and Governing Body, cited three times by the SAs and missed two times by the AOs.

In FY 2021, the validation surveys remained suspended due to the ongoing COVID-19 PHE.

Graph 12: Percentage of Health and Safety vs PE Condition-Level Deficiencies Cited on 60- Day Validation Surveys Psychiatric Hospitals FYs 2019–2020



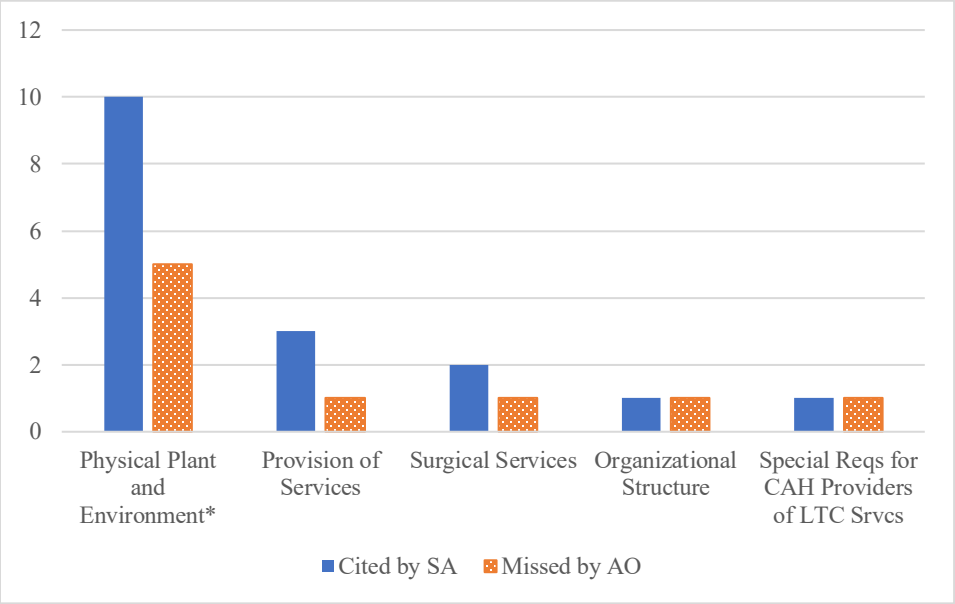
Graph 13: Percentage of PE Standards Cited on 60- Day Validation Surveys Psychiatric Hospitals FYs 2019–2020



Note: FY 2020 includes validation surveys completed from October 1, 2019 – March 4, 2020.

From FY 2019 to FY 2020, there were 17 validation surveys cited with condition-level deficiencies for psychiatric hospitals. Of the 17 surveys, 14 of the surveys had health and safety citations, seven of the surveys had PE citations, and four of the surveys were cited with both. For psychiatric hospitals, the PE Condition consists of three standards: (a) Buildings, (b) Life Safety from Fire, (c) Facilities and (d) Maintenance. Seven standards were cited for the PE condition and each of these standards were related to Life Safety from Fire.

Graph 14: Top Five Condition-Level Deficiencies Most Frequently Cited on 60-Day Validation Surveys CAHs FY 2019

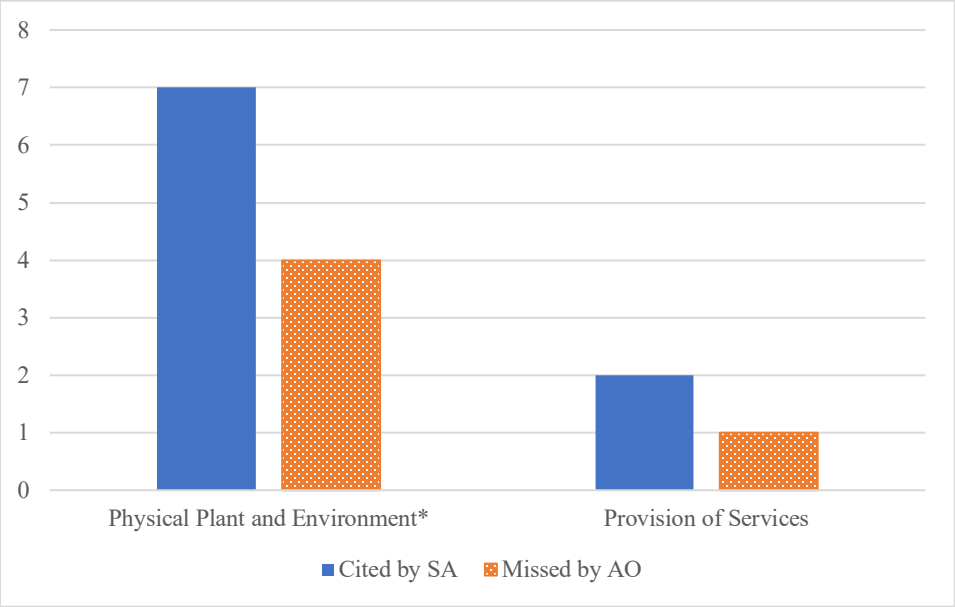


*Most frequently cited deficiency

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

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

Graph 15: Top Five Condition-Level Deficiencies Most Frequently Cited on 60-Day Validation Surveys CAHs FY 2020



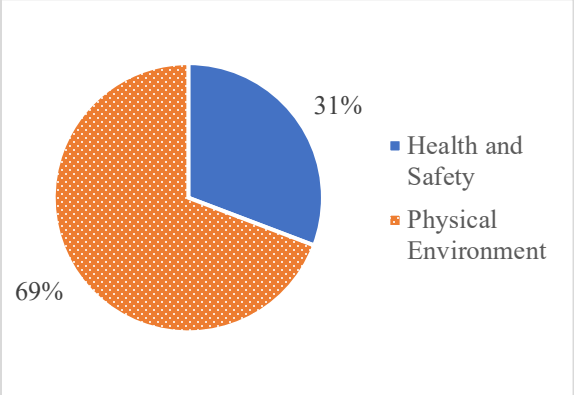
*Most frequently cited deficiency
Note: FY 2020 includes validation surveys completed from October 1, 2019 – March 4, 2020.

In FY 2020, the CAH sample consisted of 12 validation surveys. In this sample, five facilities were cited at the condition level by the SAs. The Physical Plant and Environment requirement was cited by the SAs at the condition level seven times. The AOs missed four comparable deficiencies for PE, which was also the most frequently SA-cited condition in FYs 2012–2019.

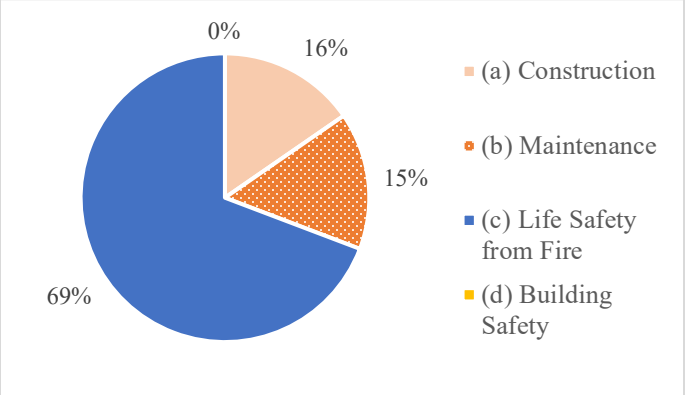
In FY 2020, the next most frequently SA-cited condition for CAHs was Provision of Services, cited two times by the SAs, and missed one time by the AOs.

In FY 2021, the validation surveys remained suspended due to the ongoing COVID-19 PHE.

Graph 16: Percentage of Health and Safety vs PE Condition-Level Deficiencies Cited on 60- Day Validation Surveys CAHs FYs 2019–2020



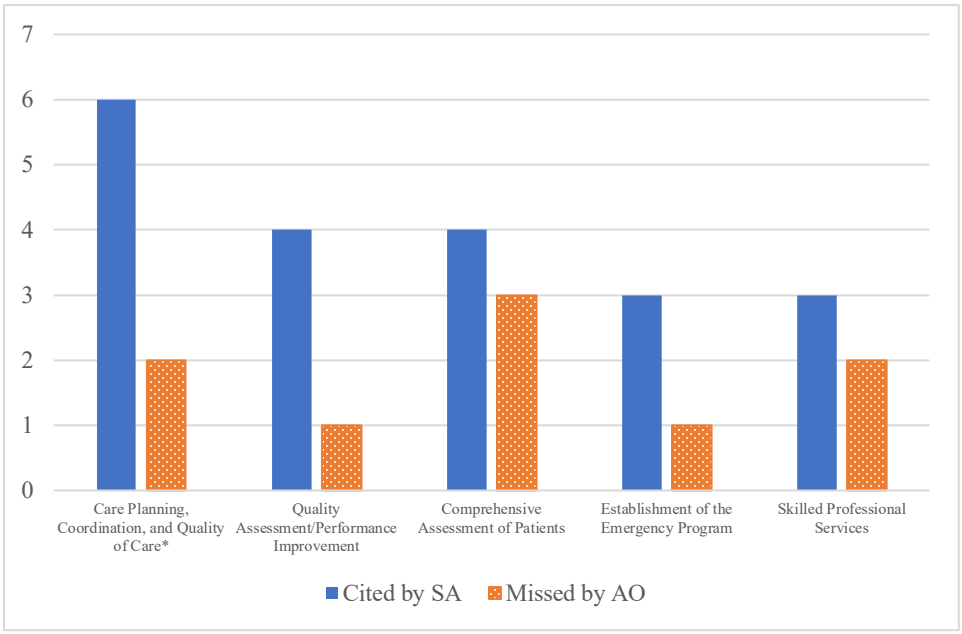
Graph 17: Percentage of PE Standards Cited on Day Validation Surveys CAHs FYs 2019–2020



Note: FY 2020 includes validation surveys completed from October 1, 2019 – March 4, 2020.

From FY 2019 to FY 2020, there were 12 validation surveys cited with condition-level deficiencies for CAHs. Of the 12 surveys, four of the surveys had health and safety citations, nine of the surveys had PE citations, and one of the surveys was cited with both. For CAHs, the PE condition consists of four standards: (a) Construction, (b) Maintenance, (c) Life Safety from Fire, and (d) Building Safety. Thirteen standards were cited for the PE condition and nine of these standards were related to Life Safety from Fire.

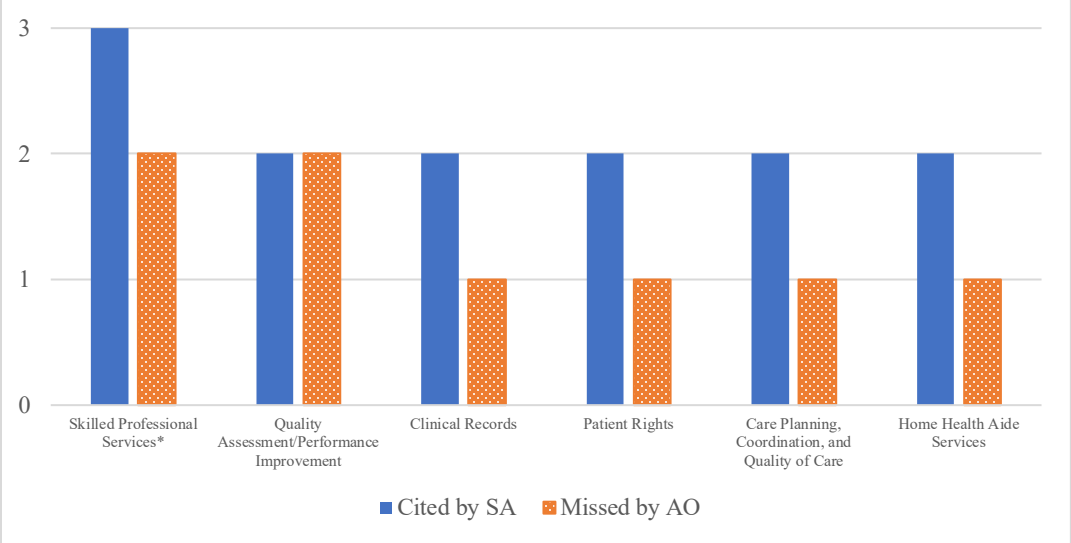
Graph 18: Top Five Condition-Level Deficiencies Most Frequently Cited on 60-Day Validation Surveys HHAs FY 2019



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

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

Graph 19: Top Five Condition-Level Deficiencies Most Frequently Cited on 60-Day Validation Surveys HHAs FY 2020

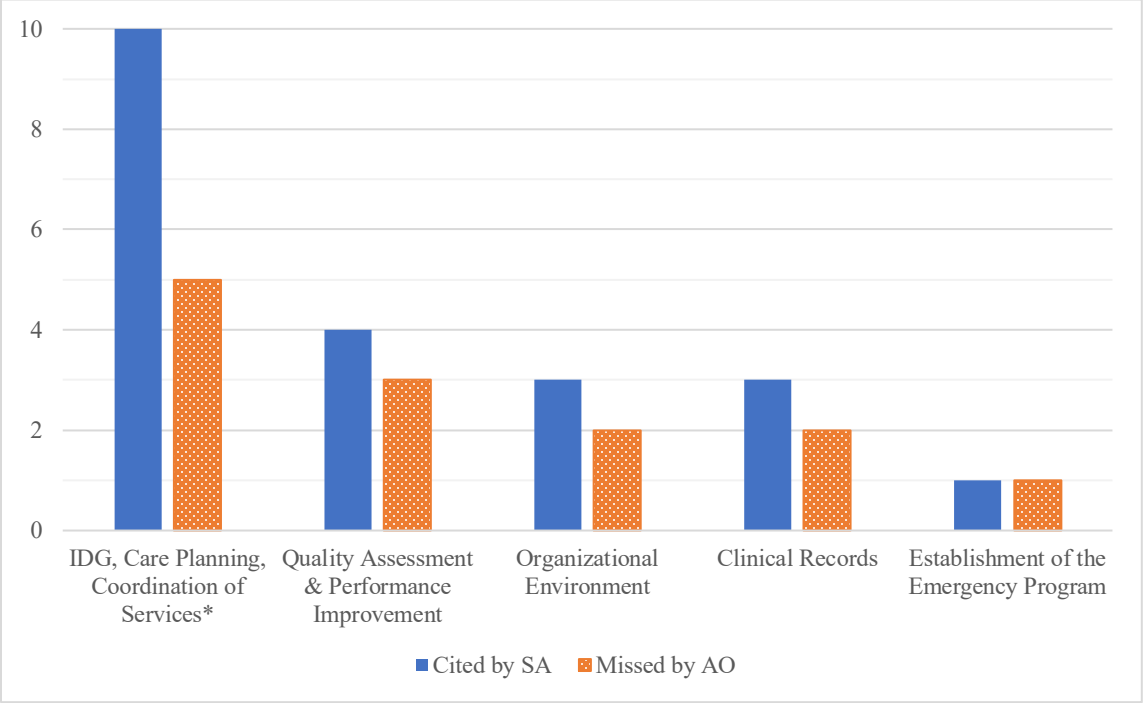


*Most frequently cited deficiency
Note: Four of the conditions all have one missed comparable; therefore, there are six categories and two disparate counts. FY 2020 includes validation surveys completed from October 1, 2019 – March 4, 2020.

In FY 2020, the HHA sample consisted of 33 validation surveys. In this sample, the SAs cited condition-level deficiencies in five agencies. The Skilled Professional Services requirement was cited at the condition level by the SAs three times. The AOs missed two comparable deficiencies. In FY 2019, the Care Planning, Coordination, and Quality of Care requirement was cited most frequently by the SAs at the condition level.

In FY 2020, the next most frequently SA-cited conditions were as follows: Quality Assessment/Performance Improvement requirement, Clinical Records requirement, Care Planning, Coordination, and Quality of Care requirement, Patient Rights, and Home Health Aide Services requirement, each cited two times by the SAs at the condition-level. Each was missed one time by the AOs with the exception of the Quality Assessment/Performance Improvement requirement. This requirement was missed two times by the AOs.

Graph 20: Top Five Condition-Level Deficiencies
Most Frequently Cited on 60-Day Validation Surveys
Hospices FY 2019

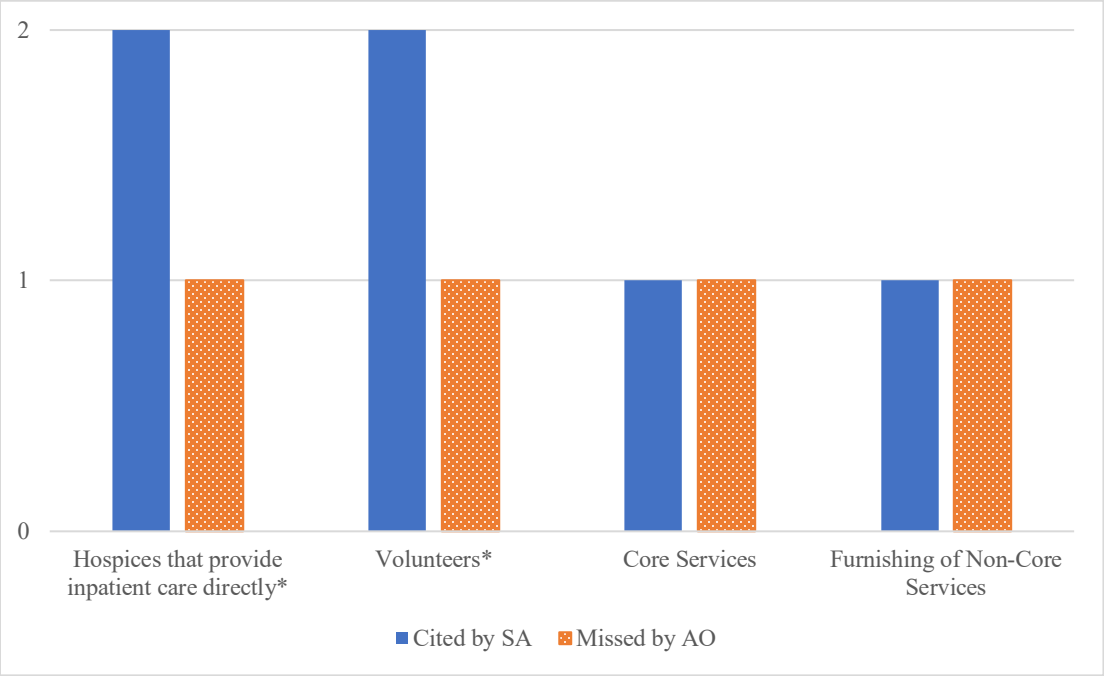


*Most frequently cited deficiency

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

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

Graph 21: Top Five Condition-Level Deficiencies Most Frequently Cited on 60-Day Validation Surveys Hospices FY 2020

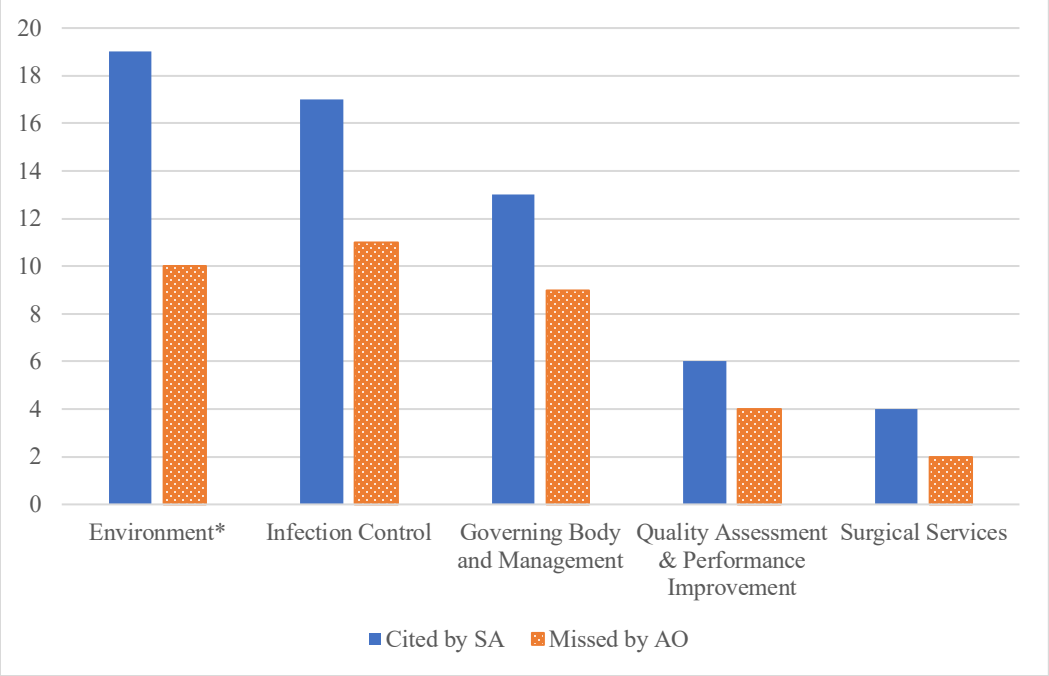


*Most frequently cited deficiency
Note: FY 2020 includes validation surveys completed from October 1, 2019 – March 4, 2020.

In FY 2020, the hospice sample consisted of 15 validation surveys. In this sample, the SAs cited condition-level deficiencies in three agencies. The Hospices that Provide Inpatient Care Directly requirement and the Volunteers requirement were cited at the condition level two times by the SAs. The AOs missed one comparable deficiency for each of the requirements. In FY 2019, the most frequently cited SA Condition was Care Planning, Coordination, and Quality of Care. In FY 2018, the Skilled Professional Services requirement was the most frequently SA-cited condition. In FY 2017, the Skilled Nursing Services requirement was cited most frequently by the SAs at the condition level. In FY 2016, the most frequently SA-cited Condition was Acceptance of Patients, Plan of Care & Medical Supervision.

In FY 2020, the next most frequently SA-cited conditions were as follows: Core Services and Furnishing of Non-Core Services, both cited one time by the SAs, and both missed one time by the AOs.

Graph 22: Top Five Condition-Level Deficiencies Most Frequently Cited on 60-Day Validation Surveys ASCs FY 2019

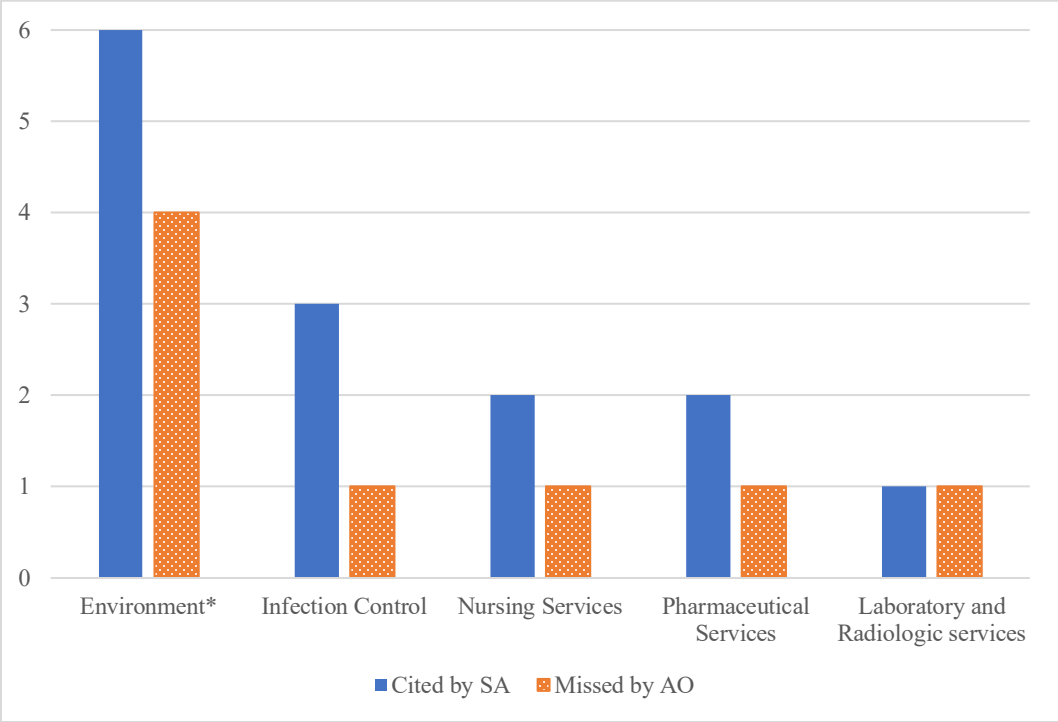


*Most frequently cited deficiency

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

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

Graph 23: Top Five Condition-Level Deficiencies Most Frequently Cited on 60-Day Validation Surveys ASCs FY 2020

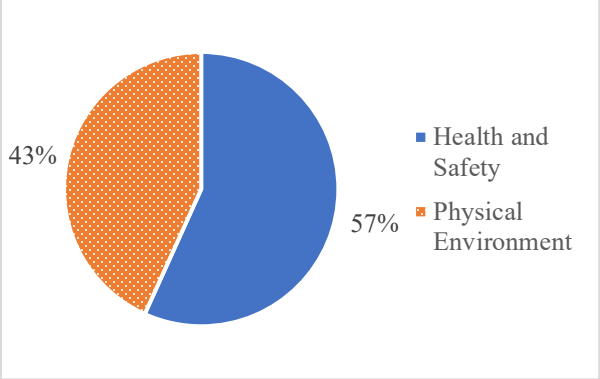


*Most frequently cited deficiency
Note: FY 2020 includes validation surveys completed from October 1, 2019 – March 4, 2020.

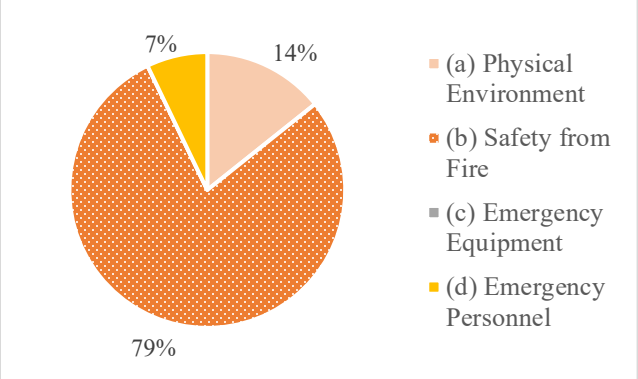
In FY 2020, the ASC sample consisted of 28 validation surveys. In this sample, the SAs cited condition-level deficiencies in five facilities. The SAs cited the PE requirement at the condition level six times. The AOs missed four comparable deficiencies for PE. In FYs 2017-2019, PE was the most frequently cited condition.

In FY 2020, the next most frequently SA-cited conditions were as follows: Infection Control, cited three times by the SAs, and missed one time by the AOs; and Nursing Services and Pharmaceutical Services, each cited two times by the SAs, and each missed one time by the AOs.

Graph 24: Percentage of Health and Safety vs PE Condition-Level Deficiencies Cited on 60- Day Validation Surveys ASCs FYs 2019–2020



Graph 25: Percentage of PE Standards Cited on 60-Day Validation Surveys ASCs FYs 2019–2020



Note: FY 2020 includes validation surveys completed from October 1, 2019 – March 4, 2020.

From FY 2019 to FY 2020, there were 31 validation surveys cited with condition-level deficiencies for ASCs. Of the 31 surveys, 21 of the surveys had health and safety citations, 16 of the surveys had PE citations, and six of the surveys were cited with both. For ASCs, the PE condition consists of four standards: (a) Physical Environment, (b) Safety from Fire, (c) Emergency equipment, and (d) Emergency Personnel. Eighteen standards were cited for the PE condition and 15 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 15-16 and Graph 26.)

Table 15: Number of 60-Day Validation Surveys for Facility Types with LSC Requirements FYs 2019-2020

Validation Survey Analysis	Hospital* FY 19	Hospital* FY 20	Psych Hospital FY 19	Psych Hospital FY 20	CAH FY 19	CAH FY 20	ASC FY 19	ASC FY 20
60-Day Validation Sample Surveys	99	40	20	5	13	12	67	28

*Acute Care and LTCHs

Note: FY 2020 includes validation surveys completed from October 1, 2019 – March 4, 2020.

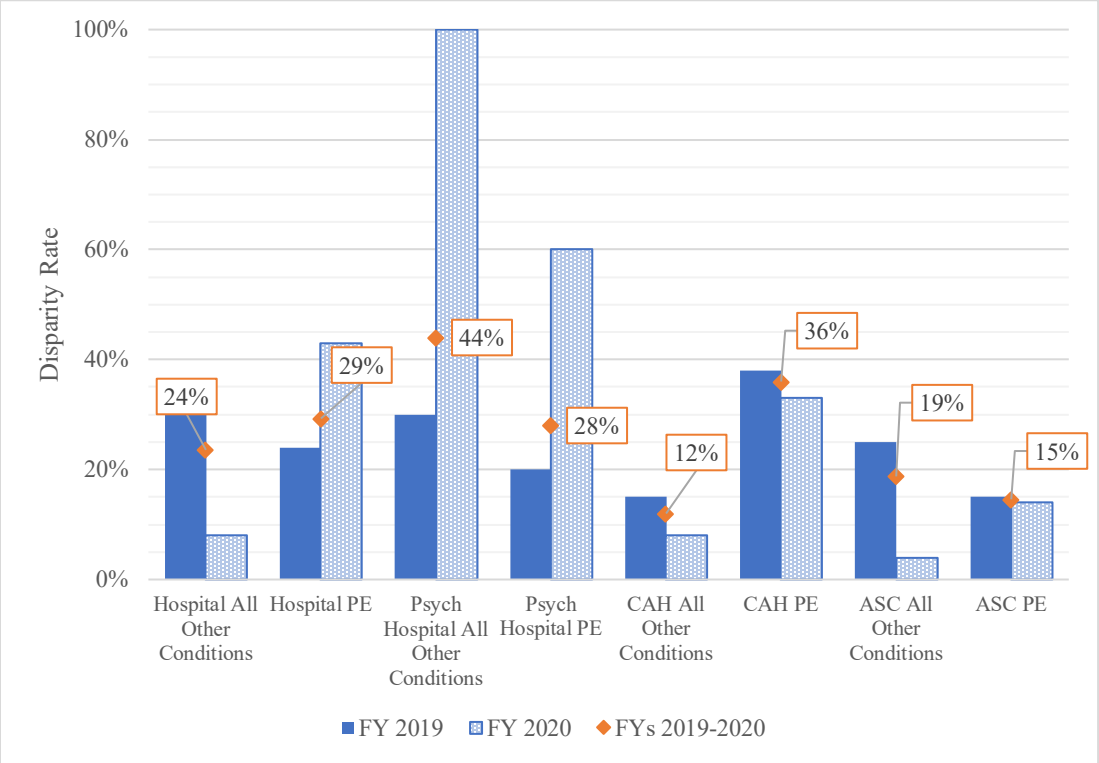
Table 16: 60-Day Validation Survey Results Comparison between All Other Conditions Cited and PE for Facility Types with LSC Requirements FYs 2019-2020

	Hospital All Other Conditions		Hospital PE		Psych Hospital All Other Conditions		Psych Hospital PE		CAH All Other Conditions		CAH PE		ASC All Other Conditions		ASC PE	
	FY 19	FY 20	FY 19	FY 20	FY 19	FY 20	FY 19	FY 20	FY 19	FY 20	FY 19	FY 20	FY 19	FY 20	FY 19	FY 20
SA Surveys with Condition-Level Deficiencies	31	6	31	17	9	5	4	3	3	1	5	4	19	2	12	4
AO Surveys with Missed Comparable Deficiencies	30	3	24	17	6	5	4	3	2	1	5	4	17	1	10	4
Disparity Rate	30%	8%	24%	43%	30%	100%	20%	60%	15%	8%	38%	33%	25%	4%	15%	14%

Note: FY 2020 includes validation surveys completed from October 1, 2019 – March 4, 2020.

In FY 2020, other health and safety conditions impacted the overall disparity rate for psychiatric hospitals. The disparity rate based on all other conditions for psychiatric hospitals is 40 percentage points higher than the PE disparity rate, as opposed to a 10 percent difference in these disparity rates in FY 2019. In FY 2020, the PE disparity rate for hospitals was 35 percentage points higher than the disparity rate for other health and safety conditions. In FY 2019, the PE disparity rate for hospitals was 6 percentage points lower than the disparity rate for other health and safety conditions. In FY 2020, the PE disparity rate for CAHs was 25 percentage points higher than the disparity rate for other health and safety conditions. In FY 2019, the PE disparity rate for CAHs was 23 percentage points higher than the disparity rate for other health and safety conditions. In FY 2020, the PE disparity rate for ASCs was 10 percentage points higher than the disparity rate for other health and safety conditions. In FY 2019, the PE disparity rate for ASCs was 10 percentage points lower than the disparity rate for other health and safety conditions. (See Graph 26.)

Graph 26: 60-Day Validation Survey Disparity Rate Results Comparison between All Other Conditions Cited and PE for Facility Types with LSC Requirements FYs 2019-2020

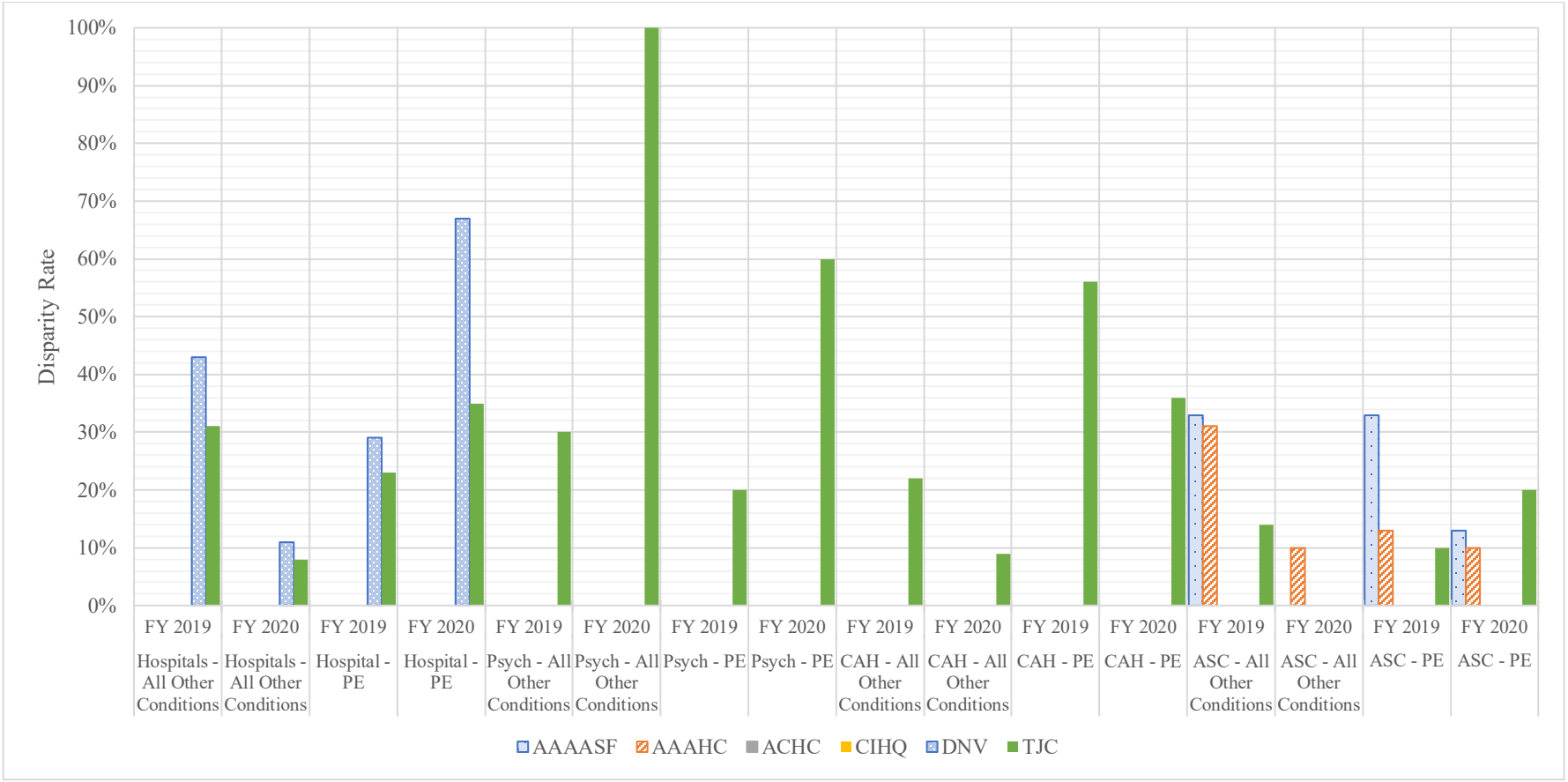


Note: FY 2020 includes validation surveys completed from October 1, 2019 – March 4, 2020.

The PE condition consists of PE standards which vary slightly depending upon the program type. However, the life safety from fire standard, or LSC deficiencies, is included in the PE condition for each of the program types with the exception of HHAs and in-home hospice care, as previously discussed. The majority of the PE disparity rates consist of these LSC deficiencies. CMS generates a report which identifies the top disparate LSC deficiencies as determined by the validation analysis. This report is provided annually to the AOs. These top LSC disparate deficiencies are consistent with deficiencies cited in FYs 2009 through FY 2020. This report is intended to provide the AOs with an understanding of the emphasis of CMS LSC surveys, which will allow the AOs to ensure their programs are appropriately surveying the same LSC provisions. An emphasis on the top disparate LSC deficiencies should assist the AOs in their efforts to reduce LSC disparities.

In past years, the AOs have had difficulty identifying deficiencies that SAs have cited related to the requirements in the 2012 edition of the LSC, which CMS adopted by regulation. However, in FY 2019 and FY 2020, the AO's PE disparity rates are lower than other health conditions for psychiatric hospitals. CMS has been working with the AOs to provide guidance on the source of this problem, and possible ways to improve performance and reduce their PE disparity rate. CMS has continued to discuss with the AOs their concerns as well as their performance in evaluating health care facility safety from fire. (See Graph 27.)

Graph 27: 60-Day Validation Survey Results Comparison between All Other Conditions cited and PE for Facility Types with LSC Requirements by AO FYs 2019-2020



*Only AOs having a validation survey sample size of five or more surveys for both FY 2019 and FY 2020 are included in the graph.
Note: FY 2020 includes validation surveys completed from October 1, 2019 – March 4, 2020.

Comparison of Deficiencies and Disparity Rates for Long-Term Care Hospitals and Acute Care Hospitals[12]

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.[13] (See Tables 17-19 and Graphs 28-31.) However, in FY 2020, CMS was unable to increase the LTCH sample size for 60-day representative sample surveys due to the COVID-19 PHE. In FY 2021, the total number of Medicare-participating LTCHs was 343 and the total number of Medicare-participating hospitals minus the LTCHs was 3,929.

[12] 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. Acute care hospitals do not include psychiatric hospitals.

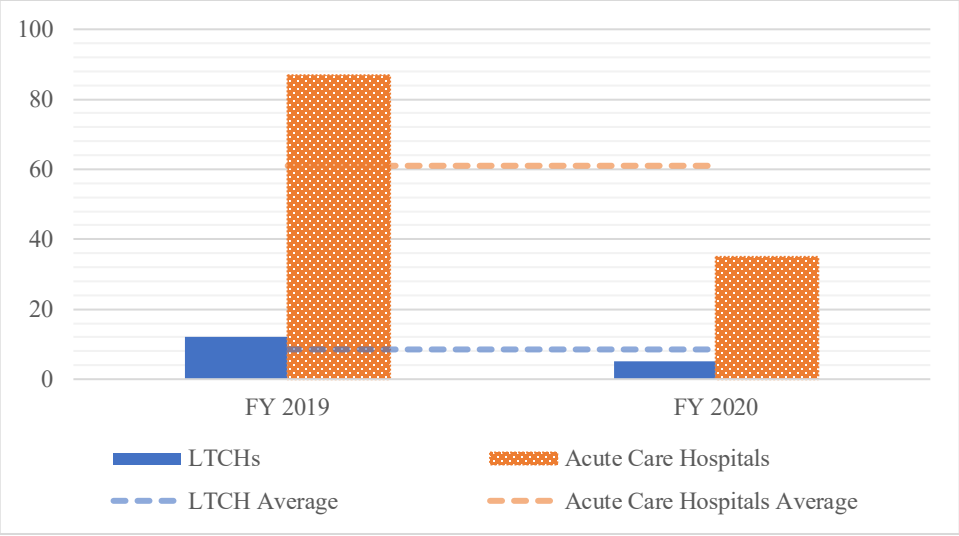
[13] "Long-Term Care Hospitals: CMS Oversight is Limited and Should be Strengthened," GAO, GAO-11-810, September 2011.

Table 17: Number of 60-Day Validation Surveys and Overall Disparity Rate LTCHs and Acute Care Hospitals FYs 2019–2020

	LTCHs FY 2019	LTCHs FY 2020	Acute Care Hospitals FY 2019	Acute Care Hospitals FY 2020	Average LTCHs FYs 2019–2020	Average Acute Care Hospitals FYs 2019–2020
60-Day Validation Sample Surveys	12	5	87	35	9	61
Overall Disparity Rate	**25%**	**20%**	**45%**	**49%**	**23%**	**47%**

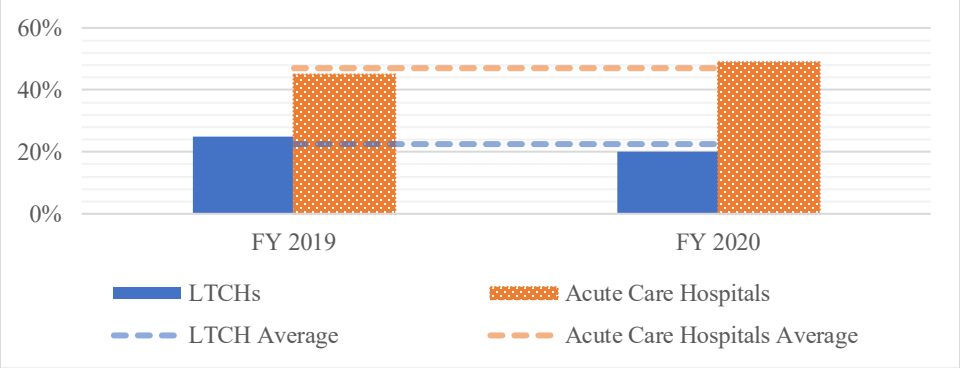
Note: FY 2020 includes validation surveys completed from October 1, 2019 – March 4, 2020.

Graph 28: Number of 60-Day Validation Surveys and Averages LTCHs and Acute Care Hospitals FYs 2019–2020



Note: Total number of Medicare-participating LTCHs is 343 and the total number of Medicare-participating acute care hospitals minus the LTCHs is 3,929. FY 2020 includes validation surveys completed from October 1, 2019 – March 4, 2020.

Graph 29: Overall Disparity Rates and Averages
LTCHs and Acute Care Hospitals FYs 2019-2020



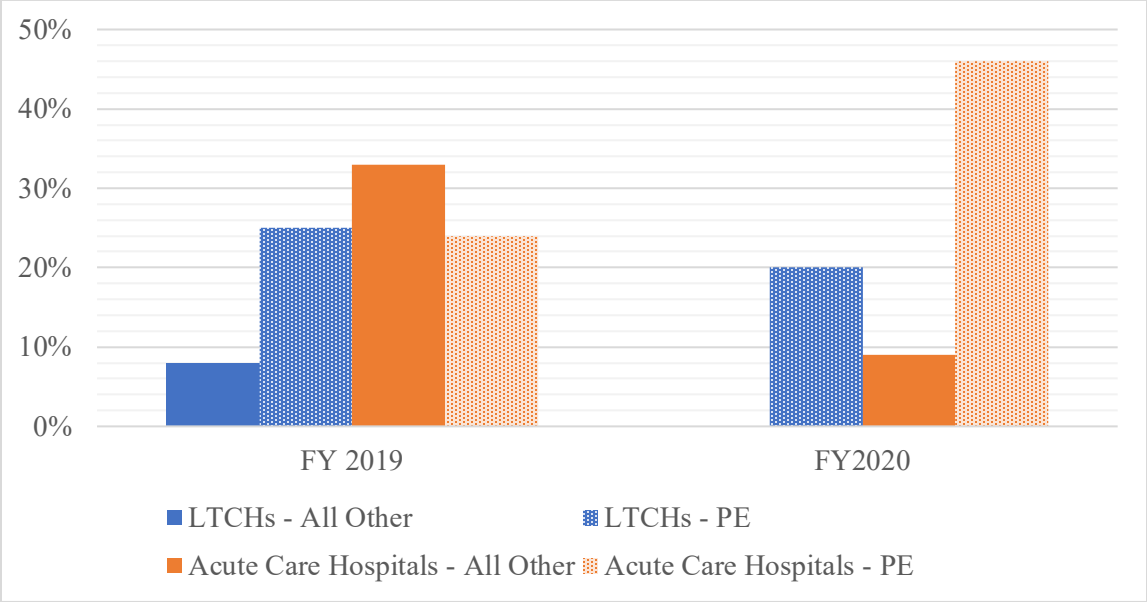
Note: Total number of Medicare-participating LTCHs is 343 and the total number of Medicare-participating acute care hospitals minus the LTCHs is 3,929. FY 2020 includes validation surveys completed from October 1, 2019 – March 4, 2020.

Table 18: Comparison of 60-Day Health and PE Validation Survey Results for LTCHs and Acute Care Hospitals FYs 2019–2020

Validation Survey Analysis	LTCHs All Other Conditions FY 2019	LTCHs All Other Conditions FY 2020	LTCHs PE FY 2019	LTCHs PE FY 2020	Acute Care Hospitals All Other Conditions FY 2019	Acute Care Hospitals All Other Conditions FY 2020	Acute Care Hospitals PE FY 2019	Acute Care Hospitals PE FY 2020
SA Surveys with Condition- Level Deficiencies	1	0	3	1	30	6	28	16
AO Surveys with Missed Comparable Deficiencies	1	0	3	1	29	3	21	16
Disparity Rate	**8%**	**0%**	**25%**	**20%**	**33%**	**9%**	**24%**	**46%**

Note: FY 2020 includes validation surveys completed from October 1, 2019 – March 4, 2020.

Graph 30: Comparison of 60-Day Health and PE Validation Survey Disparity Rate Results for LTCHs and Acute Care Hospitals FYs 2019-2020



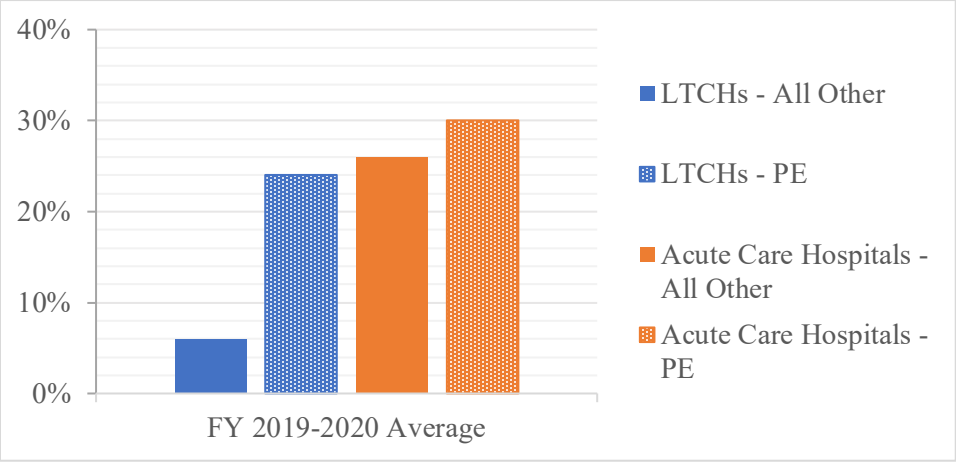
Note: FY 2020 includes validation surveys completed from October 1, 2019 – March 4, 2020.

Table 19: Comparison of Averages 60-Day Health and PE Validation Survey Results for LTCHs and Acute Care Hospitals FYs 2019–2020

	FYs 2019- 2020 Average LTCHs All Other Conditions	FYs 2019-2020 Average LTCHs PE	FYs 2019- 2020 Average Acute Care Hospitals All Other Conditions	FYs 2019- 2020 Average Acute Care Hospitals PE
SA Surveys with Condition-Level Deficiencies	0.50	2.00	18.00	22.00
AO Surveys with Missed Comparable Deficiencies	0.50	2.00	16.00	18.50
Disparity Rate	**6%**	**24%**	**26%**	**30%**

Note: FY 2020 includes validation surveys completed from October 1, 2019 – March 4, 2020.

Graph 31: Comparison of Averages 60-Day Health and PE Validation Survey Disparity Rate Results for LTCHs and Acute Care Hospitals FYs 2019-2020



Note: FY 2020 includes validation surveys completed from October 1, 2019 – March 4, 2020.

From FYs 2019–2020, there is an 18 percent difference between the overall average disparity rates in LTCHs' PE and other condition-level deficiencies, and a 4 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 for LTCHs and acute care hospitals. In FY 2020, PE is still the primary driver for acute care hospitals, comprising 46 percent of the disparity rate. For LTCHs, PE continues to be the primary driver in FY 2020, comprising 20 percent of the disparity rate.

In FY 2020, the most frequent disparate condition-level deficiencies for acute care hospitals and LTCHs were PE, Infection Control, Patient Rights, and Governing Body.

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 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 quarterly AO Liaison calls during which several topics are discussed, including disparity rate findings and possible solutions, as well as overall AO performance in other areas as described in Section 3. In March 2018, CMS initiated a validation redesign pilot (VRP) to overhaul the validation survey process. The VRP work group included CMS central office staff and CMS SOG Location staff, as well as management and staff from State Agencies and the AOs. (See Section 6 for more details). In August 2019, CMS placed the VRP pilot on hold to assess the data and lessons learned to make enhancements as needed. The VRP pilot resumed in FY 2024. CMS has also participated in AO surveyor training sessions, delivering analysis findings directly to the AO's survey cadre. In October 2018, CMS announced additional oversight initiatives to

increase oversight of the AOs.[14] To increase transparency for consumers, CMS will post new information on the CMS.Gov website, including: The latest quality-of-care deficiency findings following complaint surveys at facilities accredited by AOs; a list of providers determined by CMS to be out of compliance, with information included on the provider's AO; and overall performance data for AOs themselves.

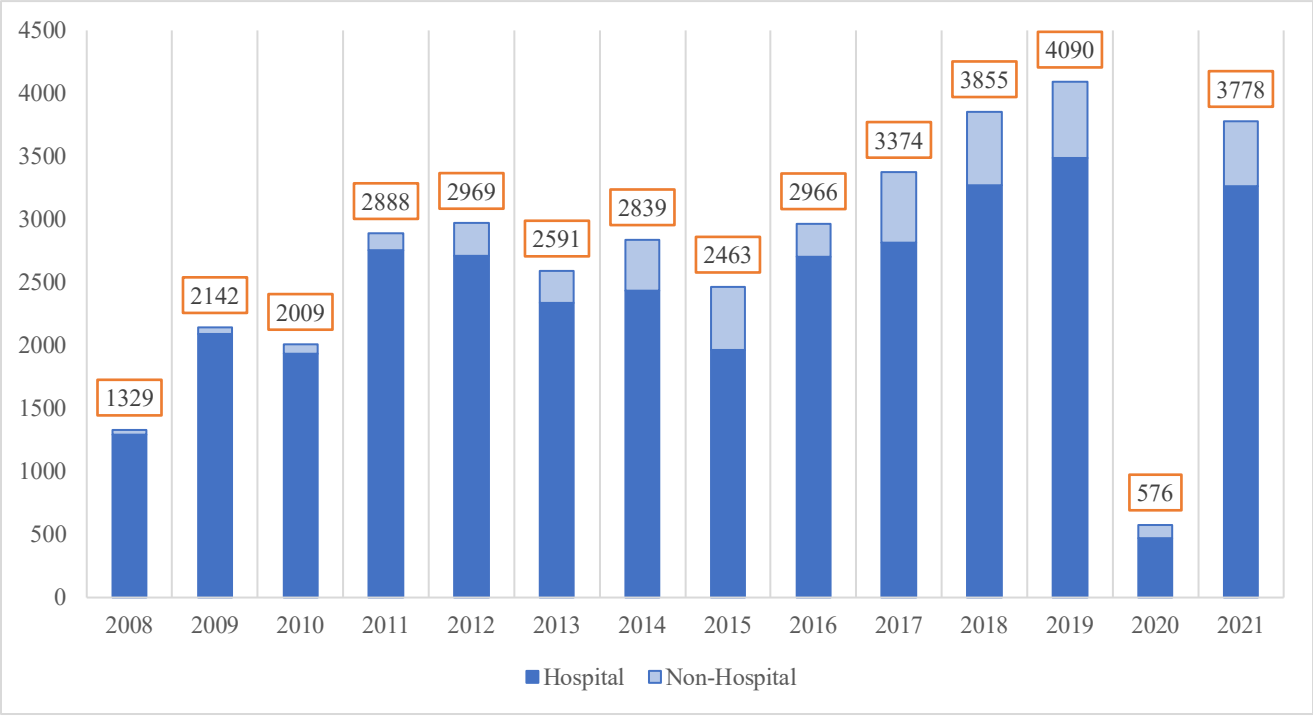
[14] https://www.cms.gov/newsroom/press-releases/cms-strengthen-oversight-medicares-accreditation-organizations

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

Background and Objectives

As discussed in Section 4 of this report, "complaint" surveys and representative sample validation surveys are the two validation survey types that comprise the Accreditation Validation Program. When a complaint is received based on allegations of noncompliance with the Medicare CoPs and CfCs, CMS performs a complaint survey to investigate the allegations. If the CMS Location determines it to be appropriate, a full survey of all the CoPs and CfCs will be conducted. In FY 2021, CMS conducted a total of 3,778 complaint surveys. This total comprised 3,266 hospital surveys, and 512 non-hospital complaint surveys. The non-hospital complaint surveys were specific to CAHs, HHAs, hospices and ASCs. (See Graph 32.)

Graph 32: Number of Complaint Surveys for Both Hospital and Non-Hospital Facilities FYs 2008-2021



The recent history of complaint surveys is as follows:

- 2008: 1,294 hospital and 35 non-hospital surveys totaling 1,329 surveys
- 2009: 2,089 hospital and 53 non-hospital surveys totaling 2,142 surveys
- 2010: 1,938 hospital and 71 non-hospital surveys totaling 2,009 surveys
- 2011: 2,755 hospital and 133 non-hospital surveys totaling 2,888 surveys
- 2012: 2,708 hospital and 261 non-hospital surveys totaling 2,969 surveys
- 2013: 2,338 hospital and 253 non-hospital surveys totaling 2,591 surveys
- 2014: 2,437 hospital and 402 non-hospital surveys totaling 2,839 surveys
- 2015: 1,968 hospital and 495 non-hospital surveys totaling 2,463 surveys
- 2016: 2,702 hospital and 264 non-hospital surveys totaling 2,966 surveys
- 2017: 2,814 hospital and 560 non-hospital surveys totaling 3,374 surveys
- 2018: 3,274 hospital and 581 non-hospital surveys totaling 3,855 surveys
- 2019: 3,491 hospital and 599 non-hospital surveys totaling 4,090 surveys
- 2020: 471 hospital and 105 non-hospital surveys totaling 576 surveys
- 2021: 3,266 hospital and 512 non-hospital surveys totaling 3,778 surveys

As discussed in Section 4, on March 4, 2020, CMS announced suspension of validation surveys across the country in response to the COVID-19 threat, allowing surveyors to focus on the most serious health and safety threats (e.g., infectious diseases and abuse) and address the spreading of COVID-19. On March 23, 2020, CMS further limited survey activity to focus on complaints and facility reported incidents (FRIs) at the immediate jeopardy level, while suspending the other survey types.[15] This change in focus accounts for the reduction of complaint surveys in FY 2020.

The results of the complaint surveys are stored in the ASPEN Complaints Tracking System (ACTS). CMS has been reviewing and analyzing the data stored in ACTS to provide an additional data source to validate the overall performance of the AOs. Graphs 34, 36, 38, 40, 41, and 42 highlight the top five condition-level deficiencies that were cited during complaint surveys on AO accredited facilities from FYs 2019-2021.

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

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

[15] https://www.cms.gov/medicareprovider-enrollment-and-certificationsurveycertificationgeninfopolicy- and/prioritization-survey-activities

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

Methodology

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

The PE summary report is similar to the health and safety summary report, but the PE summary report identifies and compares LSC categories and PE CoP and CfC 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 determined to be a disparate survey.

The data from the summary reports are 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 reported 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. As previously discussed in Section 4, a

validation survey is considered disparate when the AO has no comparable standard or condition-level finding(s) to support the SA condition-level deficiency. The AO does not receive credit for any other findings in their survey report. 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 conducted. 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. As discussed in Section 4, the FY 2020 validation surveys, non-emergent surveys, were suspended due to the COVID-19 PHE. For this reason, FY 2020 validation survey discussion throughout this section refers to validation surveys occurring October 1, 2019 – March 4, 2020. The significant reduction in the number of validation surveys performed across all program types resulted in higher than usual disparity rates for many of the AOs and in some cases statistically invalid data. There were no validation surveys conducted in FY 2021 due to the COVID-19 PHE.

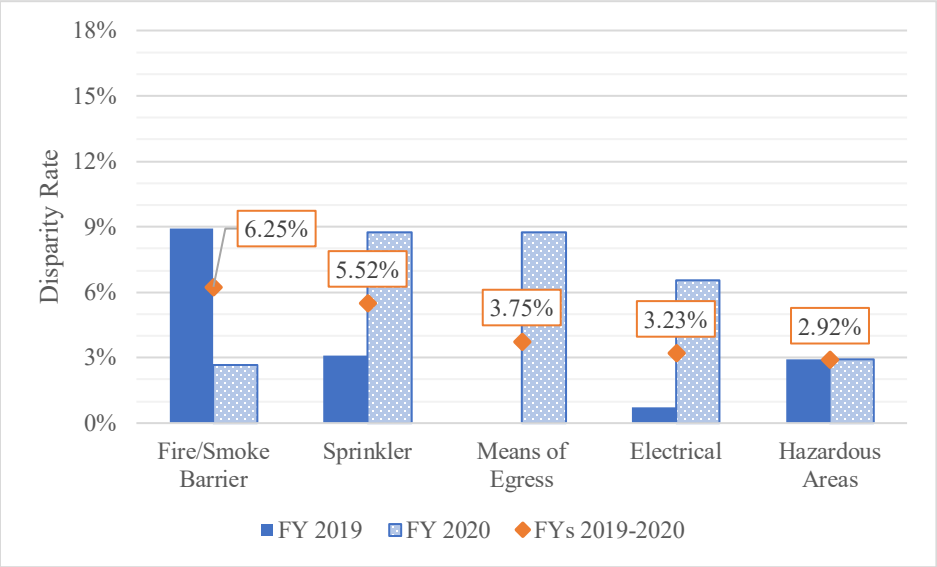
The SA performs their validation survey within 60 days of the AO survey which may influence the disparate findings. During the 60-day gap between the AO and SA survey, some factors beyond CMS's control may have changed, making it difficult to provide an accurate comparison for the facility surveys.

Findings

In FYs 2019-2020, the PE condition was the top disparate citation for hospitals and CAHs. 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, Hazardous Areas was in the top five missed citations for hospitals, psychiatric hospitals, ASCs and CAHs. The graphs below present, by program type, the top five LSC category disparity rates in FYs 2019-2020 and the top five condition-level deficiencies found during complaint surveys in FYs 2019-2021. (See Graphs 33-42.) The top five LSC categories are outlined in greater detail in Appendix B. The LSC category descriptions can be found in Appendix C.

Hospital and Long-Term Care Hospital

Graph 33: Top Five Hospital and LTCH LSC Category Disparity Rates FYs 2019–2020

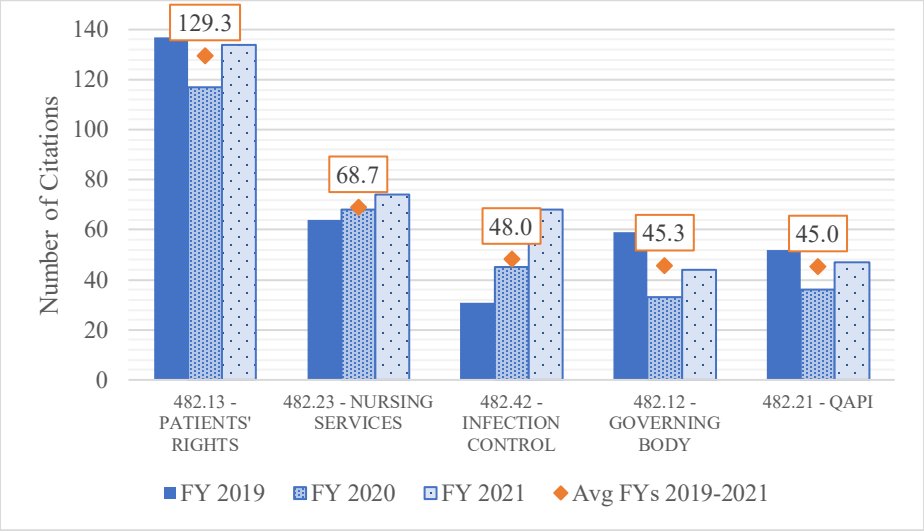


Note: FY 2020 includes validation surveys completed from October 1, 2019 – March 4, 2020.

In FYs 2019-2020, 139 hospital and LTCH validation surveys were performed and 960 LSC categories were cited by the SAs. The most frequently cited LSC category during that time was Sprinkler. During the same time period, the SA cited the Sprinkler category 165 times and the AOs missed 53 comparable citations resulting in a disparity rate of 5.52 percent. In FY 2020, the most frequently cited LSC category was Sprinkler, cited 70 times by the SA and missed 36 times by the AOs resulting in a disparity rate of 8.74 percent. The FY 2020 disparity rate is 5.64 percentage points higher than the FY 2019 Sprinkler disparity rate.

The top five disparate LSC categories found during LSC surveys for hospitals and LTCHs account for 62 percent of all the LSC category disparities cited in FYs 2019-2020.

Graph 34: Top 5 Hospital and LTCH Condition-Level Deficiencies Cited During Complaint Surveys FYs 2019-2021

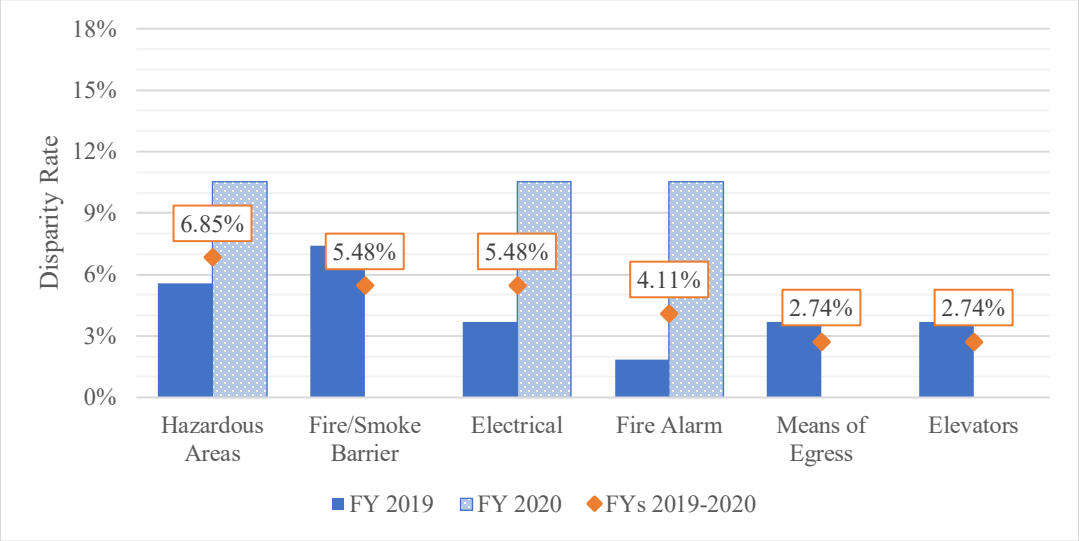


In FYs 2019-2021, there were 1,210 condition-level deficiencies cited for AO accredited hospital and LTCH facilities during complaint surveys. During that time, the most frequently cited condition was Patients' Rights, cited 388 times. The next most frequently cited conditions were Nursing Services, cited 206 times; and Infection Control, cited 144 times. In FY 2021, the most frequently cited condition was Patients' Rights, cited 134 times. In FY 2019 and FY 2020, the Patients' Rights requirement was cited at the condition level 137 times and 117 times respectively.

The top five condition-level deficiencies found during complaint surveys for hospitals and LTCHs account for 77 percent of all the conditions cited in FYs 2019-2021.

Psychiatric Hospital

Graph 35: Top Five Psychiatric Hospital LSC Category Disparity Rates FYs 2019–2020

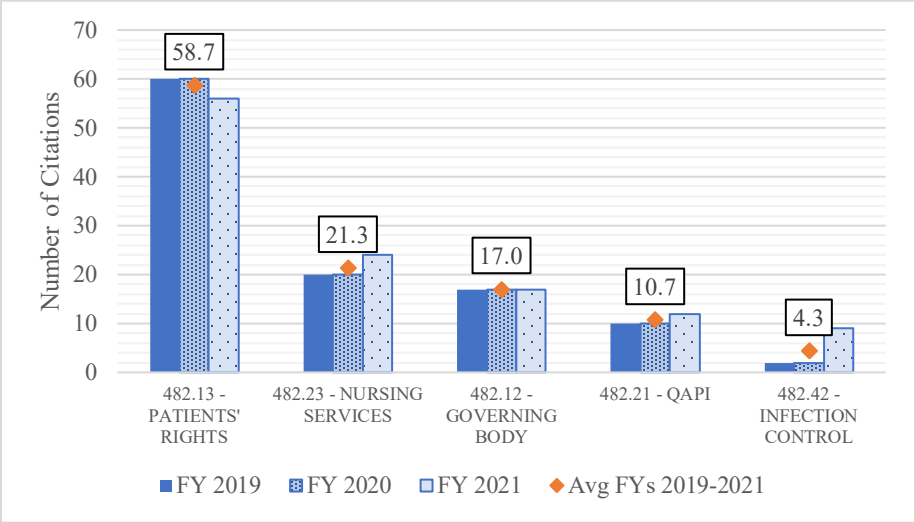


Note: Means of Egress and Elevators LSC categories have two missed comparable citations by the AO. Thus, there are six categories and four disparate counts in the graph. FY 2020 includes validation surveys completed from October 1, 2019 – March 4, 2020.

In FYs 2019-2020, 25 psychiatric hospital validation surveys were performed and 73 LSC categories were cited by the SAs. The most frequently cited LSC category during that time was Fire/Smoke Barrier. The SA cited the Fire/Smoke Barrier category 16 times. The AOs missed four comparable citations resulting in a disparity rate of 5.48 percent. In FY 2020, the most frequently cited LSC category was Electrical, cited five times by the SA and missed two times by the AOs. The FY 2020 disparity rate was 6.83 percentage points higher than the FY 2019 Electrical disparity rate.

The top five disparate LSC categories found during LSC surveys for psychiatric hospitals account for 80 percent of all the LSC category disparities cited in FYs 2019-2020.

Graph 36: Top 5 Psychiatric Hospital Condition-Level Deficiencies Cited During Complaint Surveys FYs 2019–2021

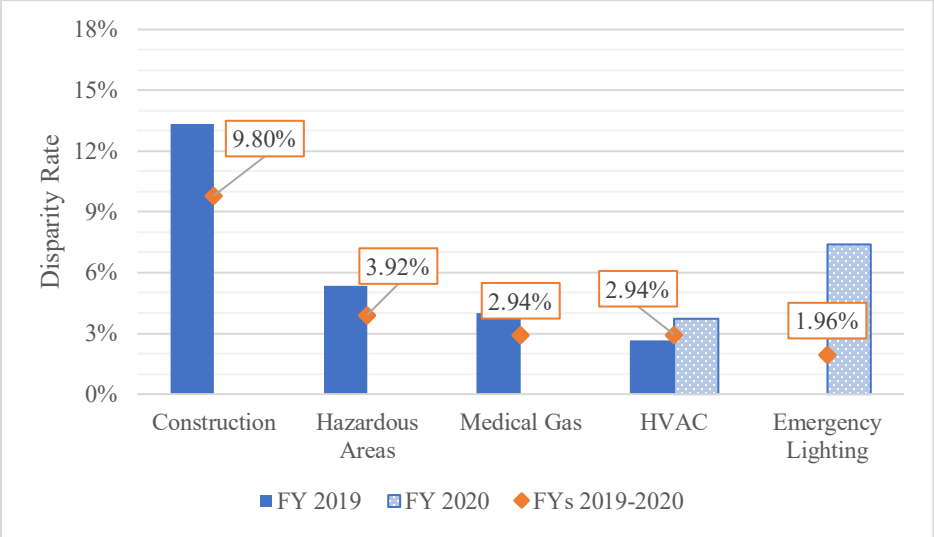


In FYs 2019-2021, there were 362 condition-level deficiencies cited for AO accredited psychiatric hospital facilities during complaint surveys. During that time, the most frequently cited condition was Patients' Rights, cited 176 times. The next most frequently cited conditions were Nursing Services, cited 64 times; and Governing Body, cited 51 times. In FY 2021, the most frequently cited condition was Patients' Rights, cited 56 times. In FY 2019 and FY 2020, the Patients' Rights requirement was cited at the condition level 60 times.

The top five condition-level deficiencies found during complaint surveys for psychiatric hospitals account for 89 percent of all the conditions cited in FYs 2019-2021.

Ambulatory Surgery Center

Graph 37: Top Five ASC LSC Category Disparity Rates
FYs 2019–2020

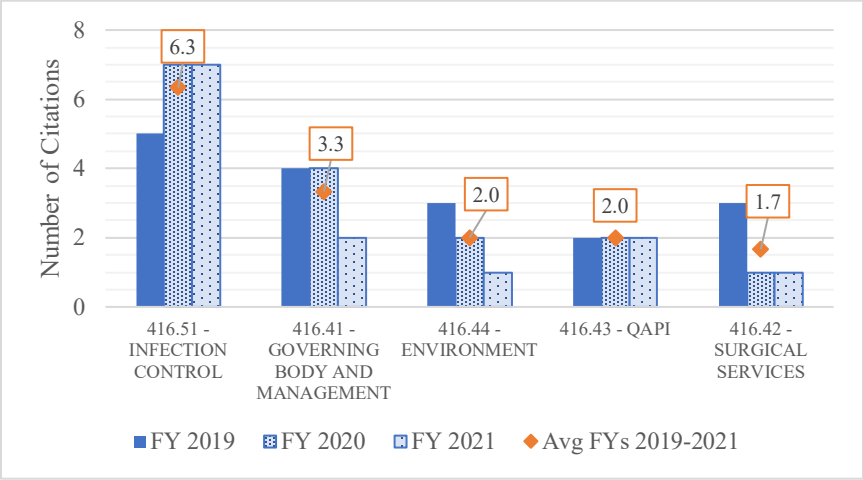


Note: FY 2020 includes validation surveys completed from October 1, 2019 – March 4, 2020.

In FYs 2019-2020, 95 ASC validation surveys were performed and 102 LSC categories were cited by the SAs. The most frequently cited LSC category during that time was Construction. The SA cited the Construction category 11 times. The AOs missed 10 comparable citations resulting in a disparity rate of 9.80 percent. In FY 2020, the most frequently cited LSC category was Emergency Lighting. The SA cited the Emergency Lighting category four times. The AOs missed two comparable citations resulting in a disparity rate of 7.41 percent. In FY 2019, both the SA and AOs cited the Emergency Lighting category three times. In FY 2019, the Emergency Lighting LSC category was not disparate.

The top five disparate LSC categories found during LSC surveys for ASCs account for 79 percent of all the LSC category disparities cited in FYs 2019-2020.

Graph 38: Top 5 ASC Condition-Level Deficiencies Cited During Complaint Surveys FYs 2019-2021

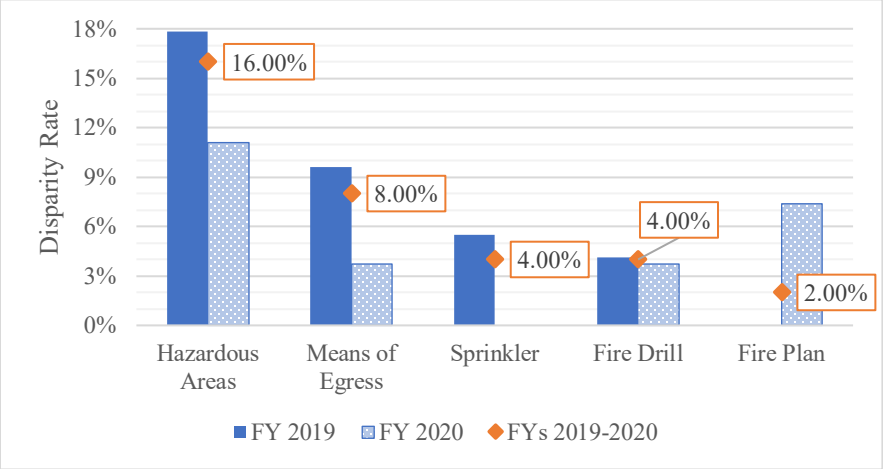


In FYs 2019-2021, there were 56 condition-level deficiencies cited for AO accredited ASCs during complaint surveys. During that time, the most frequently cited condition was Infection Control, cited 19 times. The next most frequently cited condition was Governing Body and Management, cited 10 times. In FY 2021, the most frequently cited condition-level deficiency was Infection Control, cited seven times. In FY 2019 and FY 2020, the Infection Control requirement was cited at the condition level five times and seven times respectively.

The top five condition-level deficiencies found during complaint surveys for ASCs account for 91 percent of all the conditions cited in FYs 2019-2021.

Critical Access Hospital

Graph 39: Top Five CAH LSC Category Disparity Rates FYs 2019–2020

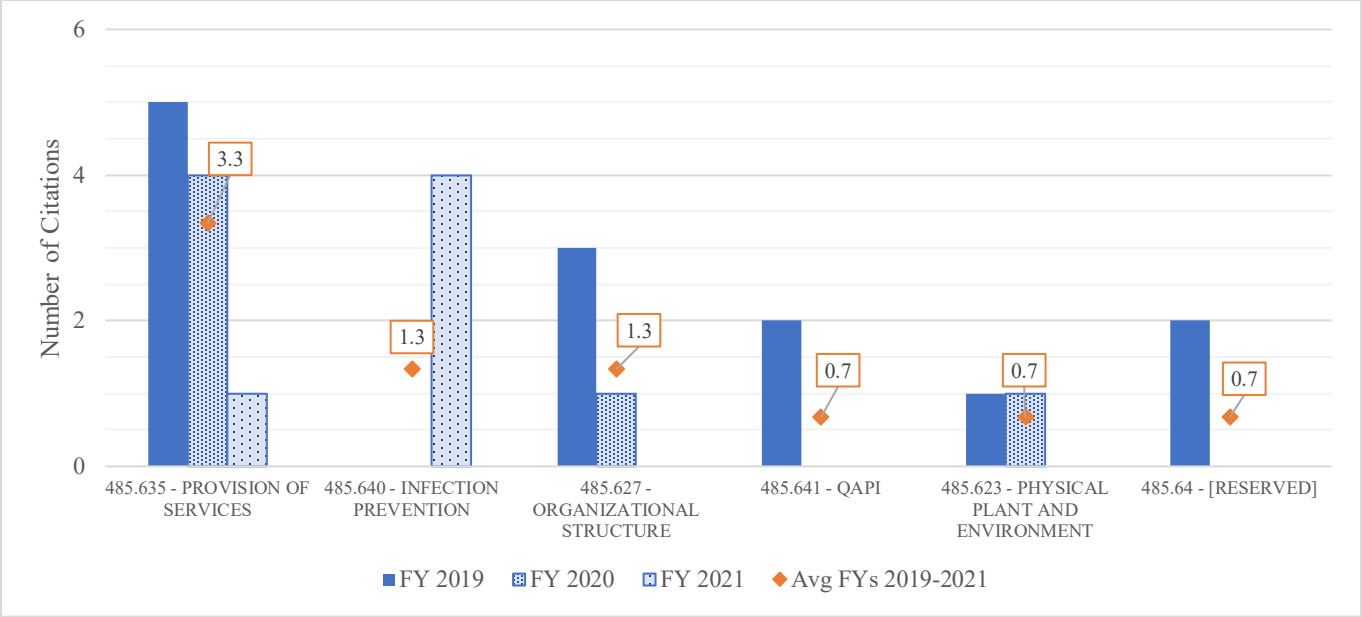


Note: FY 2020 includes validation surveys completed from October 1, 2019 – March 4, 2020.

In FYs 2019-2020, 25 CAH validation surveys were performed and 100 LSC categories were cited by the SAs. The most frequently cited LSC category during that time was Sprinkler. The SA cited the Sprinkler category 18 times. The AOs missed four comparable citations resulting in a disparity rate of 4.00 percent. In FY 2020, the most frequently cited LSC category was Hazardous Areas, cited three times by the SA and missed three times by the AOs resulting in a disparity rate of 11.11 percent. The FY 2020 Hazardous Areas disparity rate is 6.7 percentage points lower than the FY 2019 Hazardous Areas disparity rate.

The top five disparate LSC categories found during LSC surveys for CAHs account for 89 percent of all the LSC category disparities cited in FYs 2019-2020.

Graph 40: Top 5 CAH Condition-Level Deficiencies Cited During Complaint Surveys FYs 2019–2021



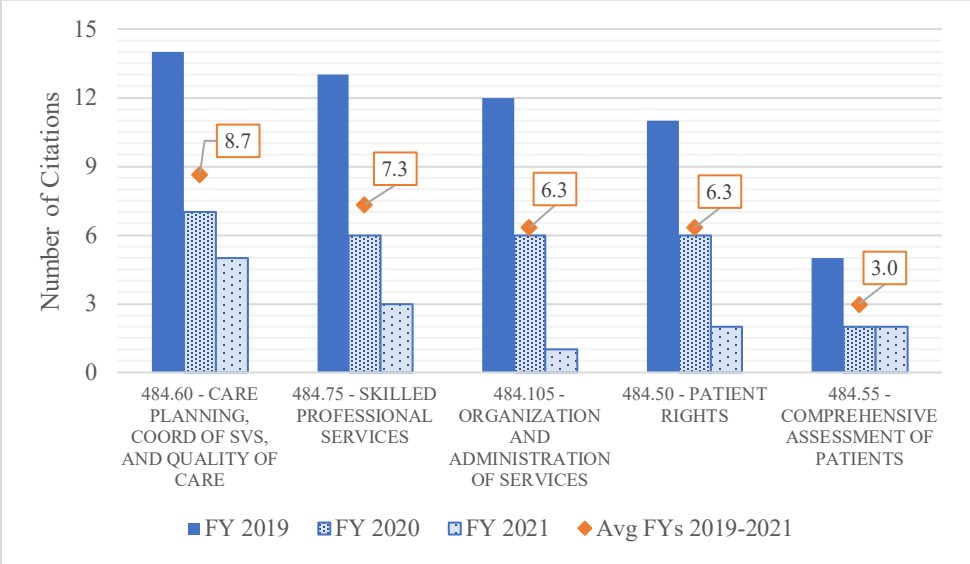
Note: QAPI, Physical Plane and Reserved LSC categories have two missed comparable citations by the AO. Therefore, there are six categories and three disparate counts included in the graph.

In FYs 2019-2021, there were 26 condition-level deficiencies cited for AO accredited CAHs during complaint surveys. During that time, the most frequently cited condition was Provision of Services, cited 10 times. The next most frequently cited conditions were Organizational Structure, and Infection Prevention cited four times. In FY 2021, the most frequently cited condition was Infection Prevention, cited four times. In FYs 2019 and 2020, Infection Prevention was not cited.

The top five condition-level deficiencies found during complaint surveys for CAHs account for 92 percent of all the conditions cited in FYs 2019-2021.

Home Health Agency

Graph 41: Top 5 HHA Condition-Level Deficiencies Cited During Complaint Surveys FYs 2019–2021

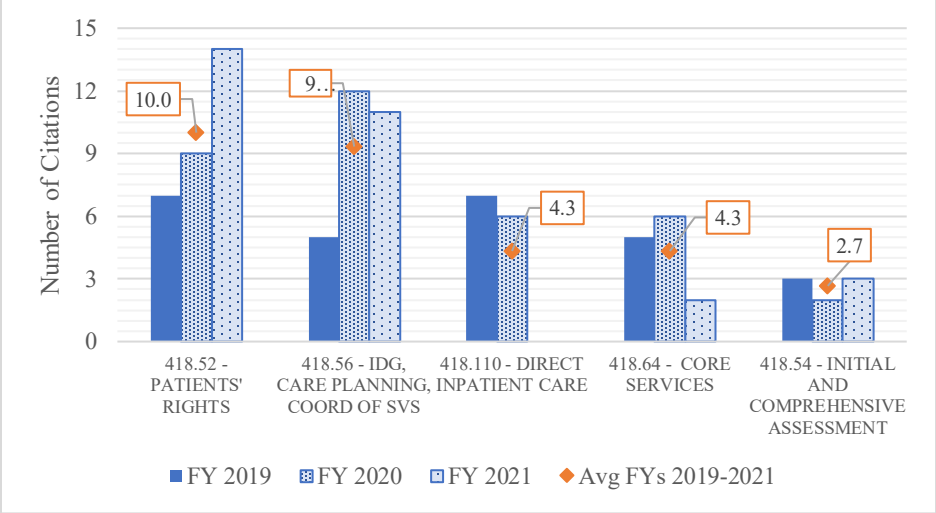


In FYs 2019-2021, there were 124 condition-level deficiencies cited for AO accredited HHAs during complaint surveys. During that time, the most frequently cited condition was Care Planning, Coordination of Services, and Quality of Care, cited 26 times. The next most frequently cited condition was Skilled Professional Services, cited 22 times. In FY 2021, the most frequently cited condition was Care Planning, Coordination of Services, and Quality of Care, cited five times. FYs 2019 and 2020, the number of Care Planning, Coordination of Services, and Quality of Care requirement citations were 14 and seven respectively.

The top five condition-level deficiencies found during complaint surveys for HHAs account for 77 percent of all the conditions cited in FYs 2019-2021.

Hospice

Graph 42: Top 5 Hospice Condition-Level Deficiencies Cited During Complaint Surveys FYs 2019–2021



In FYs 2019-2021, there were 123 condition-level deficiencies cited for AO accredited hospice facilities during complaint surveys. During that time, the most frequently cited condition was Patients' Rights, cited 30 times. The next most frequently cited condition was IDG, Care Planning, Coordination of Services, cited 28 times. In FY 2021, the most frequently cited condition was Patients' Rights, cited 14 times. FYs 2019 and 2020, the number of Patients' Rights requirement citations was seven and nine respectively.

The top five condition-level deficiencies found during complaint surveys for hospice facilities account for 68 percent of all the conditions cited in FYs 2019-2021.

Conclusion

CMS has identified the top conditions and LSC categories driving the disparity rate. The PE/Environment requirement is one of the leading disparate conditions for hospitals and CAHs in FYs 2019-2020, accounting for 30 percent and 36 percent of all disparate surveys respectively during that time. The largest portion of the PE/Environment condition-level findings are LSC related. The SA and AO LSC survey validation findings are divided into various categories for analysis and comparison, yielding the top five disparate LSC categories. In FYs 2019-2020, Hazardous Areas was included in the top five disparate categories for hospitals, psychiatric hospitals, ASCs and CAHs. In FYs 2019-2020, Fire Smoke Barrier is the top disparate LSC category which accounts for 17 percent of all the missed LSC category citations during that time. Sprinkler is the second highest top disparate LSC category in FYs 2019-2020 and accounts for nearly 15 percent of the missed LSC category citations during that time. Fire/Smoke Barrier, Sprinkler, Means of Egress, Hazardous Areas, and Electrical are the top five missed LSC citations for the PE/Environment conditions. These top five disparities account for 62 percent of all the missed LSC category citations.

A comparison of AOs having five or more validation surveys for a given program type in both FY 2019 and FY 2020 are discussed below. Those AOs include AAAASF, AAAHC, DNV, and TJC.

Among the AOs with a CMS-approved hospital and LTCHs accreditation program, DNV-GL had the highest average health and safety disparity rate, 27 percent, and the highest average PE disparity rate, 48 percent. For AOs with CMS-approved ASC accreditation programs, AAAHC had the highest average health and safety disparity rate, 21 percent, while AAASF had the highest average PE disparity rate at 23 percent.

The Joint Commission is the only AO CMS-approved CAH accreditation program having a valid survey sample size. TJC's average health and safety disparity rate and PE disparity rate were 16 percent and 46 percent respectively.

Recommendations

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

If the AOs were to focus on their top disparate conditions, they would have an opportunity to positively impact their disparity rate. For example, in FY 2019, if the AOs would address the top five disparate conditions for hospitals, they could potentially eliminate 78 percent of the disparate citations.

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

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 2021. Currently, 34 percent (15,143 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. As of September 30, 2021, there are currently nine CMS-recognized AOs and 24 approved accreditation programs.

CMS has worked to enhance systems and processes to ensure a robust and consistent approach to its monitoring and oversight of CMS-recognized AO performance and activities of their approved accreditation programs. In FY 2021, 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

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

Communication

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

Consultation

CMS increased opportunities for AOs as well as other stakeholders to provide input into the development of sub-regulatory guidance concerning Medicare standards and survey processes. AOs and other key stakeholders are provided the opportunity to review and provide comment on guidance prior to release. CMS has committed to ongoing consultation with the AOs and stakeholders in an effort to improve the resulting guidance. For example, CMS engaged on guidance for OPT Appendix G of the State Operations Manual (SOM) and Chapters 2 and 3, under development. CMS also consulted with AOs and stakeholders on various other policy guidance for emergency preparedness, Quality Assessment and Performance Improvement (QAPI) and infection control and antibiotic stewardship for hospitals and CAHs, as well as hospice updates based on implementation of the CAA, certification transition work, and continuously engages with AOs through CMS' CMS/AO Liaison Program.

Accrediting Organization Education

CMS affords AO staff many opportunities for education. CMS provides detailed written and verbal feedback to the AOs as part of the deeming application and data review processes. This feedback includes specific references to Medicare regulatory requirements as well as the SOM references and attachments. Formal education is provided periodically at the request of individual AOs. AOs are also provided the opportunity to participate in face-to-face as well as online SA surveyor training which can be accessed at https://qsep.cms.gov/welcome.aspx. In addition to quarterly AO liaison calls, CMS held weekly to biweekly calls to discuss survey activities and provide guidance during the COVID-19 PHE.

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

Interoperability

Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Interoperability and Patient Access for Medicare Advantage Organization and Medicaid Managed Care Plans, State Medicaid Agencies, CHIP Agencies and CHIP Managed Care Entities, Issuers of Qualified Health Plans on the Federally-facilitated Exchanges, and Health Care Providers (85 FR 25510, May 1, 2020). The final rule is known as the "Interoperability Final Rule" and impacts hospital provisions at 42 C.F.R. 482.24(d), psychiatric hospital provisions at 42 C.F.R. 482.61(f) and CAH provisions at 42 C.F.R. 485.638(d). This final rule can be accessed at https://www.govinfo.gov/content/pkg/FR-2020-05-01/pdf/2020-05050.pdf.

While the final rule was published in FY 2020, CMS did not require the AOs to crosswalk and submit their comparable standards for the revised hospital, psychiatric hospital, and CAH standards until FY 2021. (See Table 1.)

Emergency Preparedness Guidelines

On March 26, 2021, CMS released interpretive guidelines and updates to Appendix Z of the SOM as a result of the revisions to the *Medicare and Medicaid Programs; Regulatory Provisions to Promote Program Efficiency, Transparency, and Burden Reduction (CoPs) (CMS 3346-F) Final Rule*, specifically adjustment of cycles of updates required for non-long term care providers and changes to the training and testing program. Due to the COVID-19 PHE, CMS also expanded Emerging Infectious Diseases (EIDs) guidance related to practices, lessons learned, and planning considerations.[16]

COVID-19 Staff Vaccine Requirements

CMS published an interim final rule with comment period (IFC) on November 5, 2021, which can be accessed at 86 FR 61555. This interim final rule required certain providers and suppliers participating in the Medicare and Medicaid programs to ensure staff were fully vaccinated for COVID-19, unless exempt, because vaccination of staff was necessary for the health and safety of individuals to whom

[16] QSO-21-15-ALL (https://www.cms.gov/files/document/qso-21-15-all.pdf)

care and services were furnished. Along with this emergency regulation, CMS developed and issued a number of policy memos that outlined facility requirements and provided surveyor guidance on the expected approach to be taken when assessing compliance with these requirements. Memos QSO-22-07-ALL (published December 28, 2021), QSO - 22-09-ALL (published January 14, 2022), and QSO-22-11-ALL (published January 20, 2022) all provided the same guidance on the new interim regulations as described above. It is important to note that QSO-23-02-ALL (published October 26, 2022) superseded the previously published memos, providing updated information and guidance on survey processes and interpretation of the interim rule. This memo later expired on June 5, 2023.

Validation Redesign Pilot Project

In March 2018, CMS appointed a workgroup to redesign the validation survey process. The overall goal of the validation redesign pilot (VRP) is to redesign the validation program where the SAs evaluate the ability of the AO surveyors to survey for compliance to CMS conditions versus conducting a second survey of the facility, as is the current practice. Facilities will be surveyed simultaneously by the AO and SA, using the same Medicare certification full survey process (e.g., surveying for compliance with the Medicare CoPs or CfCs). Using the CMS/AO Observation Worksheet and Rating Guide developed by CMS, the SA surveyor team evaluates the skill, knowledge, and performance of the AO's survey process and score the AO accordingly. There will be no separate SA validation survey conducted. SA surveyors/observers will complete an AO Observation worksheet and abbreviated 2567 upon completion of the AO survey. The AO will provide the survey report with the POCs going to the SOG Locations. The data from the CMS/AO Observation worksheet will be used for the disparity data report. During the FY 2019 reporting period, there were a total of 24 VRP direct observation validation surveys conducted. In August 2019, CMS placed the VRP pilot on hold to assess the data and lessons learned to make enhancements to the process as needed. The VRP pilot resumed in FY 2024. Following completion of the surveys and analysis of the findings, the outcomes will be discussed in future reports.

SECTION 7: Clinical Laboratory Improvement Amendments of 1988 (CLIA) Validation Program

Introduction

CLIA expanded survey and certification of clinical laboratories from interstate commerce laboratories to most facilities testing and reporting out human specimens, regardless of location. The Secretary regulates testing by these laboratories whether the testing is provided to beneficiaries of CMS programs or to others, including certain testing performed in physicians' offices, for a total of 323,086 CLIA-certified facilities at the end of calendar year (CY) 2021. 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 complexity, 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 18,060 CLIA-certified laboratories every 2 years. CMS-approved AOs conduct on-site surveys of an additional 15,192 laboratories every 2 years as well. Data from these inspections reflect significant improvements in the quality of testing over time. The CLIA program is 100 percent user-fee financed, and is jointly administered by three HHS components: (1) CMS manages the financial aspects, contracts and trains state surveyors to inspect labs, and oversees program administration including enrollment, fee assessment, regulation and policy development, approval of AOs, exempt states and proficiency testing providers, certificate generation, enforcement and data system design; (2) the Centers for Disease Control and Prevention (CDC) conducts research, provides scientific and technical support, jointly develops regulations with CMS, develops and disseminates educational materials, and coordinates the Secretary's Clinical Laboratory Improvement Advisory Committee (CLIAC); and (3) the Food and Drug Administration (FDA) performs test categorization, including waiver approvals.

This report on the CLIA Validation Program covers the evaluations of FY 2021 performance by the seven AOs approved by CMS under CLIA. The seven organizations are:

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

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

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

Legislative Authority and Mandate

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

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

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

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

The CLIA regulations, at 42 CFR § 493.575, provide that if the validation inspection results over a 1-year period indicate a rate of disparity[17] 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

[17] 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 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.

Validation Reviews

The validation review methodology focuses on the actual implementation of an organization's accreditation program, which is described in its request for approval as an AO. Those standards are reviewed as a whole, and, if appropriate, are approved by CMS as being equivalent to or more stringent than the CLIA condition-level requirements.[18] This equivalency is the basis for CMS granting the AO its deeming authority.

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

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

Number of Validation Surveys Performed

As directed by the CLIA statute, Section 353(e)(2)(D)(i) of the PHS Act, the number of validation surveys should be sufficient to "allow a reasonable estimate of the performance" of each AO. A representative sample of approximately 15,192 accredited laboratories received a validation survey in 2021. 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, approximately 466 of the accredited laboratories used AABB, A2LA, ACHC, or ASHI accreditation for CLIA purposes. Given these proportions, combined with the challenge the COVID-19 PHE presented for surveyors to complete a minimal sample size, 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

[18] 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.

by COLA, CAP, or TJC, thus the sample sizes for these organizations were larger. Due to the COVID-19 PHE, CLIA validations surveys were placed "on hold" from March 2020 through September 2021. Typically, 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 results presented in this section represent the limited number of surveys selected.

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

Results of the Validation Reviews of Each Accrediting Organization AABB

Rate of disparity: N/A

In FY 2021, approximately 226 laboratories used their AABB accreditation for CLIA program purposes. No validation surveys were conducted during this survey cycle, so no additional data is reported. (See Table 20.)

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. In FY 2021, 4 laboratories used their A2LA accreditation for CLIA purposes. No validation surveys were conducted during this survey cycle, so no additional data is reported. (See Table 20.)

Accreditation Commission for Health Care

Rate of disparity: N/A

In FY 2021, approximately 116 laboratories used their ACHC accreditation. No validation surveys were conducted during this survey cycle, so no additional data is reported. (See Table 20.)

American Society for Histocompatibility and Immunogenetics

Rate of disparity: N/A

In FY 2021, approximately 120 laboratories used their ASHI accreditation for CLIA purposes. No validation surveys were conducted during this survey cycle, so no additional data is reported. (See Table 20.)

College of American Pathologists

Rate of disparity: N/A

In FY 2021, approximately 6,677 laboratories used their CAP accreditation for CLIA program purposes. A total of 11 validation surveys were conducted in CAP-accredited laboratories. One laboratory was cited with condition-level deficiencies. The survey was removed for administrative purposes. None of the 10 remaining laboratories were cited with CLIA condition-level deficiencies, so no additional data is reported. (See Table 20.)

COLA

Rate of disparity: 0 percent

In FY 2021, approximately 5,930 laboratories used their COLA accreditation for CLIA program purposes. A total of 16 validation surveys were conducted in COLA-accredited laboratories. One laboratory was cited with condition-level deficiencies. COLA noted comparable findings for all the CLIA condition-level deficiencies cited in this survey; thus, there were no disparate cases yielding a disparity rate of 0 percent. (See Table 20.)

The Joint Commission

Rate of disparity: N/A

In FY 2021, 2,119 laboratories used their TJC accreditation for CLIA program purposes. During this validation period, a total of 2 validation surveys were conducted in TJC-accredited laboratories. No laboratories were cited with CLIA condition-level deficiencies. (See Table 20.)

Table 20: Validation Survey Results for Clinical Laboratories
FY 2021

Number of	AABB	A2LA	ACHC	ASHI	CAP	COLA	TJC	Total
Accredited Labs	226	4	116	120	6,677	5,930	2,119	15,192
Validation Surveys	0	0	0	0	11	16	2	29
Surveys with Condition-Level Deficiencies	*N/A	*N/A	*N/A	*N/A	0	1	0	1
Surveys with One or More Condition-Level Deficiencies Missed by AO	*N/A	*N/A	*N/A	*N/A	0	0	0	0
Disparity Rate	*N/A	*N/A	*N/A	*N/A	*N/A	**0%**	***N/A**	***N/A**

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

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

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

APPENDIX A: Fiscal Years 2019-2020 State Agency and Accrediting Organization Comparison of Condition-Level Deficiency Findings

Appendix A Table 1: Hospitals Number and Type of Condition-Level Deficiencies Cited on 60-Day Validation Surveys FY 2019

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

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

Appendix A Table 2: Hospitals Number and Type of Condition-Level Deficiencies Cited on 60-Day Validation Surveys FY 2020

Medicare Conditions Sample Size 40	Cited by SA	Missed by AO
Physical Environment*	**33**	**17**
Infection Control	4	1
Patient Rights	3	2
Governing Body	2	1
Anesthesia Services	1	1
Nursing Services	1	0
TOTAL	44	22

*Most frequently cited deficiency
Note: FY 2020 includes validation surveys completed from October 1, 2019 – March 4, 2020.

Appendix A Table 3: Psychiatric Hospitals Number and Type of Condition-Level Deficiencies Cited on 60-Day Validation Surveys FY 2019

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

*Most frequently cited deficiency

Appendix A Table 4: Psychiatric Hospitals Number and Type of Condition-Level Deficiencies Cited on 60-Day Validation Surveys FY 2020

Medicare Conditions Sample Size 5	Cited by SA	Missed by AO
Special Medical Record Requirements for Psych Hospitals*	**6**	**3**
Patient Rights	5	3
Physical Environment	5	3
Governing Body	3	2
Special Staff Requirements for Psych Hospitals	2	2
QAPI	1	1
Nursing Services	1	1
Utilization Review	1	1
Respiratory Care Services	1	1
TOTAL	25	17

*Most frequently cited deficiency
Note: FY 2020 includes validation surveys completed from October 1, 2019 – March 4, 2020.

Appendix A Table 5: CAHs Number and Type of Condition-Level Deficiencies Cited on 60-Day Validation Surveys FY 2019

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

*Most frequently cited deficiency

Appendix A Table 6: CAHs Number and Type of Condition-Level Deficiencies Cited on 60-Day Validation Surveys FY 2020

Medicare Conditions Sample Size 12	Cited by SA	Missed by AO
Physical Plant and Environment*	**7**	**4**
Provision of Services	2	1
TOTAL	9	5

*Most frequently cited deficiency
Note: FY 2020 includes validation surveys completed from October 1, 2019 – March 4, 2020.

Appendix A Table 7: HHAs Number and Type of Condition-Level Deficiencies Cited on 60-Day Validation Surveys FY 2019

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

*Most frequently cited deficiency

Appendix A Table 8: HHAs Number and Type of Condition-Level Deficiencies Cited on 60-Day Validation Surveys FY 2020

Medicare Conditions Sample Size 33	Cited by SA	Missed by AO
Skilled Professional Services*	**3**	**2**
Quality Assessment/Performance Improvement	2	2
Clinical Records	2	1
Patient Rights	2	1
Care Planning, Coordination, and Quality of Care	2	1
Home Health Aide Services	2	1
Organization and Administration of Services	1	1
Reporting of OASIS Information	1	1
Infection Prevention and Control	1	1
TOTAL	16	11

*Most frequently cited deficiency
Note: FY 2020 includes validation surveys completed from October 1, 2019 – March 4, 2020.

Appendix A Table 9: Hospices Number and Type of Condition-Level Deficiencies Cited on 60-Day Validation Surveys FY 2019

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

*Most frequently cited deficiency

Appendix A Table 10: Hospices Number and Type of Condition-Level Deficiencies Cited on 60-Day Validation Surveys FY 2020

Medicare Conditions Sample Size 15	Cited by SA	Missed by AO
Hospices that provide inpatient care directly*	**2**	**1**
Volunteers*	**2**	**1**
Core Services	1	1
Furnishing of Non-Core Services	1	1
TOTAL	6	4

*Most frequently cited deficiency
Note: FY 2020 includes validation surveys completed from October 1, 2019 – March 4, 2020.

Appendix A Table 11: ASCs Number and Type of Condition-Level Deficiencies Cited on 60-Day Validation Surveys FY 2019

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

*Most frequently cited deficiency

Appendix A Table 12: ASCs Number and Type of Condition-Level Deficiencies Cited on 60-Day Validation Surveys FY 2020

Medicare Conditions Sample Size 28	Cited by SA	Missed by AO
Environment*	**6**	**4**
Infection Control	3	1
Nursing Services	2	1
Pharmaceutical Services	2	1
Laboratory and Radiologic Services	1	1
Governing Body and Management	1	1
TOTAL	15	9

*Most frequently cited deficiency

Note: FY 2020 includes validation surveys completed from October 1, 2019 – March 4, 2020.

APPENDIX B: Fiscal Years 2019-2020 Top Five Missed LSC Categories by Program Type

Appendix B Table 1: Top Five LSC Missed Categories Hospitals and LTCHs FYs 2019-2020

LSC Category	Cited by SA	Missed by AO	Percent of Missed by AO	Category Disparity Rate
Fire/Smoke Barrier	158	60	18.02%	6.25%
Sprinkler	165	53	15.92%	5.52%
Means of Egress	89	36	10.81%	3.75%
Electrical	112	31	9.31%	3.23%
Hazardous Areas	54	28	8.41%	2.92%
TOTAL	578	208	62.46%	21.67%

Note: FY 2020 includes validation surveys completed from October 1, 2019 – March 4, 2020.

Appendix B Table 2: Top Five LSC Missed Categories Psychiatric Hospitals FYs 2019-2020

LSC Category	Cited by SA	Missed by AO	Percent of Missed by AO	Category Disparity Rate
Hazardous Areas	5	5	20.00%	6.85%
Fire/Smoke Barrier	16	4	16.00%	5.48%
Electrical	13	4	16.00%	5.48%
Fire Alarm	7	3	12.00%	4.11%
Means of Egress	4	2	8.00%	2.74%
Elevators	3	2	8.00%	2.74%
TOTAL	48	20	80.00%	27.40%

Note: FY 2020 includes validation surveys completed from October 1, 2019 – March 4, 2020.

Appendix B Table 3: Top Five LSC Missed Categories Critical Access Hospitals FYs 2019-2020

LSC Category	Cited by SA	Missed by AO	Percent of Missed by AO	Category Disparity Rate
Hazardous Areas	16	16	16.00%	16.00%
Means of Egress	14	8	8.00%	8.00%
Sprinkler	18	4	4.00%	4.00%
Fire Drill	5	4	4.00%	4.00%
Fire Plan	2	2	2.00%	2.00%
TOTAL	55	34	34.00%	34.00%

Note: FY 2020 includes validation surveys completed from October 1, 2019 – March 4, 2020.

Appendix B Table 4: Top Five LSC Missed Categories Ambulatory Surgery Centers FYs 2019-2020

LSC Category	Cited by SA	Missed by AO	Percent of Missed by AO	Category Disparity Rate
Construction	11	10	35.71%	9.80%
Hazardous Areas	8	4	14.29%	3.92%
Medical Gas	9	3	10.71%	2.94%
HVAC	5	3	10.71%	2.94%
Emergency Lighting	7	2	7.14%	1.96%
TOTAL	40	22	78.57%	21.57%

Note: FY 2020 includes validation surveys completed from October 1, 2019 – March 4, 2020.

APPENDIX C: Life Safety Code Category Definitions

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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