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

Center for Clinical Standards and Quality/Survey & Certification Group

Ref: S&C: 16-07-AO

DATE: **January 29, 2016**

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: FY 2015 Report to Congress (RTC): Review of Medicare's Program Oversight of Accrediting Organizations (AOs) and the Clinical Laboratory Improvement Amendments of 1988 (CLIA) Validation Program

Memorandum Summary

Annual Report to Congress: The 2015 annual RTC details the review, validation, and oversight of the FY 2014 activities of the approved AOs Medicare accreditation programs as well as the CLIA Validation Program.

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

Background

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

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

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

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

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

- American Association of Blood Banks (AABB)
- American Association for Laboratory Accreditation (A2LA)
- American Osteopathic Association (AOA)
- American Society for Histocompatibility and Immunogenetics (ASHI)
- COLA
- College of American Pathologists (CAP)
- The Joint Commission (TJC)

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

/s/

Thomas E. Hamilton

Attachment:

cc: Survey and Certification Regional Office Management

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

Fiscal Year 2015

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

INTENTIONALLY LEFT BLANK

Contents

Review of Medicare's Program for Oversight of Accrediting Organizations

Introduction

In order to be eligible to receive Medicare reimbursement, certain types of health care facilities must demonstrate compliance with the Medicare conditions of participation (CoPs), conditions for coverage (CfCs), or conditions for certification. 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 for CMS review and approval, provider-and supplier-specific accreditation programs intended to demonstrate compliance with the applicable Medicare standards. AOs charge fees to facilities that seek their accreditation. Generally, AOs offer facilities at least two accreditation options: accreditation alone, or accreditation under a CMS-approved program for the purpose of participating in Medicare. CMS reviews and provides oversight only for those accreditation programs submitted by an AO requesting to have the program recognized as a Medicare accreditation program. Accordingly, this report addresses AO activity only as it relates to CMS-approved Medicare accreditation programs.

The 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] 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. Also reviewed are the qualifications of the surveyors, staff, and the AO's financial status. Upon approval, any provider or supplier accredited by the AO's approved program could be "deemed" by CMS to have met the applicable Medicare conditions and are referred to as having deemed status.
Section 1875(b) of the Act requires CMS to submit this annual report to Congress on its 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

[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. 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 (SA).
[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" is used to cover CoPs, CfCs, and Conditions for Certification.

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 for the following facility types: hospitals, psychiatric hospitals, critical access hospitals (CAHs), home health agencies (HHAs), hospices, ambulatory surgery centers (ASCs), outpatient physical therapy and speech-language pathology services (OPTs), and rural health clinics (RHCs).[4] The 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 to ascertain whether the AO can adequately ensure that facilities comply with Medicare requirements;

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 in order to check the adequacy of the AO survey; and

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

Overview

This report reviews AO activities in fiscal year (FY) 2014, October 1, 2013 – September 30, 2014, compares this activity to past years, and describes the current CMS oversight of approved Medicare accreditation programs as follows:

Section 1 – CMS-Approval of Medicare Accreditation Programs
Discusses the process used for CMS approval and renewal of AO Medicare accreditation programs; the types of CMS reviews and decisions; the number of these reviews that were performed and decisions made since FY 2009; the current AOs with approved Medicare accreditation programs; and, the most recent CMS approval or review status for each AO Medicare accreditation program.

[4]Note that other types of facilities may also participate in Medicare via an approved accreditation program, but to date, no AO has sought and received approval for any of these additional facility types.

Section 2 – **Scope of AO Medicare Accreditation Programs**
Presents the current number of deemed status and non-deemed Medicare-certified facilities by program type and discusses the growth in deemed status facilities within the Medicare program since FY 2008.

Section 3 – **Summary of AO Medicare Accreditation Program Activity**
Discusses the overall Medicare accreditation survey activities of each AO in FY 2014, including the number of initial and renewal accreditation surveys performed and the types of accreditation decisions made for each of the AOs' approved accreditation programs.

Section 4 – State Survey Validation of AO Surveys
Describes the AO Validation Program and presents the number of representative sample validation surveys that have been performed for hospital and non-hospital facilities since FY 2007. The section also describes the components of the analysis of the 60-day validation surveys used in assessing each AO program's ability to ensure compliance with Medicare conditions. The validation performance results for FYs 2008-2014 are presented by facility type for each AO. The FY 2014 AO and 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).

Section 5 – **AO Performance Measures**
Describes the AO reporting requirements, and CMS' methods for collecting AO quarterly data on Medicare accreditation program activities and deemed facilities. Presents and discusses the FY 2014 AO performance measures and the results for each AO; and, compares FYs 2013 and 2014 performance measure results.

Section 6 – **AO Self-Reported Program Improvements**
Presents each AO's self-report of FY 2014 program improvement activities.

Section 7 – CMS Improvements
Describes the various areas in which CMS has executed and improved its program management and oversight activities in FY 2014.

SECTION 1: CMS-Approval of Medicare Accreditation Programs

Application and Renewal Process

Approval of a National AO's Medicare Accreditation Program

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

- Requirements for accreditation meeting or exceeding the Medicare requirements;
- Survey procedures;
- 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 found out of compliance with conditions or requirements; and
- Ability to provide the necessary data for validation to CMS.

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

Throughout this report, regulatory references are to the 2014 *Code of Federal Regulations*. Since then, the Federal rules for recognizing and overseeing AOs have been updated. A final rule was issued at 80 FR 29796 (May 22, 2015), effective July 21, 2015.

The regulations at 42 CFR 488.4 and 488.8 (recodified in 2015 as 42 CFR 488.5) set forth the detailed requirements an AO must satisfy in order to receive and maintain CMS recognition and approval of a Medicare accreditation program, as well as 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 six-year maximum. Some AOs are given approval on a conditional basis, while CMS reviews and monitors the accreditation program during a probationary period to determine if the program continues to meet or exceed Medicare requirements.

The application and renewal process provides the opportunity for a comprehensive evaluation of an AO's Medicare accreditation program's performance. This process includes the AO's ability to ensure deemed status facilities' compliance with Medicare conditions, and its ability to comply with CMS' administrative requirements that facilitate ongoing oversight of the AO's CMS-approved

accreditation program(s). The CMS evaluation process includes the following components:

- On-site observations:
  - Corporate on-site review; and
  - Survey observation.
- Comparability review between AO standards and Medicare conditions.
- Comprehensive review of the AO's:
  - Policies and procedures;
  - Adequacy of resources to perform required surveys;
  - Survey processes and enforcement;
  - Surveyor evaluation and training;
  - Electronic data management; and
  - Financial status.

Other Reviews of AO Medicare Accreditation Programs

CMS performs other reviews which focus on specific issues, including the following categories:

- *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, to ensure that the program continues to meet or exceed Medicare requirements. Such reviews are conducted in accordance with 42 CFR 488.4(b)(3)(iii) when an AO notifies CMS of any proposed changes in accreditation requirements, and when AO requirements are revised in response to changes in CMS requirements at 42 CFR 488.4(b)(3)(iv). The AO must notify CMS in writing of any proposed changes in its approved Medicare accreditation program at least 30 days in advance of the effective date of the changes. Additionally, when CMS adopts changes to the applicable Medicare requirements, the AO must submit documentation that it has revised its Medicare program to comply with the new requirement(s) within 30 days of CMS' notification to the AO of the change(s). During this review process, an AO may be required to make changes in its accreditation program in order to maintain CMS-approval.

- *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.

- *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 488.4.

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

Table 1
CMS Review of AO Medicare Accreditation Programs
(FYs 2009-2014)

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

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

From FY 2009 through FY 2014 CMS completed 42 reviews of renewal and initial applications (which include approvals published in the *Federal Register* as well as initial applications withdrawn by the AO prior to publication). In this same timeframe, CMS completed 248 other reviews. In total, 290 comprehensive reviews were completed.

Approved AO Medicare Accreditation Programs

CMS reviews, and approves separately, each type of provider or supplier Medicare accreditation program for which an AO seeks CMS approval. AOs currently have CMS-approval for eight provider/supplier program types: hospital, psychiatric hospital, CAH, HHA, hospice, ASC, OPT, and RHC. As of September 30, 2014, there were nine national AOs with 21 approved Medicare accreditation programs. (See Tables 2 and 3)

Table 2
AOs with Approved Medicare Accreditation Programs
(FY 2014)

AO Acronym	Description
AAAASF	American Association for Accreditation of Ambulatory Surgery Facilities
AAAHC	Accreditation Association for Ambulatory Health Care
ACHC	Accreditation Commission for Health Care
AOA/HFAP	American Osteopathic Association/Healthcare Facilities Accreditation Program
CHAP	Community Health Accreditation Program
CIHQ	Center for Improvement in Healthcare Quality
DNV GL*	DNV GL-Healthcare
TCT	The Compliance Team
TJC	The Joint Commission

*Formally, Det Norske Veritas Healthcare, Inc (DNVHC)

Table 3
Approved Medicare Accreditation Programs by AO
(FY 2014)

AO	Hospital	Psych Hospital	CAH	HHA	Hospice	ASC	OPT	RHC	Total
AAAASF						X	X	X	3
AAAHC						X			1
ACHC				X	X				2
AOA/HFAP	X		X			X			3
CHAP				X	X				2
CIHQ	X								1
DNV GL	X		X						2
TCT								X	1
TJC	X	X	X	X	X	X			6
Total	4	1	3	3	3	4	1	2	21

The number of CMS-approved Medicare accreditation programs has grown steadily over the past several years resulting in 21 approved programs in FY 2014. Since FY 2014, CMS has approved another new Medicare AO, TCT, and its associated RHC accreditation program.

Approval of Medicare Accreditation Programs

American Association for Accreditation of Ambulatory Surgery Facilities (AAAASF)

Ambulatory Surgery Center

AAAASF's ASC Medicare accreditation program was initially approved December 2, 1998. AAAASF's current term of approval is effective November 27, 2012 through November 27, 2018. The final notice announcing this decision was published in the *Federal Register* (77 FR 70446)(November 26, 2012), effective November 27, 2012 and can be accessed at http://www.gpo.gov/fdsys/pkg/FR-2012-11-26/pdf/2012-28640.pdf.

Outpatient Physical Therapy and Speech-Language Pathology Services

AAAASF's OPT Medicare accreditation program was initially approved April 22, 2011. AAAASF's current term of approval is effective April 22, 2015 through April 22, 2019. The final notice announcing this decision was published in the *Federal Register* (80 FR 21244) (April 17, 2015), effective April 22, 2015 through April 22, 2019 and can be accessed at http://www.gpo.gov/fdsys/pkg/FR-2015-04-17/pdf/2015-08917.pdf.

Rural Health Clinic

AAAASF's RHC Medicare accreditation program was granted a four-year term of approval effective May 23, 2012 to May 23, 2016. The final notice was published in the *Federal Register* (77 FR 17068)(May 23, 2012) and can be accessed at http://www.gpo.gov/fdsys/pkg/FR-2012-03-23/pdf/2012-6331.pdf.

Performance Review:

In response to significant changes in the AO's corporate structure, an on-site corporate visit was conducted in October 2013. Based on the extent and serious nature of the corporate on-site findings, CMS opened a deeming authority review for AAAASF's CMS-approved ASC, OPT and RHC accreditation programs.

In accordance with the previous version of CMS regulations at §§ 488.8(f)(2) and 488.8(f)(3)(i), CMS provided AAAASF 18 months to correct identified areas of non-compliance and adopt comparable requirements. CMS completed its formal review in June 2015, and determined that AAAASF fully addressed and resolved all concerns.

Accreditation Association for Ambulatory Health Care (AAAHC)

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, 2012 through December 20, 2018. The final notice announcing this decision was published in the *Federal Register* (77 FR 70782) (November 27, 2012) effective December 12 2012, and can be accessed at http://edocket.access.gpo.gov/2012/pdf/2012-28728.pdf.

Accreditation Commission for Health Care (ACHC)

Home Health Agency

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

Hospice

ACHC's hospice Medicare accreditation program was initially approved November 27, 2009. ACHC's current term of approval is effective November 27, 2013 through November 27, 2019. The final notice announcing this decision was published in the *Federal Register* (78 FR 66364) (November 5, 2013), effective November 27, 2013 and can be accessed at http://www.gpo.gov/fdsys/pkg/FR-2013-11-05/pdf/2013-26374.pdf.

American Osteopathic Association/Healthcare Facilities Accreditation Program (AOA/HFAP)

Hospital

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

Critical Access Hospital

AOA/HFAP's CAH Medicare accreditation program was initially approved December 27, 2001. AOA/HFAP's current term of approval is effective December 27, 2013 through December 27, 2019. The final notice announcing this decision was published in the *Federal Register* (78 FR 71619)(November 29, 2013), effective December 27, 2013, and can be accessed at http://www.gpo.gov/fdsys/pkg/FR-2013-11-29/pdf/2013-28521.pdf.

Ambulatory Surgery Center

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

Community Health Accreditation Program (CHAP)

Home Health Agency

CHAP's HHA Medicare accreditation program was initially approved August 27, 1992. CHAP's current term of approval is effective March 31, 2012 through March 31, 2018. The final notice announcing this decision was published in the *Federal Register* (77 FR 17072) (March 23, 2012), effective March 31, 2012 and can be accessed at http://www.gpo.gov/fdsys/pkg/FR-2012-03-23/pdf/2012-6598.pdf.

Hospice

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

Performance Review:

In response to significant changes in the AO's corporate structure, an on-site corporate visit was conducted October 2013. Based on the extent and serious nature of the corporate on-site findings, CMS opened a deeming authority review for CHAP's CMS-approved HHA accreditation program.

In accordance with the previous version of the regulations at §488.8(f)(3)(i), *"If CMS determines, following the deeming authority review, that the accreditation organization has failed to adopt requirements comparable to CMS' or submit new requirements timely, the accreditation organization may be given conditional approval of its deeming authority during a probationary period of up to one year."*

Based on this regulatory authority, CMS provided CHAP one year to correct identified areas of noncompliance and adopt comparable requirements. CMS completed its formal review September 2014, and determined that CHAP fully addressed and resolved all concerns.

Center for Improvement in Healthcare Quality (CIHQ)

Hospital

CIHQ's hospital Medicare accreditation program was initially approved for a four-year term effective July 26, 2013 through July 26, 2017. The final notice announcing this approval was published in the *Federal Register* (75 FR 45231) (July 26, 2013), effective July 26, 2013, and can be accessed at http://www.gpo.gov/fdsys/pkg/FR-2013-07-26/pdf/2013-18014.pdf.

DNV GL-Healthcare (DNV GL)

Hospital

DNV GL's hospital Medicare accreditation program was initially approved September 29, 2008. DNV GL's current term of approval is effective September 26, 2012 through September 26, 2018. The final notice announcing this decision was published in the *Federal Register* (77 FR 51537) (August 24, 2012), effective September 26, 2012, and can be accessed at

http://www.gpo.gov/fdsys/pkg/FR-2012-08-24/pdf/2012-20199.pdf.

Critical Access Hospital

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

The Compliance Team (TCT)

Rural Health Clinics

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

The Joint Commission (TJC)

Hospital

TJC's hospital Medicare accreditation program was initially approved July 15, 2010. Prior to July 15, 2010, TJC's hospital accreditation program had statutory status and did not require CMS review and approval. TJC's current term of approval is effective July 15, 2014 through July 15, 2020. The final notice announcing this decision was published in the *Federal Register* (79 FR 36522) (June 27, 2014), effective July 15, 2014, and can be accessed at http://www.gpo.gov/fdsys/pkg/FR-2014-06-27/pdf/2014-15101.pdf.

Psychiatric Hospital

TJC's psychiatric hospital Medicare accreditation program was initially approved for a four-year period effective February 25, 2011 through February 25, 2015. The final notice announcing this decision was published in the *Federal Register* (76 FR 10598) (February 25, 2011), effective February 25, 2011, and can be accessed at http://edocket.access.gpo.gov/2011/pdf/2011-4294.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, 2011 through November 21, 2017. The final notice announcing this decision was published in the *Federal Register* (76 FR 59134) (September 23, 2011), effective November 21, 2011, and can be accessed at http://www.gpo.gov/fdsys/pkg/FR-2011-09-23/pdf/2011-24496.pdf.

Home Health Agency

TJC's HHA Medicare accreditation program was initially approved September 28, 1993. TJC's

current term of approval is effective March 31, 2014 through March 31, 2020. The final notice announcing this decision was published in the *Federal Register* (79 FR 14079) (March 12, 2014), effective March 31, 2014, and can be accessed at http://www.gpo.gov/fdsys/pkg/FR-2014-03-12/pdf/2014-05328.pdf.

Hospice

TJC's hospice Medicare accreditation program was initially approved June 18, 1999. TJC's current term of approval is effective June 18, 2015 through June 18, 2021. The final notice announcing this decision was published in the *Federal Register* (80 FR 29714) (May 22, 2015), effective June18, 2015, and can be accessed at http://www.gpo.gov/fdsys/pkg/FR-2015-05-22/pdf/2015-12524.pdf.

Ambulatory Surgery Center

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

SECTION 2: Scope of AO Medicare Accreditation Programs

Medicare-Certified Facilities by Program Type

In FY 2014, AOs were responsible for assuring compliance with Medicare conditions for 36 percent of all Medicare-certified facilities in the eight program types for which there was an approved AO program. (See Table 4)

Table 4
Deemed & Non-Deemed Medicare-Certified Facilities
Program Types with a Medicare Accreditation Program Option
(FY 2014)

Program Type	Deemed* (percentage)	Non-Deemed** (percentage)	Total***
Hospital	3,629 (80)	890 (20)	4,519
Psychiatric Hospital	425 (77)	125 (23)	550
CAH	439 (33)	890 (67)	1,329
HHA	4,652 (37)	7,827 (63)	12,479
Hospice	1,562 (38)	2,517 (62)	4,079
ASC	1,507 (28)	3,909 (72)	5,416
OPT	97 (5)	2,051 (95)	2,148
RHC	140 (3)	3,923 (97)	4,063
Total	12,451 (36)	22,132 (64)	34,583

* As reported by AOs in the Accrediting Organization System for Storing User Recorded Experiences (ASSURE).
** Surveyed by a SA for compliance with Medicare conditions.
***As reported by CMS Data Team 11/14/2014.

In FY 2014, 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, ranging from a high of 80 percent for hospitals to a low of three percent for RHC facilities. The hospital category continues to have the largest percentage of facilities participating in Medicare via deemed status.

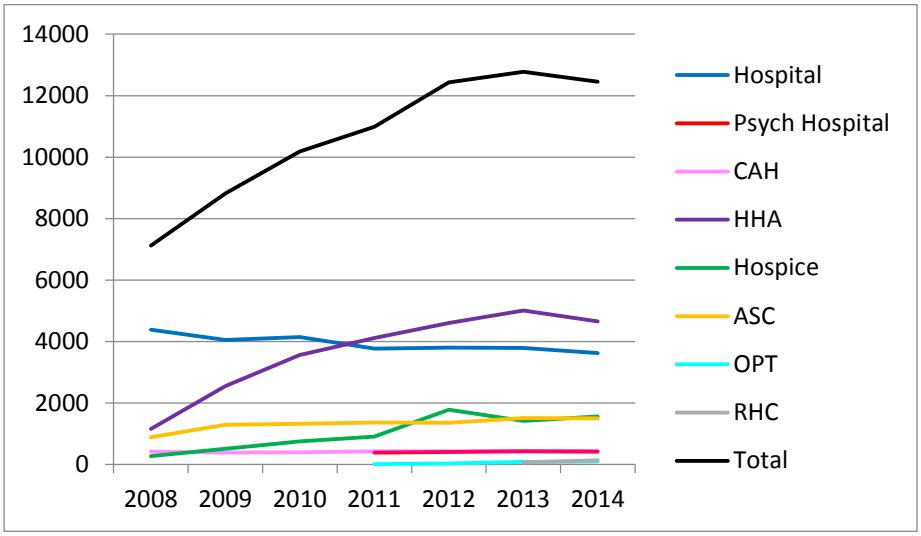
Growth in Medicare Deemed Facilities

The total number of Medicare-participating certified health care facilities across all program types has increased 40 percent from 24,752 in FY 2008 to 34,583 in FY 2014. Since FY 2008, the majority of those newly-participating facilities that could choose an accreditation option, enrolled and became certified in the Medicare program entered the program via accreditation from a CMS-approved Medicare accreditation program and deemed status.
The growth in the number of deemed facilities is likely attributable, in part, to CMS' workload priorities for SAs. The long-standing CMS policy for SAs has been that initial surveys for newly enrolling facilities with an approved accreditation option have a lower priority as compared to

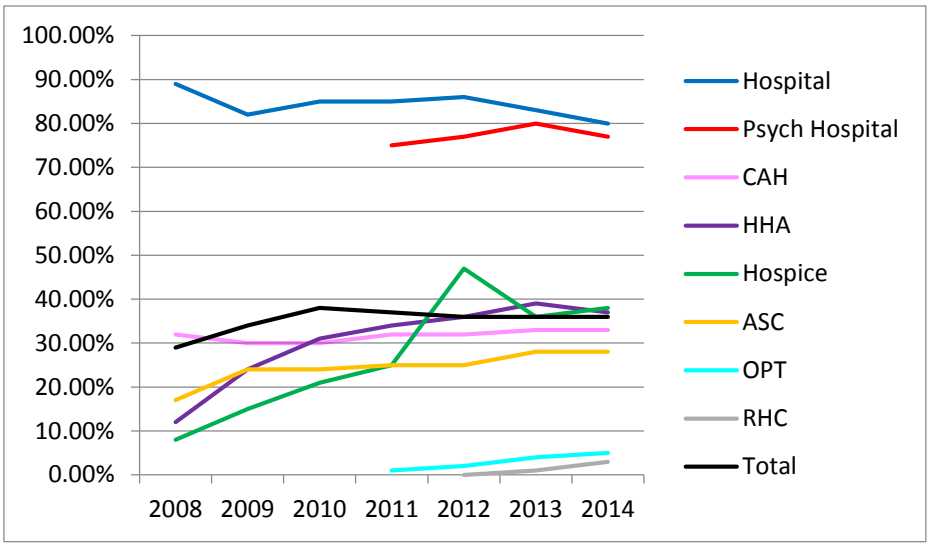
statutorily mandated recertification surveys of already participating nursing homes and HHAs, validation surveys, complaint investigations, other recertification surveys, and initial surveys of new applicants for which no accreditation option exists. As a result, an increasing number of facilities seeking 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 1 and 2 below show the number of facilities certified each year by CMS by virtue of a CMS-recognized Medicare accreditation program, and the percentage of all Medicare-certified facilities that these deemed facilities represent. These graphs represent the eight program types for which there is currently more than one year of data.

Graph 1
Number of Deemed Facilities by Program Type
(FYs 2008-2014)



Graph 2
Deemed Facilities as Percentage of Medicare-Certified Facilities by Program Type (FYs 2008-2014)



- **Total:** Five AO Medicare accreditation programs, hospitals, CAHs, HHAs, hospices, and ASCs, have been approved since FY 2008. The first OPT and psychiatric hospital Medicare accreditation programs were approved in FY 2011[5]. The first RHC Medicare accreditation program was approved in FY 2012. Although the number of Medicare-certified facilities increased 40 percent from 24,752 in FY 2008 to 34,583 in FY 2014, the growth in deemed facilities during that same period is much larger.
    - The number of facilities participating in Medicare via deemed status increased from 7,128 in FY 2008 to 12,451 in FY 2014, a 75 percent increase.
    - While SAs continue to survey the majority of facilities requiring certification, the proportion of all certified facilities in these categories represented by deemed status facilities grew from 29 percent to 36 percent.

- **Hospital:** The number of Medicare-certified hospitals was largely unchanged between FYs 2008 and 2014. The hospital and psychiatric hospital programs are the only categories in which the majority of facilities participate in Medicare by virtue of accreditation under an approved Medicare accreditation program.
    - The number of deemed hospitals decreased from 4,381 in FY 2008 to 3,629 in FY 2014, a reduction of 17 percent. Please note: this decrease in percentage is adjusted based on the separate reporting of 425 deemed psychiatric hospitals.
    - The proportion of all Medicare-certified hospitals that were deemed decreased from 89 percent to 80 percent during this period.

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

- **Psychiatric Hospital:** The number of Medicare-certified psychiatric hospitals increased from 516 in FY 2011 to 550 in FY 2014, a seven percent increase.
    - The number of deemed psychiatric hospitals increased from 388 in FY 2011 to 425 in FY 2014, a 10 percent increase.
    - The proportion of all Medicare-certified psychiatric hospitals which were deemed increased from 75 percent to 77 percent during the same time period.

- **CAH:** The number of Medicare-certified CAHs increased from 1,310 in FY 2008 to 1,329 in FY 2014, a one percent increase.
    - The number of deemed CAHs increased from 415 in FY 2008 to 439 in FY 2014, a six percent increase.
    - The proportion of all Medicare-certified CAHs which were deemed increased slightly from 32 percent to 33 percent.

- **HHA:** There has been significant growth in the Medicare HHA program. The number of Medicare-certified HHAs increased from 9,893 in FY 2008 to 12,479 in FY 2014, a 26 percent increase. There has also been corresponding significant growth in the number and proportion of deemed HHAs.
    - The number of deemed HHAs increased from 1,161 in FY 2008 to 4,652 in FY 2014, a 301 percent increase.
    - The proportion of all Medicare-certified HHAs which were deemed increased significantly from 12 percent to 37 percent.

- **Hospice:** There has also been significant growth in the Medicare hospice program. The number of Medicare-certified hospices increased from 3,388 in FY 2008 to 4,079 in FY 2014, a 20 percent increase. There has also been corresponding significant growth in the number and proportion of deemed hospices.
    - The number of deemed hospices increased from 278 in FY 2008 to 1,562 in FY 2014, a 462 percent increase.
    - The proportion of all Medicare-certified hospices which were deemed significantly increased from eight percent to 38 percent during the same time period.

- **ASC:** The number of Medicare-certified ASCs increased from 5,217 in FY 2008 to 5,416 in FY 2014, a four percent increase.
    - The number of deemed ASCs increased significantly from 893 in FY 2008 to 1,507 in FY 2014, a 69 percent increase.
    - The proportion of all Medicare-certified ASCs which were deemed increased from 17 percent to 28 percent during the same time period.

- **OPT:** The number of Medicare-certified OPTs decreased from 2,471 in FY 2011 to 2,148 in FY 2014, a 13 percent decrease.
    - The number of deemed OPTs increased from 13 in FY 2011 to 97 in FY 2014, a 646 percent increase. This large percentage increase is due to the relative recent availability of an accreditation option for OPTs. CMS-approved the first Medicare OPT accreditation program April 2011. Therefore, there was a small number of deemed OPTs in FY 2011.
    - The proportion of all Medicare-certified OPTs which were deemed increased from one percent to five percent during the same time period.

- **RHC:** The number of Medicare-certified RHCs decreased from 4,108 in FY 2012 to 4,063 in FY 2014, a one percent decrease.
    - The number of deemed RHCs increased from three in FY 2012 to 140 in FY 2014, a 4,567 percent increase. This large percentage increase is due to the relative recent availability of an accreditation option for RHCs. CMS-approved the first Medicare RHC accreditation program May 2012. Therefore, there was an extremely low number of deemed RHCs in FY 2012.
    - The proportion of all Medicare-certified RHCs which were deemed increased from less than one percent to three percent during the same time period.

SECTION 3: Summary of AO Medicare Accreditation Program Activity

Medicare Accreditation Program Survey Activity

An AO with a CMS-recognized Medicare accreditation program is responsible for evaluating a facility through an on-site survey to determine whether the facility complies with the health care quality and patient safety standards required by the Medicare conditions. The evaluation performed by the AO includes, but is not limited to, observation and review of the following: care processes in the facility, the physical environment (PE), 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 new Medicare certification as well as those of facilities currently participating in Medicare and previously overseen by a SA or another AO. The AO may award accreditation under a Medicare accreditation for up to three years. A renewal survey must be completed prior to the expiration date of the facility's Medicare accreditation to ensure that the facility remains in compliance with CMS requirements.

In FY 2014, the AOs reported having performed 1,607 initial surveys and 3,232 renewal surveys. The total number of deemed status facilities in FY 2014 was 12,451. (See Table 5)

Table 5
Total Number of Deemed Facilities
Initial Surveys and Renewal Surveys by AO Accreditation Program
(FY 2014)

Program Type/ AOs	Total Deemed Facilities	Initial Surveys	Renewal Surveys
Hospital			
AOA/HFAP	157	4	58
CIHQ	7	10	0*
DNV GL	271	44	57
TJC	3,194	40	997
Psychiatric Hospital			
TJC	425	29	122
CAH			
AOA/HFAP	31	0	16
DNV GL	58	16	24
TJC	350	6	95
HHA			
ACHC	642	138	162
CHAP	2,206	350	426
TJC	1,804	183	640
Hospice			
ACHC	118	38	22
CHAP	769	154	131
TJC	675	192	140
ASC			
AAAASF	161	26	36
AAAHC	812	125	170
AOA/HFAP	25	1	8
TJC	509	106	117
OPT			
AAAASF	97	60	9
RHC			
AAAASF	138	82	2
TCT	2	3	0**
Total	**12,451**	**1,607**	**3,232**

Source: As reported by the AOs in ASSURE.
* The CIHQ Hospital accreditation program received initial approval in FY 2013. Therefore, no renewal surveys were due to be conducted in FY 2014.
** TCT RHC accreditation program received initial approval in FY 2014. Therefore, no renewal surveys were due to be conducted in FY 2014.

Summary of Survey Activity for Each AO with CMS-Approved Medicare Accreditation Program(s)

Below are summaries of all types of Medicare accreditation surveys performed, and all types of accreditation decisions made by each AO for each of their Medicare accreditation programs in FY 2014. The various accreditation decisions are also presented as a percentage of the total surveys performed by each AO for each of their Medicare accreditation program(s).

American Association for Accreditation of Ambulatory Surgery Facilities (AAAASF)

Program Type	Total Deemed	Initial Surveys	Renewal Surveys
ASC	161	26	36
OPT	97	60	9
RHC	138	82	2
Total	396	168	47

Accreditation Decisions	ASC (percent)	OPT (percent)	RHC (percent)
Full Accreditation	52 (84)	62 (90)	78 (93)
Denial	3 (5)	7 (10)	4 (5)
Pending	7 (11)	0 (0)	2 (2)
Total Surveys	62 (100)	69 (100)	84 (100)

AAAASF awarded full accreditation to 84 percent of the total ASCs surveyed, 90 percent of the total OPTs surveyed and 93 percent of the total RHCs surveyed.

Accreditation Association for Ambulatory Health Care (AAAHC)

Program Type	Total Deemed	Initial Surveys	Renewal Surveys
ASC	812	125	170

Accreditation Decisions	ASC (percent)
Full Accreditation	263 (89)
Denial	13 (4)
Pending	19 (7)
Total Surveys	295 (100)

AAAHC awarded full accreditation to 89 percent of the total ASCs surveyed.

Accreditation Commission for Health Care (ACHC)

Program Type	Total Deemed	Initial Surveys	Renewal Surveys
HHA	642	138	162
Hospice	118	38	22
Total	760	176	184

Accreditation Decisions	HHA (percent)	Hospice (percent)
Full Accreditation	254 (85)	46 (77)
Denial	44 (15)	14 (23)
Pending	2 (<1)	0 (0)
Total Surveys	300 (100)	60 (100)

ACHC awarded full accreditation to 85 percent of the total HHAs surveyed and 77 percent of the total hospice facilities surveyed.

American Osteopathic Association/Healthcare Facilities Accreditation Program (AOA/HFAP)

Program Type	Total Deemed	Initial Surveys	Renewal Surveys
ASC	25	1	8
CAH	31	0	16
Hospital	157	4	58
Total	213	5	82

Accreditation Decisions	ASC (percent)	CAH (percent)	Hospital (percent)
Full Accreditation	8 (89)	13 (81)	58 (93)
Denial	1 (11)	0 (0)	1 (2)
Pending	0 (0)	3 (19)	3 (5)
Total Surveys	9 (100)	16 (100)	62 (100)

AOA/HFAP awarded full accreditation to 89 percent of the total ASCs surveyed, 81 percent of the total CAHs surveyed and 93 percent of the total hospitals surveyed.

Community Health Accreditation Program (CHAP)

Program Type	Total Deemed	Initial Surveys	Renewal Surveys
HHA	2,206	350	426
Hospice	769	154	131
Total	2,975	504	557

Accreditation Decisions	HHA (percent)	Hospice (percent)
Full Accreditation	640 (82)	241 (85)
Denial	132 (17)	43 (15)
Pending	4 (1)	1 (<1)
Total Surveys	776 (100)	285 (100)

CHAP awarded full accreditation to 82 percent of the total HHAs surveyed and 85 percent of the total hospice facilities surveyed.

Center for Improvement in Healthcare Quality (CIHQ)

Program Type	Total Deemed	Initial Surveys	Renewal Surveys
Hospital	7	10	0*

*The accreditation program for hospitals received initial approval in FY 2013. Therefore, no renewal surveys were due to be performed in FY 2014.

Accreditation Decisions	Hospital (percent)
Full Accreditation	7 (70)
Denial	3 (30)
Pending	0 (0)
Total Surveys	10 (100)

CIHQ awarded full accreditation to 70 percent of the total hospitals surveyed.

DNV GL-Healthcare (DNV GL)

Program Type	Total Deemed	Initial Surveys	Renewal Surveys
CAH	58	16	24
Hospital	271	44	57
Total	329	60	81

Accreditation Decisions	CAH (percent)	Hospital (percent)
Full Accreditation	37 (93)	99 (98)
Denial	0 (0)	0 (0)
Pending	3 (7)	2 (2)
Total Surveys	40 (100)	101 (100)

DNV GL awarded full accreditation to 93 percent of the total CAHs surveyed and 98 percent of the total hospitals surveyed.

The Compliance Team (TCT)

Program Type	Total Deemed	Initial Surveys	Renewal Surveys
RHC	2	3	0*

*TCT's accreditation program for RHC's received initial approval in FY 2014. Therefore, no renewal surveys were due to be performed this FY.

Accreditation Decisions	RHC (percent)
Full Accreditation	3 (100)
Denial	0 (0)
Pending	0 (0)
Total Surveys	3 (100)

TCT awarded full accreditation to 100 percent of the total RHCs surveyed.

The Joint Commission (TJC)

Program Type	Total Deemed	Initial Surveys	Renewal Surveys
ASC	509	106	117
CAH	350	6	95
HHA	1,804	183	640
Hospice	675	192	140
Hospital	3,194	40	997
Psychiatric Hospital	425	29	122
Total	6,957	556	2,111

Accreditation Decisions	ASC (percent)	CAH (percent)	HHA (percent)	Hospice (percent)	Hospital (percent)	Psychiatric Hospital (percent)
Full Accreditation	204 (92)	94 (93)	639 (78)	276 (83)	900 (87)	129 (86)
Denial	0 (0)	0 (0)	7 (1)	3 (1)	2 (<1)	0 (0)
Pending	18 (8)	7 (7)	174 (21)	53 (16)	134 (13)	21 (14)
Total Surveys	222 (100)*	101 (100)	820 (100)*	332 (100)	1,036 (100)*	150 (100)*

* Note: “Conditional” accreditation decisions granted to 1 ASC, 3 HHAs, 1 hospital, and 1 psychiatric hospital are not included in the above table.

TJC awarded full accreditation to:

- 92 percent of the total ASCs surveyed;
- 93 percent of the total CAHs surveyed;
- 78 percent of the total HHAs surveyed;
- 83 percent of the total hospice facilities surveyed;
- 87 percent of the total hospitals surveyed; and
- 86 percent of the total psychiatric hospitals surveyed.

SECTION 4: State Survey Validation of AO Surveys

Accreditation Validation Program

Section 1864(c) of the Act permits SA validation surveys of provider and supplier types deemed for Medicare participation under Section 1865(a) of the Act as a means of validating the AOs' accreditation processes. A facility certified on the basis of being "deemed" to meet the Medicare conditions, based on accreditation under a CMS-approved Medicare accreditation program and recommendation for deemed status by the AO, is not subject to routine surveys by SAs to determine compliance with all applicable Medicare conditions. However, these deemed status facilities may be subject to validation surveys authorized by CMS and generally conducted by an SA.

The Accreditation Validation Program is a significant 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") – these are focused surveys based on complaints which, if substantiated, could indicate serious noncompliance with one or more Medicare conditions; and

- Representative sample validation surveys – these full surveys are routinely performed for a representative sample of deemed facilities as part of the annual CMS AO representative sample validation survey program. These surveys, generally, must be completed by the SA no more than 60 days after an AO full accreditation survey of the same facility. In some cases, representative sample "mid-cycle validation surveys" may be conducted independent of a preceding AO survey.

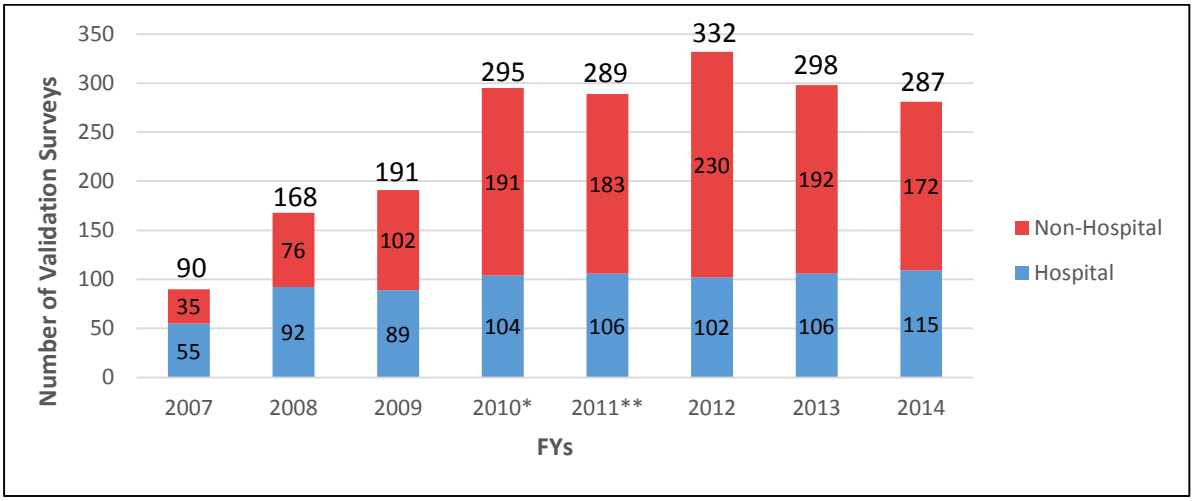
Note: The discussion in this section of the methodology for and results of CMS validation of the AOs' Medicare accreditation programs is based only upon analysis of 60-day representative sample validation surveys.

Prior to 2009, section 1875 of the Act required CMS to report to Congress annually only on TJC's hospital program.[6] Nevertheless, in FY 2007, CMS began conducting 60-day representative sample validation surveys for selected non-hospital facility types (CAHs, HHAs, and ASCs), in addition to those already being performed for deemed status hospitals. In FY 2010, hospice 60-day validation surveys were added, and in FY 2011, psychiatric hospital 60-day validation surveys. In FY 2014, CMS conducted a total of 287 representative sample 60-day validation surveys for six facility types across all AOs[7]. This total comprised 115 hospital surveys (including 12 psychiatric hospitals) and 172 non-hospital validation surveys (See Graph 3).

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

[7] In FY 2014, no validation surveys were targeted for CIHQ hospitals due to the small number of deemed facilities in this recently approved Medicare accreditation program. In addition, OPT and RHC providers were not part of the validation sample in FY 2014.
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.

Graph 3
Number of Representative Sample Validation Surveys for Both Hospital and Non-Hospital Facilities (FYs 2007-2014)



Since 2007, CMS has worked to strengthen oversight of AOs. From FYs 2007-2012, the number of validation surveys conducted expanded significantly as more attention and Federal resources were made available to this priority area; however, FYs 2013-2014 showed slight decreases in the amount of surveys completed. These decreases were due to decreased funding available for validation surveys subsequent to the FY 2013 budget sequestration. The recent history of validation survey samples is as follows:

- 2007: 55 hospital and 35 non-hospital surveys totaling 90 surveys.
- 2008: 92 hospital and 76 non-hospital surveys totaling 168 surveys.
- 2009: 89 hospital and 102 non-hospital surveys totaling 191 surveys.
- 2010: 104 hospital and 191 non-hospital surveys, including 72 ASC mid-cycle surveys, totaling 295 surveys.
- 2011: 106 hospital surveys, including 33 LTCH mid-cycle surveys, and 183 non-hospital surveys totaling 289 surveys.
- 2012: 102 hospital and 230 non-hospital surveys totaling 332 surveys.
- 2013: 106 hospital and 192 non-hospital surveys totaling 298 surveys.
- 2014: 115 hospital and 172 non-hospital surveys totaling 287 surveys.

These numbers represent a 219 percent increase in the overall number of validation surveys conducted, from 90 in FY 2007 to 281 in FY 2014. During the same time period, the number of non-hospital validation surveys conducted increased by 391 percent, from 35 surveys in FY 2007 to 172 surveys in FY 2014. The number of hospital validation surveys conducted increased by 109 percent, from 55 surveys in FY 2007 to 115 surveys in FY 2014.

60-Day Validation Surveys

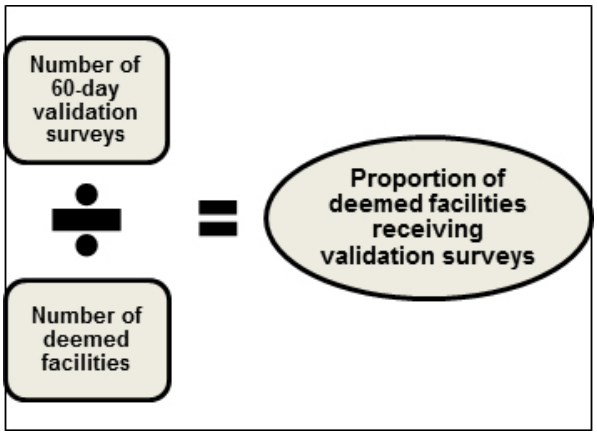
The purpose of 60-day validation surveys is to assess the AO's ability to ensure compliance with Medicare conditions. These validation surveys are on-site full surveys completed by SA surveyors no later than 60 days after the end date of an AO's Medicare accreditation program full survey. The SA performs 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. CMS determines the number of validation surveys to perform for each AO based on the number of facilities the AO surveys each month, as well as the overall budgeted targets, by State and facility type, for validation surveys. CMS then attempts 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



The proportion of facilities that received a 60-day validation survey in FY 2014 is as follows:

- **Hospitals**: Three percent of deemed hospitals received a validation survey in FY 2014 (103) validation surveys conducted out of 3,629 deemed facilities).

- **Psychiatric Hospitals**: Three percent of deemed facilities received a validation survey in FY 2014 (12 validation surveys conducted out of 425 deemed facilities).

- **CAHs:** Six percent of deemed CAHs received a validation survey in FY 2014 (27 validation surveys conducted out of 439 deemed facilities).

- **HHAs:** Two percent of deemed HHAs received a survey in FY 2014 (75 validation surveys conducted out of 4,652 deemed facilities).

- **Hospices:** One percent of deemed hospices received a validation survey in FY 2014 (16 validation surveys conducted out of 1,562 deemed facilities).

- **ASCs:** Four percent of deemed ASCs received a validation survey in FY 2014 (54 validation surveys conducted out of 1,507 deemed facilities).

Validation Analysis

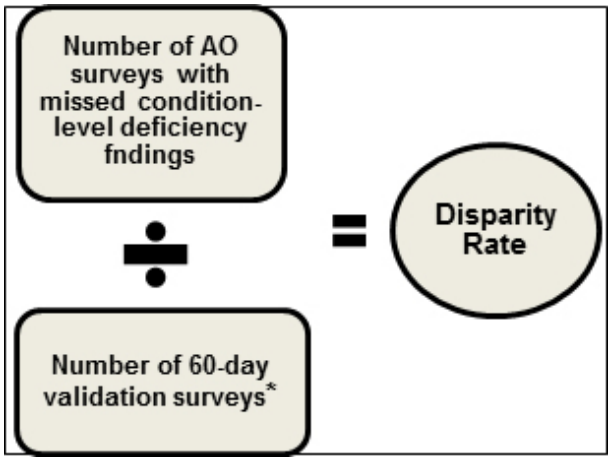
Condition-Level Deficiencies and Disparity Rate

Once 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 problems in a facility. The premise of the analysis is that condition-level deficiencies cited by the SA during the 60-day validation survey would also have been present 60 days prior, during the AO's Medicare accreditation survey, and should also have been cited by the AO.

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

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

Figure 2
Disparity Rate Calculation



* The number of 60-day validation surveys includes the total number of 60-day validation surveys conducted regardless of whether or not the SA-cited condition-level deficiencies.

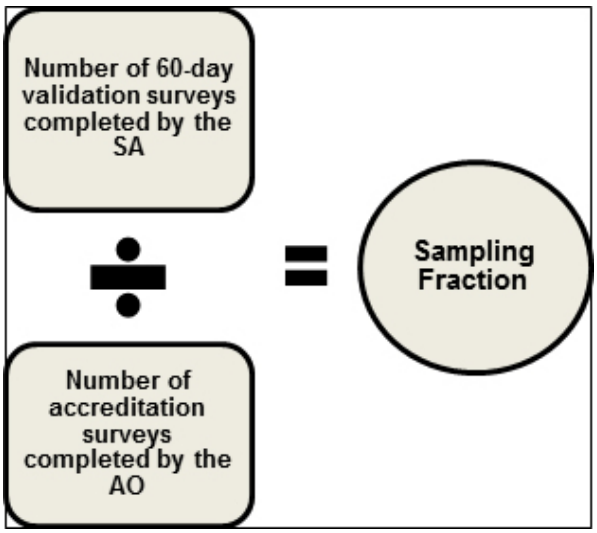
The methodology for the disparity rate is set by regulation at 42 CFR 488.1. The numerator is the number of surveys where the AO did not cite a comparable serious (condition-level) deficiency cited by the SA. The denominator is the total number of surveys in the 60-day representative validation sample.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

A lower disparity rate indicates better AO performance. The regulations at 42 CFR 488.8(d) require that CMS identify any AO with a disparity rate exceeding 20 percent.

Sampling Fraction

The sampling fraction is the proportion of AO surveys 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 five percent. CMS has worked to increase this sampling fraction for each AO and to include a minimum of five 60-day validation surveys per year for each AO program, no matter how small the program.

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

Validation Performance Results: Each Facility Type

The table below presents the results of the 60-day validation surveys for all AOs from FY 2008 through FY 2014 by facility type. (See Table 6)

Table 6
60-Day Validation Survey Results for Each Facility Type
(FYs 2008-2014)

	FY 2008	FY 2009	FY 2010	FY 2011	FY 2012	FY 2013	FY 2014
HOSPITAL							
60-Day Validation Sample	92	89	104	73	102	96	103
SA: Condition-level Deficiencies	43	39	47	36	50	52	41
Missed by AO	30	32	40	32	45	44	39
Disparity Rate	33%	36%	38%	44%	44%	46%	38%
Sampling Fraction	.06	.06	.07	.05	.08	.07	.09
PSYCHIATRIC HOSPITAL							
60-Day Validation Sample *	-	-	-	-	8	10	12
SA: Condition-level Deficiencies	-	-	-	-	6	6	10
Missed by AO	-	-	-	-	6	6	9
Disparity Rate	-	-	-	-	75%	60%	75%
Sampling Fraction	-	-	-	-	.05	.06	.08
CAH							
60-Day Validation Sample	17	22	23	20	33	35	27
SA: Condition-level Deficiencies	9	16	16	11	15	17	16
Missed by AO	7	15	15	9	12	14	14
Disparity Rate	41%	68%	65%	45%	36%	40%	52%
Sampling Fraction	.15	.14	.16	.14	.13	.23	.17
HHA							
60-Day Validation Sample	21	51	76	77	102	80	75
SA: Condition-level Deficiencies	5	9	15	15	30	15	16
Missed by AO	3	8	11	12	19	11	11
Disparity Rate	14%	16%	14%	16%	19%	14%	15%
Sampling Fraction	.03	.03	.05	.05	.05	.04	.04

HOSPICE							
60-Day Validation Sample**	0	0	20	20	21	18	16
SA: Condition-level Deficiencies	NA	NA	5	3	2	1	3
Missed by AO	NA	NA	5	1	2	1	1
Disparity Rate	NA	NA	25%	5%	10%	6%	6%
Sampling Fraction	NA	NA	.06	.07	.04	.03	.02
ASC							
60-Day Validation Sample***	38	29	0	66	66	61	54
SA: Condition-level Deficiencies	17	12	NA	34	25	30	22
Missed by AO	16	12	NA	30	21	24	17
Disparity Rate	42%	41%	NA	45%	32%	39%	31%
Sampling Fraction	.06	.05	NA	.11	.11	.10	.09

*Not part of the validation program as a separate program type until FY 2012. The psychiatric hospital accreditation program received initial CMS-approval in FY 2011.
*Validation program did not include hospice in FY 2009.
***No 60-day ASC validation surveys were performed in FY 2010. Instead, mid-cycle validation surveys were performed.

In FY 2014, with the exception of hospices, HHAs, and the DNV GL Hospital program, the disparity rate score for each facility type exceeded the 20 percent threshold established in regulation. In cases where the disparity rate for the AO's Medicare accreditation program exceeded the 20 percent threshold, CMS notified the AO of the finding.

To ensure and confirm AO improvement after notification, we employ a multifaceted approach that utilizes not only the representative sample validation survey disparity rate, but also a number of other quantitative measures of AO performance. These measures include on-going data exchange between AOs and CMS regarding deemed facilities, data management and analysis, CMS-AO communication and, AO education, and performance management. As a result of these efforts, we have many data points and improved information regarding AO performance

Note: The hospice and HHA disparity rates are significantly different than the other facility types due to the lower percentage of surveys with condition-level deficiencies cited by SAs in the 60-day validation samples for both hospice and HHA for FYs 2010-2014. This lower deficiency rate is primarily due to these facility types not having deficiencies related to PE conditions. There is no PE condition for HHAs since these services are provided in the patient's home. Although hospices do have a PE condition, a number of hospice services are provided in the patient's home as well.

In FY 2014, the disparity rate for psychiatric hospitals was 75 percent. The disparity rate for CAHs was 52 percent. These disparity rates not only exceed the 20 percent threshold, but have increased by 15 percent and 12 percent respectively from FY 2013.

Validation Performance Results: Individual AOs

Each AO receives feedback on the results of CMS' analysis of 60-day validation surveys for its deemed status facilities. The series of tables below, presents the results of the 60-day validation surveys by facility type for each of the AO Medicare accreditation programs from FYs 2008-2014. (See Tables 7-12)

When the number of 60-day validation surveys completed by the SA is less than five surveys, the disparity rate is not presented. The small 60-day validation sample sizes limited the analysis of some AO programs. Since 2008, CMS has tried to significantly increase the number of 60-day validation samples. With minimal exception, the sample size for every AO program was either maintained or increased from FYs 2011 to 2012. However, in FY 2014, due to decreased funding, the number of validation surveys for CAHs, HHAs, hospices and ASCs decreased. There was a slight increase in the number of validation surveys for hospitals and psychiatric hospitals. (See Tables 8 and 9) CMS hopes to maintain a larger sample size in the future based on the availability of Federal funds. The presentation of validation results for several time periods provides a more complete examination of the consistency of individual AO performance. Therefore, the results for the FYs 2008-2013 60-day validation surveys for individual AOs have been combined in the tables below to provide a more robust and reliable estimate of the disparity rates.

As was true for the national disparity rates for each facility type, the disparity rates between FYs 2008 and 2014 for each of the individual AO programs that received 60-day validation surveys consistently exceeded 20 percent, with the same exceptions of AO hospice and HHA programs. Additionally, in FY 2014, the disparity rate for DNV GL's hospital program fell below the 20 percent threshold.

Hospital

The AOs with hospital programs in FY 2014 were AOA/HFAP, CIHQ, DNV GL, and TJC. (See Table 7)

Table 7
Hospital 60-Day Validation Survey Results by AO
(FYs 2008-2014)

	AOA/ HFAP FYs 2008 - 2013	AOA/ HFAP FY 2014	DNV GL FYs 2009 - 2013*	DNV GL FY 2014	TJC FYs 2008 - 2013	TJC FY 2014	Total FYs 2008 - 2013	Total FY 2014
60-Day Validation Sample	29	7	31	20	496	76	556	103
SA: Condition - level Deficiencies	19	4	16	3	232	34	267	41
Missed by AO	19	4	14	3	190	32	223	38
Disparity Rate	66%	57%	45%	15%	38%	42%	40%	38%
Sampling Fraction	.04	.11	.08	.20	.07	.07	.07	.09

*DNV GL hospital accreditation program received initial CMS-approval September 2008. Therefore, there were no DNV GL Hospital validation surveys conducted in FY 2008.

- **AOA/HFAP:** In FY 2014, the disparity rate was 57 percent based on the completion of seven validation surveys. The number of validation surveys conducted represents an 11 percent sample of the surveys conducted by AOA/HFAP. The FY 2014 disparity rate is lower than the average disparity rate of 66 percent for FYs 2008-2013 which was based on a four percent sample of the surveys conducted during that period.

- **DNV GL:** In FY 2014, the disparity rate was 15 percent based on the completion of 20 validation surveys. The number of validation surveys conducted represents a 20 percent sample of the surveys conducted by DNV GL. The FY 2014 disparity rate is significantly lower than the average disparity rate of 45 percent for FYs 2009-2013 which was based on an eight percent sample of the surveys conducted during that period.

- **TJC:** In FY 2014, the disparity rate was 42 percent based on the completion of 76 validation surveys. The number of validation surveys conducted represents a seven percent sample of surveys conducted by TJC. The FY 2014 disparity rate is slightly higher than the average disparity rate for FYs 2008-2013 which was also based on a seven percent sample of surveys conducted during that period.

Psychiatric Hospital

The only AO with a CMS-approved psychiatric hospital Medicare accreditation program in FY 2014 was TJC. 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 2012-2014)

	TJC FY 2012	TJC FY 2013	TJC FY 2014	Total FYs 2012-2014
60-Day Validation Sample	8	10	12	30
SA: Condition-level Deficiencies	6	6	10	22
Missed by AO	6	6	9	21
Disparity Rate	75%	60%	75%	70%
Sampling Fraction	.05	.06	.08	.06

- **TJC**: In FY 2014, the disparity rate was 75 percent based on 12 validation surveys completed. The number of validation surveys completed represents an eight percent sample of the surveys conducted by the TJC. The FY 2014 disparity rate is higher than the disparity rate of 60 percent for FY 2013 which was based on a six percent sample of the surveys conducted during that period.

Critical Access Hospital

The AOs with CAH accreditation programs in FY 2014 were AOA/HFAP, DNV GL, and TJC. (See Table 9)

Table 9
CAH 60-Day Validation Survey Results by AO
(FYs 2008-2014)

	AOA/ HFAP FYs 2008-2013	AOA/ HFAP FY 2014	DNV GL FYs 2011*-2013	DNV GL FY 2014	TJC FYs 2008-2013	TJC FY 2014	Total FYs 2008-2013	Total FY 2014
60-Day Validation Sample	16	1	10	4	124	22	150	27
SA: Condition-level Deficiencies	10	1	6	2	68	13	84	16
Missed by AO	9	0	4	2	57	12	70	14
Disparity Rate	56%	NA	40%	NA	46%	55%	47%	52%
Sampling Fraction	.26	.06	.07	.10	.16	.22	.15	.17

NA: Not applicable due to sample size less than five.
* DNV GL accreditation program received initial CMS-approval November FY 2011.

- **AOA/HFAP:** In FY 2014, no disparity rate was calculated due to the small validation survey sample size. The number of validation surveys completed represents a six percent sample of the surveys conducted by the AOA/HFAP. In FYs 2008-2013, the average disparity rate was 56 percent based on a 26 percent sample of the surveys conducted during that period.

- **DNV GL:** In FY 2014, no disparity rate was calculated due to the small validation sample size. The number of validation surveys completed represents a 10 percent sample of the surveys conducted by the DNV GL. In FYs 2011-2013, the average disparity rate was 40 percent based on a seven percent sample of surveys conducted during that period.

- **TJC:** In FY 2014, the disparity rate was 55 percent based on the completion of 22 validation surveys. The number of validation surveys completed represents a 22 percent sample of the surveys conducted by TJC. The FY 2014 disparity rate is higher than the average disparity rate of 46 percent for FYs 2008-2013 which was based on a 16 percent sample of surveys conducted during that period.

Home Health Agency

The AOs with HHA accreditation programs in FY 2014 were ACHC, CHAP, and TJC. (See Table 10)

Table 10
HHA 60-Day Validation Survey Results by AO
(FYs 2008-2014)

	ACHC FYs 2008-2013	ACHC FY 2014	CHAP FYs 2008-2013	CHAP FY 2014	TJC FYs 2008-2013	TJC FY 2014	Total FYs 2008-2013	Total FY 2014
60-Day Validation Sample	67	23	206	28	134	24	407	75
SA: Condition-level Deficiencies	13	3	43	4	33	9	89	16
Missed by AO	7	3	32	4	25	4	64	11
Disparity Rate	10%	13%	16%	14%	19%	17%	16%	15%
Sampling Fraction	.04	.08	.05	.04	.04	.03	.04	.04

- **ACHC:** In FY 2014, the disparity rate was 13 percent based on the completion of 23 validation surveys. The number of validation surveys completed represents an eight percent sample of surveys conducted by ACHC. The FY 2014 disparity rate is slightly higher than the average disparity rate of 10 percent in FYs 2008-2013 which was based on a four percent sample of surveys conducted during that period.

- **CHAP:** In FY 2014, the disparity rate was 14 percent based on the completion of 28 validation surveys. The number of validation surveys completed represents a four percent sample of the surveys conducted by CHAP. The FY 2014 disparity rate is a slightly lower than the average disparity rate of 16 percent in FYs 2008-2013 based on a five percent sample of the surveys conducted during that time.
- **TJC:** In FY 2014, the disparity rate was 17 percent based on the completion of 24 validation surveys. The number of validation surveys completed represents a three percent sample of the surveys conducted by TJC. The FY 2014 disparity rate is slightly lower than the average disparity rate of 19 percent in FYs 2008-2013 based on a four percent sample of the surveys conducted during that period.

Hospice

The AOs with hospice accreditation programs in FY 2014 were ACHC, CHAP and TJC. Hospice validation surveys were initiated in FY 2010. (See Table 11)

Table 11
Hospice 60-Day Validation Survey Results by AO
(FYs 2010-2014)

	ACHC FYs 2012-2013*	ACHC FY 2014	CHAP FYs 2010-2013	CHAP FY 2014	TJC FYs 2010-2013	TJC FY 2014	Total FYs 2010-2013	Total FY 2014
60-Day Validation Sample	2	1	40	7	37	8	79	16
SA: Condition-level Deficiencies	0	1	9	1	2	1	11	3
Missed by AO	NA	0	8	1	1	0	9	1
Disparity Rate	NA	NA	20%	14%	3%	0%	11%	6%
Sampling Fraction	.03	.02	.04	.02	.05	.02	.05	.02

*ACHC hospice accreditation program received initial CMS-approval in FY 2010.
NA: Not applicable due to sample size less than five or SAs cited no condition-level deficiencies.

- **ACHC:** In FY 2014, the disparity rate was not calculated due to the small validation sample size. In FYs 2012-2013, the average disparity rate was not calculated due to the small validation sample size.

- **CHAP:** In FY 2014, the disparity rate was 14 percent based on the completion of seven validation surveys. The number of validation surveys completed represents a two percent sample of the surveys performed by CHAP. The FY 2014 disparity rate is slightly lower than the average the disparity rate of 20 percent in FYs 2010-2013 based on a four percent sample of the surveys conducted during that period.

- **TJC:** In FY 2014, the disparity rate was zero percent based on eight validation sample surveys and no condition level deficiencies missed by the AO. The number of validation surveys completed represents a two percent sample of the surveys performed by TJC. In FYs 2010-2013, the average disparity rate was three percent based on a five percent sample of the surveys conducted during that period.

Ambulatory Surgery Center

The AOs with ASC accreditation programs in FY 2014 were AAAASF, AAAHC, AOA/HFAP, and TJC. (See Table 12)

Table 12
ASC 60-Day Validation Survey Results by AO
(FYs 2008-2014)

	AAAASF		AAAHC		AOA/HFAP		TJC		Total	
	FYs 2008-2013*	FY 2014	FYs 2008-2013*	FY 2014	FYs 2008-2013 **	FY 2014	FYs 2008-2013*	FY 2014	FYs 2008-2013*	FY 2014
60-Day Validation Sample	18	4	183	26	2	1	57	23	260	54
SA: Condition -level Deficiencies	11	0	81	13	1	0	25	9	118	22
Missed by AO	10	N/A	70	9	1	N/A	22	8	103	17
Disparity Rate	56%	N/A	38%	35%	N/A	N/A	39%	35%	40%	35%
Sampling Fraction	.07	.06	.09	.09	.11	.11	.08	.10	.09	.08

*No 60-day ASC validation surveys were performed in FY 2010. Instead, mid-cycle validations surveys were performed.
**Very few AOA/HFAP ASC validation survey selections have been made since FY 20084 due to the low numbers of deemed ASCs.
NA: Not applicable due to sample size less than five, no validation surveys conducted, or. SAs cited no condition-level deficiencies.

- **AAAASF:** In FY 2014, 4 ASC validation surveys were conducted. The number of validation surveys completed represents a six percent sampling fraction. In FYs 2008-2013, the average disparity rate was 56 percent. The number of validation surveys completed represents a seven percent sample of the surveys performed by AAAASF during that period.

- **AAAHC:** In FY 2014, the disparity rate was 35 percent based on the completion of 26 validation surveys. The number of validation surveys completed represents a nine percent sample of the surveys performed by AAAHC. The FY 2014 disparity rate is slightly lower than the average disparity rate of 38 percent in FYs 2008-2013 which was also based on a nine percent sampling fraction of the surveys conducted during that period.

- **AOA/HFAP:** In FY 2014, one ASC validation survey was conducted. The number of validation surveys completed represents eleven percent of the surveys performed by AOA/HFAP. In FYs 2008-2013, the average disparity rate was not calculated due to the small validation sample size. The number of validation surveys completed represents an 11 percent sample of the surveys performed by AOA/HFAP during that period. The number of deemed ASCs has been consistently low. Therefore, the pool of surveys from which to draw a representative sample is very small.

- **TJC:** In FY 2014, the disparity rate was 35 percent based on the completion of 23 validation surveys. The number of validation surveys completed represents a 10 percent sample of the surveys performed by TJC. The FY 2014 disparity rate is slightly lower than the average disparity rate of 39 percent in FYs 2008-2013 based on an eight percent sample of the surveys conducted during that period.

Validation Performance Results: PE 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 for the past several years with one exception. In FY 2014, the SAs identified more health and safety condition-level deficiencies than PE condition-level deficiencies in psychiatric hospitals.

Comparison of SA and AO Condition-Level Citation Findings

The first analysis yields the number of facilities cited by SAs for specific condition-level deficiencies and the number of surveys where the AOs missed citing comparable deficiencies. These results are discussed below by each specific facility type. (See Tables 13-18)

Table 13
Number and Type of Condition-Level Deficiencies
Cited on 60-Day Validation Surveys
Hospital
(FY 2014)

Medicare Conditions Sample Size - 103	Cited by SA	Missed by AO
Governing Body	9	6
Patient Rights	4	4
Quality Assurance Performance Improvement (QAPI)	3	3
Nursing Services	5	4
Medical Record Services	2	1
Pharmaceutical Services	5	3
Food and Dietetic Services	2	2
Utilization Review	1	1
Physical Environment*	**30**	**30**
Infection Control	7	4
Surgical Services	4	3
Anesthesia Services	2	2
Emergency Services	1	1

* Most frequently cited deficiency. Please note: Physical Environment refers to the number of physical environment CoPs, which includes the National Fire Protection Association Life Safety Code requirements CMS has adopted as part of its health and safety standards.

In FY 2014, the hospital sample consisted of 103 validation surveys. In this sample, 41 facilities were cited at the condition-level by the SAs. PE was the most prevalent condition-level deficiency cited by the SAs with 30 SA condition-level citations. The AOs missed the same number of comparable deficiencies for PE. The findings regarding PE were similar in FYs 2010-2013.

In FY 2014, the next most frequently SA-cited conditions were: Governing Body, cited nine times by the SAs and missed six times by the AOs, and Infection Control, cited seven times by the SAs and missed four times by the AOs.

Table 14
Number and Type of Condition-Level Deficiencies
Cited on 60-Day Validation Surveys
Psychiatric Hospital
(FY 2014)

Medicare Conditions Sample Size – 12	Cited by SA	Missed by AO
Governing Body	2	2
Patient Rights	2	1
QAPI	1	1
Medical Record Services	1	0
Food and Dietetic Services	2	2
Physical Environment	5	4
Rehabilitation Services	1	1
Special Medical Record Requirements for Psychiatric Hospitals*	**7**	**4**
Special Staff Requirements for Psychiatric Hospitals	3	1

* Most frequently cited deficiency

In FY 2014, the psychiatric hospital sample consisted of 12 validation surveys. In this sample, 10 facilities were cited at the condition-level by the SAs. Special Medical Record Requirements for psychiatric hospitals was the most prevalent condition-level deficiency cited by the SAs with seven SA condition-level citations. The AO missed four comparable deficiencies.

In FY 2014, the next most frequently SA-cited condition for psychiatric hospitals was PE, with five SA condition-level citations and four comparable deficiencies missed by the AO. In FY 2013, the most frequently cited condition-level deficiency by the SAs was PE with four SA condition-level citations. The AO missed two comparable deficiencies for PE that same year. Although the PE condition-level citation wasn't the most frequently cited condition for psychiatric hospitals in FY 2014, the SAs cited more PE condition-level deficiencies than the number cited in FY 2013. In comparison, the AO had a larger number of missed SA condition-level PE citations than the number missed in FY 2013.

Table 15
Number and Type of Condition-Level Deficiencies
Cited on 60-Day Validation Surveys
CAH
(FY 2014)

Medicare Conditions Sample Size – 27	Cited by SA	Missed by AO
Physical Plant and Environment*	**10**	**10**
Organizational Structure	3	2
Provision of Services	3	0
Clinical Records	1	0
Surgical Services	3	2
Periodic Evaluation and Quality Assurance (QA) Review	1	1
Special Requirements for CAH Providers of LTC Services	1	0

* Most frequently cited deficiency

In FY 2014, the CAH sample consisted of 27 validation surveys. In this sample, 16 facilities were cited at the condition-level by the SAs. PE was the most prevalent condition-level deficiency cited by the SAs with 10 SA condition-level citations. The AOs missed the same number of comparable deficiencies for PE. PE was also the most frequently cited condition in FYs 2010-2013.

In FY 2014, the next most frequently SA-cited conditions for CAHs were for Organizational Structure and Surgical Services with three SA condition-level citations and two comparable deficiencies missed by the AOs.

Table 16
Number and Type of Condition-Level Deficiencies
Cited on 60-Day Validation Surveys
HHA
(FY 2014)

Medicare Conditions Sample Size – 75	Cited by SA	Missed by AO
Patient Rights	1	1
Organization, Services, and Administration*	**9**	**5**
Group of Professional Personnel	7	3
Acceptance of Patients, Plan of Care & Medical Supervision	8	3
Reporting Oasis Information	2	2
Skilled Nursing Services	5	4
Therapy Services	1	1
Home Health Aide Services	7	1
Clinical Records	6	3
Evaluation of the Agency's Program	6	3
Comprehensive Assessment of Patients	4	3

* Most frequently cited deficiency

In FY 2014, the HHA sample consisted of 75 validation surveys. In this sample, 16 facilities were cited for condition-level deficiencies by the SAs. The most frequently cited conditions were: Organization, Services, and Administration, with nine SA condition-level citations and five comparable deficiencies missed by the AOs and Acceptance of Patients, Plan of Care & Medical Supervision, with eight condition-level SA citations and three comparable deficiencies missed by the AOs. Organization, Services, and Administration and Acceptance of Patients, Plan of Care & Medical Supervision were also the most frequently cited conditions in FY 2013.

In FY 2014, the next most frequently cited conditions were Group of Professional Personnel, with seven SA condition-level citations and three comparable deficiencies missed by the AOs, Home Health Aide Services with seven SA condition-level citations and one comparable deficiency missed by the AOs.

Table 17
Number and Type of Condition-Level Deficiencies
Cited on 60-Day Validation Surveys
Hospice
(FY 2014)

Medicare Conditions Sample Size – 16	Cited by SA	Missed by AO
Interdisciplinary Group (IDG), Care Planning, Coordination of Services	1	0
Medical Director	1	1
Organizational Environment	1	0
Volunteers	1	0

In FY 2014, the Hospice sample consisted of 16 validation surveys. In this sample, three facilities were cited for condition-level deficiencies by the SAs. IDG, Care Planning, Coordination of Services, Medical Director, Organizational Environment and Volunteers were all cited for condition-level deficiencies by the SAs, but only the Medical Director condition-level deficiency was missed by the AO. In FY 2013, one facility was cited for condition-level deficiencies by the SA. Initial IDG, Care Planning, Coordination of Services and Organizational Environment were each cited at the condition-level once by the SAs and all were missed by the AOs.

Table 18
Number and Type of Condition-Level Deficiencies
Cited on 60-Day Validation Surveys ASC
(FY 2014)

Medicare Conditions Sample Size – 54	Cited by SA	Missed by AO
Governing Body and Management	11	7
Surgical Services	4	3
Quality Assessment & Performance Improvement	6	3
Physical Environment*	**14**	**11**
Medical Staff	1	1
Nursing Services	1	1
Medical Records	2	2
Pharmaceutical Services	1	0
Laboratory and Radiologic Services	2	2
Infection Control	12	4
Patient Admission, Assessment and Discharge	1	1

* Most frequently cited deficiency

In FY 2014, the ASC sample consisted of 54 validation surveys. In this sample, 22 facilities were cited for condition-level deficiencies by the SAs. The most frequently cited condition was PE, with 14 SA condition-level citations. The AOs missed 11 comparable deficiencies for PE. PE was also the most prevalent SA condition-level deficiency for ASCs in FYs 2009 and 2011-2013. In FY 2010, the 60-day validation sample did not include ASCs.

The next most frequently cited conditions were Infection Control, cited 12 times by SAs and missed four times by AOs, and Governing Body and Management, cited 11 times by SAs, and missed seven times by AOs. These findings were similar to the FY 2013 findings.

Comparison of Deficiencies for PE 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 and yields two disparity rates for each type of facility. (See Tables 19 and 20)

Table 19
Number of 60-Day Validation Surveys
for Facility Types with Life Safety Code (LSC) Requirements
(FY 2014)

Validation Survey Analysis	Hospital*	Psych Hospital	CAH	ASC
60-Day Validation Sample Surveys	103	12	27	54

*Acute Care and LTCHs

Table 20
60-Day Validation Survey Results
Comparison between All Other CoPs Cited and PE
for Facility Types with LSC Requirements
(FY 2014)

	Hospital All Other CoPs	Hospital PE	Psych Hospital All Other CoPs	Psych Hospital PE	CAH All Other CoPs	CAH PE	ASC All Other CoPs	ASC PE
SA: Condition-level Deficiencies	23	30	11	5	8	10	18	14
Missed by AO	16	30	6	4	4	10	8	11
Disparity Rate	16%	29%	50%	33%	15%	37%	15%	20%

In FY 2014, PE continued to have a significant impact on each facility type's overall disparity rate. The FY 2014 results show that the PE condition is still the single largest driver of the disparity rate for hospitals and CAHs. For hospitals and CAHs, the range of disparity rates based on the PE condition are between 13 and 22 percentage points higher than the disparity rates calculated based on other health and safety conditions. The PE disparity rate for ASCs was the same as the disparity

rate for other health and safety conditions in FY 2013. However, FY 2014 results show that the PE condition is the single largest driver of the disparity rate for ASCs as well. For ASCs, the disparity rate based on the PE condition is five percentage points higher than the disparity rate for other health and safety conditions. In FY 2014, the PE disparity rate for psychiatric hospitals was 17 percentage points lower than the disparity rate for other health and safety conditions. PE is an extremely significant driver of the disparity rate for CAHs, yielding a 22 percentage point difference between the PE and all other health and safety conditions disparity rates.

The majority of the PE disparity consists of LSC deficiencies. CMS generates a report which identifies the top disparate LSC deficiencies as determined by the validation analysis. This report is provided annually to the AOs. These top LSC disparate deficiencies are consistent with deficiencies cited in FYs 2009 through 2013. This report is shared with the AOs and is intended to provide the AOs with an understanding of the emphasis of CMS LSC surveys which will allow the AOs to ensure their programs are surveying the same LSC provisions. An emphasis on the top disparate LSC deficiencies should assist the AOs in their efforts to reduce LSC disparities.

The AOs have had difficulty identifying deficiencies that SAs have cited related to the requirements in the 2000 edition of the LSC, which CMS adopted by regulation. CMS has been working with all AOs to provide guidance on the source of this problem and possible ways to improve performance. CMS has continued to discuss with the AOs their concerns as well as their performance in the area of evaluating health care facility safety from fire. CMS is currently engaged in the rulemaking process to update the Federal regulations to the 2012 edition of the LSC. While we do not believe that the difference in LSC editions accounts for AOs' problems in identifying LSC deficiencies, this is an issue that AOs and the healthcare industry, have raised and could affect the survey process.

Comparison of Deficiencies and Disparity Rates for LTCHs and All Other Hospital Subtypes[8]

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.[9] (See Tables 21 and 22) CMS attempted to increase the LTCH sample size for 60-day representative sample surveys. However, due to the scheduling of LTCH Medicare accreditation surveys by the AOs and the concentration of LTCHs in certain states, CMS' ability to increase the sample size is limited. The need to mobilize a State survey team within 60 days of AO surveys that are not entirely predictable is the main limiting factor, as the fixed surveyor capacity of SAs makes it impractical for SAs in those states to conduct a larger number of validation surveys.

[8]Long-term care hospitals (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, that need hospital-level care for relatively extended periods. Other Hospital Subtypes are specific to acute care hospitals and do not include psychiatric hospitals.

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

Table 21
Number of 60-Day Validation Surveys and Overall Disparity Rate
LTCHs and All Other Hospital Subtypes
(FYs 2013-2014)

	FY 2013 LTCHs	FY 2014 LTCHs	FY 2013 All Other Hospitals*	FY 2014 All Other Hospitals*	FYs 2013-2014 Average LTCHs	FYs 2013-2014 Average All Other Hospitals*
60-Day Validation Surveys	17	8	79	95	13	87
Overall Disparity Rate	24%	38%	51%	39%	27%	38%

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

Table 22
Comparison of 60-Day Health and PE Validation Survey Results for LTCHs and All Other Hospital Subtypes
(FYs 2013-2014)

	FY 2013 LTCHs All Other Conditions	FY 2014 LTCHs All Other Conditions	FY 2013 LTCHs PE	FY 2014 LTCHs PE	FY 2013 All Other Hospitals All Other Conditions	FY 2014 All Other Hospitals All Other Conditions	FY 2013 All Other Hospitals PE	FY 2014 All Other Hospitals PE
SA: Condition-level Deficiencies	5	1	2	3	34	22	31	26
Missed by AO	2	0	2	3	16	16	29	26
Disparity Rate	12%	0%	12%	38%	20%	17%	37%	27%

Table 23
Comparison of Averages
60-Day Health and PE Validation Survey Results for LTCHs and All Other Hospital Subtypes
(FYs 2013-2014)

	FYs 2013-2014 Average LTCHs All Other Conditions	FYs 2013-2014 Average LTCHs PE	FYs 2013-2014 Average All Other Hospitals All Other Conditions	FYs 2013-2014 Average All Other Hospitals PE
SA: Condition-level Deficiencies	3	2.5	28	28.5
Missed by AO	1	2.5	16	27.5
Disparity Rate	8%	20%	18%	32%

From FYs 2013-2014, there is a 24 percent difference between the overall average disparity rates in LTCHs and all other hospital subtypes. However, when comparing the drivers of the average disparity rates, PE is the biggest driver in both LTCHs and all other hospital subtypes. Excluding PE, the most frequent disparate condition-level deficiencies for all other hospital subtypes in FY 2014 include Governing Body, Patient Rights, Infection Control and Nursing Services. PE was the only disparate condition-level deficiency for LTCHs in FY 2014. In FY 2013, the most frequent disparate condition-level deficiencies for all other hospital subtypes and LTCHs were Governing Body, Infection Control and QAPI.

SECTION 5: AO Performance Measures

AO Reporting Requirements

A major focus of CMS' ongoing work with each AO is monitoring and improving the AO's ability to provide CMS with complete, timely, and accurate information regarding deemed status facilities, as required at 42 CFR 488.4 (recodified in the 2015 final rule as § 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, it is imperative that CMS be notified promptly in order to take appropriate follow-up enforcement action. It is also essential for CMS to have information concerning upcoming AO survey schedules to effectively implement the validation program. To this end, AOs must submit the following to CMS:

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

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

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

AO Performance Measures and Scoring

In FY 2009, CMS instituted performance measures for AOs. These measures are reviewed and updated annually. These measures provide CMS with a method of assessing each AO's ability to provide CMS with timely, accurate and complete information regarding the various aspects of facility survey and monitoring activities, and enable CMS to determine the Medicare accreditation status of certified health care facilities.
Each performance measure is scored on a quarterly basis. For survey schedule measures and Web-ASSURE import file uploads, the quarterly score is calculated based on monthly scores. Annual scores are the average of all four quarterly scores. Measures are scored as a percentage of correct submissions for a specific month/quarter.

FY 2014 AO Performance Measures

In FY 2014, AOs were scored on their performance on 13 measures in four key performance focus areas: ASSURE Database; Facility Notification Letters; Survey Schedule; and Formal Correspondence. (See Table 24)

Table 24
FY 2014 AO Performance Measures

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

- The accuracy and completeness of deemed facility data in ASSURE as measured by:
  - The number of CMS CCNs present (not missing more than 180 days)
  - The number of pending surveys (not pending more than 180 days)
- The timeliness of conducting triennial (renewal) surveys
- The facilities with condition-level findings denied on initial surveys
- The timeliness of uploading Web-ASSURE import files
- The no-match lists as measured by:
  - The timeliness of electronic submission of no-match data follow-up activity
  - The evidence of no-match reconciliation

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

- The accuracy and completeness of the letters submitted as measured by:
  - All required attachments are included
  - Do not contain duplicate notices

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

- The accuracy of monthly survey schedules (specifically, no instances of arrival of the SA to conduct a validation survey and being informed that the accreditation survey had not been conducted as indicated on the survey schedule)
- The timeliness of reporting changes in the survey schedule and incorporating these changes in the next survey schedule submission (and in the proper format)
- The accuracy of the data in ASSURE regarding number of surveys reported as completed for the quarter and the number of surveys actually completed each quarter

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

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

Significant Changes for FY 2014 AO Performance Measures

Retired FY 2014 Performance Measures

In FY 2014, CMS retired one of the FY 2013 performance measures in one key performance focus area.

Facility Notification Letters

- Only required notifications submitted

New FY 2014 Performance Measures

CMS added four new performance measures in one key performance focus area in FY 2014.

ASSURE Database:

- Facilities denied on initial surveys with condition-level findings*
- Timeliness of uploading Web-ASSURE import files
- No-match lists
  - Timeliness of electronic submission of no-match data follow-up activity
  - Evidence of no-match reconciliation

* Our goal is not that AOs deny all initial applications; however, initial surveys that result in condition level findings must be denied accreditation. These facilities are required to undergo another full survey with no condition level findings before an AO can grant full accreditation and make a recommendation for deemed status.

Performance Measure Results

The FY 2013 and FY 2014 performance data for all AOs is presented below in two tables. (See Table 25) The first table presents results for performance measures that were monitored in FYs 2013 and 2014. A comparison is presented by FY for these measures. The second table presents results for performance measures specific to FY 2014, including the addition of four new measures (See Table 26). Therefore, the data in Table 26 cannot be directly compared to the FY 2013 performance measure results and are presented independently. Both tables present the performance measures according to the key focus areas. All results include quarterly averages utilizing standard rounding rules. The data represent the percent frequency with which the task required by the measure was performed in an accurate, timely, complete manner. A discussion of the performance measure scoring and results follows the tables.

Table 25
Performance Measure Results (Percentage) for All AOs
Comparable Measures for FYs 2013-2014

	FY 2013	FY 2014
Number of CCNs present (not missing more than 180 days)	98	99
Number of pending surveys (not pending more than 180 days)	100	100
Timely triennial surveys	100	100
Letters submitted with attachments	97	92
No duplicate notices submitted	95	100
AO conducted survey as reported on survey schedule	99	100
Timely submission of schedule changes and proper in-corporation into the next monthly schedule.	99	99
Number of surveys performed matches number reported in ASSURE	90	93
Responses to CMS on or before specified due date	93	89

Table 26
Performance Measure Results (Percentage) for All AOs
FY 2014
(Not Comparable to FY 2013 Measures)

	FY 2014
Denied initial surveys with condition level citations	45
Timely uploading of Web-ASSURE import files	98
Timely electronic submission of no-match data follow-up	96
Evidence of no-match reconciliation	100

Scoring Definitions:

- "Performed well" means a 100 percent score.
- "Substantial improvement" means improved by at least nine percent in FY 2014 compared to the previous year.
- "Opportunity for improvement" means any score below 90 percent in FY 2014.
- "Lower score" means a decrease of at least nine percent in FY 2014 compared to the previous year.

Highlights

1. **Assure Database**
   - All AOs scored 100 percent for the measure "Number of pending surveys (not pending more than 180 days)" in both FY 2013 and FY 2014.
   - All AOs scored at the 95 percent level or higher on every comparable measure in both FYs 2013 and 2014.
   - Only four AOs had sample sizes greater than five for "Denied initial surveys with conditions". All but one AO showed opportunity for improvement for this new FY 2014 measure.
   - All AOs performed well regarding the new FY 2014 measure "Evidence of no-match reconciliation" with the exception of one who did not have any information for this measure.

2. **Facility Notification Letters**
   - In FY 2013, all but one AO scored at the 97 percent level or higher for the measure, "Letters Submitted with Attachments", with the overall score impacted by this one AO. In FY 2014, two AOs showed opportunity for improvement for the same measure with an overall lower score impacted by these AOs.

3. **Survey Schedule**
   - In FY 2013, all but two AOs achieved a 100 percent score on two of the three measures. In FY 2014, all but one AO achieved a 100 percent score on two of the three measures.
   - The measure "Number of surveys performed matches the number reported in ASSURE" shows an opportunity for improvement for some AOs in both FYs 2013 and 2014.

4. **Formal CMS Correspondence**
   - In FY 2013, all but one AO achieved a 100 percent score with the overall score impacted by this one AO. In FY 2014, all but three AOs achieved a 100 percent score with the overall score impacted by the three AOs.

CMS continues to work closely with AOs to improve performance in areas that need improvement as well as to maintain high levels of performance in other areas. The goal is for all AOs to consistently score at or near 100 percent on all measures to ensure that AOs are effectively managing their Medicare accreditation programs and communicating vital program information to CMS.

AO Specific Discussion

American Association for Accreditation of Ambulatory Surgery Facilities (AAAASF)

Table 27
Performance Measure Results (Percentage) for AAAASF
Comparable Measures for FYs 2013-2014

	FY 2013	FY 2014
Number of CCNs present (not missing more than 180 days)	100	100
Number of pending surveys (not pending more than 180 days)	100	100
Timely triennial surveys	100	100
Letters submitted with attachments	97	66
No duplicate notices submitted	97	100
AO conducted survey as reported on survey schedule	100	100
Timely submission of schedule changes and proper in-corporation into the next monthly schedule.	100	100
Number of surveys performed matches number reported in ASSURE	97	94
Responses to CMS on or before specified due date	50	100

Table 28
Performance Measure Results (Percentage) for AAAASF
FY 2014
(Not Comparable to FY 2013 Measures)

	FY 2014
Denied initial surveys with condition level citations	0
Timely uploading of Web-ASSURE import files	92
Timely electronic submission of no-match data follow-up	75
Evidence of no-match reconciliation	100

For the performance measures that can be compared to FY 2013 scores, AAAASF continued to perform well on each of the three ASSURE Database performance measures in FY 2014. In summary, AAAASF performed well on seven of nine applicable comparable measures. AAAASF showed opportunity for improvement on one of the nine comparable measures, "notification letters submitted with attachments", for which they also had a lower score. AAAASF performed well on one of the four new FY 2014 ASSURE Database performance measures, "evidence of no-match reconciliation", but showed opportunity for improvement with regard to "denied initial surveys with

conditions" and "timely electronic submission of no-match data follow-up". For all measures where AAAASF demonstrated an opportunity for improvement or a lower score as compared to FY 2013, CMS worked with the AO to determine possible causes and provided guidance on improving future scores.

Accreditation Association for Ambulatory Health Care (AAAHC)

Table 29
Performance Measure Results (Percentage) for AAAHC
Comparable Measures for FYs 2013-2014

	FY 2013	FY 2014
Number of CCNs present (not missing more than 180 days)	95	96
Number of pending surveys (not pending more than 180 days)	100	100
Timely triennial surveys	100	100
Letters submitted with attachments	99	100
No duplicate notices submitted	99	98
AO conducted survey as reported on survey schedule	100	100
Timely submission of schedule changes and proper in-corporation into the next monthly schedule.	100	100
Number of surveys performed matches number reported in ASSURE	85	82
Responses to CMS on or before specified due date	100	100

Table 30
Performance Measure Results (Percentage) for AAAHC
FY 2014
(Not Comparable to FY 2013 Measures)

	FY 2014
Denied initial surveys with condition level citations	NA
Timely uploading of Web-ASSURE import files	100
Timely electronic submission of no-match data follow-up	100
Evidence of no-match reconciliation	100

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

For the performance measures that can be compared to FY 2013 scores, AAAHC continued to

perform well on the measures, “timely triennial surveys”, “number of pending surveys (not pending more than 180 days)”, “AO conducted survey as reported on survey schedule”, “timely submission of schedule changes and proper in-corporation into the next monthly schedule”, and “responses to CMS on or before specified due date” in FY 2014. In summary, AAAHC performed well on six of nine comparable applicable measures in FY 2014. AAAHC showed opportunity for improvement on one of the nine comparable measures, “number of surveys performed matches number reported in ASSURE”. AAAHC performed well on three of the four new FY 2014 ASSURE Database performance measures, “timely uploading of Web-ASSURE import files”, “timely electronic submission of no-match data follow-up” and “evidence of no-match reconciliation”, but showed opportunity for improvement on the “denied initial surveys with conditions” measure. For all measures where AAAHC demonstrated an opportunity for improvement compared to FY 2013, CMS worked with AAAHC to determine possible causes and provided guidance on improving future scores.

Accreditation Commission for Health Care (ACHC)

Table 31
Performance Measure Results (Percentage) for ACHC
Comparable Measures for FYs 2013-2014

	FY 2013	FY 2014
Number of CCNs present (not missing more than 180 days)	100	100
Number of pending surveys (not pending more than 180 days)	100	100
Timely triennial surveys	100	100
Letters submitted with attachments	100	100
No duplicate notices submitted	99	100
AO conducted survey as reported on survey schedule	100	100
Timely submission of schedule changes and proper in-corporation into the next monthly schedule.	92	100
Number of surveys performed matches number reported in ASSURE	91	93
Responses to CMS on or before specified due date	100	100

Table 32
Performance Measure Results (Percentage) for ACHC
FY 2014
(Not Comparable to FY 2013 Measures)

	FY 2014
Denied initial surveys with condition level citations	97
Timely uploading of Web-ASSURE import files	100
Timely electronic submission of no-match data follow-up	100
Evidence of no-match reconciliation	100

For the performance measures that can be compared to FY 2013 scores, ACHC continued to perform well on all of the ASSURE Database measures as well as "letters submitted with attachments", "AO conducted survey as reported on survey schedule" and "responses to CMS on or before specified due date". In summary, ACHC also performed well on two additional measures in FY 2014, "no duplicate notices submitted" and "timely submission of schedule changes and proper incorporation into the next monthly schedule". Overall, ACHC performed well in eight of the nine applicable comparable measures in FY 2014. ACHC performed well on three of the four new FY 2014 ASSURE Database performance measures, "timely uploading of Web-ASSURE import files", "timely electronic submission of no-match data follow-up" and "evidence of no-match reconciliation".

American Osteopathic Association/Healthcare Facilities Accreditation Program (AOA/HFAP)

Table 33
Performance Measure Results (Percentage) for AOA/HFAP
Comparable Measures for FYs 2013-2014

	FY 2013	FY 2014
Number of CCNs present (not missing more than 180 days)	100	100
Number of pending surveys (not pending more than 180 days)	100	100
Timely triennial surveys	100	100
Letters submitted with attachments	84	100
No duplicate notices submitted	100	100
AO conducted survey as reported on survey schedule	100	100
Timely submission of schedule changes and proper in-corporation into the next monthly schedule.	100	100
Number of surveys performed matches number reported in ASSURE	76	93
Responses to CMS on or before specified due date	100	100

Table 34
Performance Measure Results (Percentage) for AOA/HFAP
FY 2014
(Not Comparable to FY 2013 Measures)

	FY 2014
Denied initial surveys with condition level citations	NA
Timely uploading of Web-ASSURE import files	100
Timely electronic submission of no-match data follow-up	100
Evidence of no-match reconciliation	100

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

For the performance measures that can be compared to FY 2013 scores, AOA/HFAP continued to perform well on all of the ASSURE Database measures as well as "no duplicate notices submitted", "AO conducted survey as reported on survey schedule", "timely submission of schedule changes and proper in-corporation into the next monthly schedule", and "responses to CMS on or before specified due date". In summary, AOA/HFAP also performed well and demonstrated substantial improvement on the measure, "facility notification letters submitted with attachments". Overall, they performed well on eight of the nine applicable, comparable performance measures. AOA/HFAP demonstrated substantial improvement on the measure, "number of surveys performed matches number reported in ASSURE". AOA/HFAP performed well on three of the four new FY 2014 ASSURE Database performance measures, "timely uploading of Web-ASSURE import files", "timely electronic submission of no-match data follow-up" and "evidence of no-match reconciliation". However, they showed opportunity for improvement on the "denied initial surveys with conditions" measure.

Community Health Accreditation Program (CHAP)

Table 35
Performance Measure Results (Percentage) for CHAP
Comparable Measures for FYs 2013-2014

	FY 2013	FY 2014
Number of CCNs present (not missing more than 180 days)	98	99
Number of pending surveys (not pending more than 180 days)	100	100
Timely triennial surveys	100	100
Letters submitted with attachments	100	91
No duplicate notices submitted	100	100
AO conducted survey as reported on survey schedule	92	100
Timely submission of schedule changes and proper in-corporation into the next monthly schedule.	100	92
Number of surveys performed matches number reported in ASSURE	95	94
Responses to CMS on or before specified due date	100	75

Table 36
Performance Measure Results (Percentage) for CHAP
FY 2014
(Not Comparable to FY 2013 Measures)

	FY 2014
Denied initial surveys with condition level citations	81
Timely uploading of Web-ASSURE import files	N/A
Timely electronic submission of no-match data follow-up	100
Evidence of no-match reconciliation	100

N/A: AO enters data manually; does not use the upload function.

For the performance measures that can be compared to FY 2013 scores, CHAP continued to perform well on the measures, “timely triennial surveys”, “number of pending surveys (not pending more than 180 days)” and “no duplicate facility notification letters submitted”. In summary, CHAP also performed well on the measure, “AO conducted survey as reported on survey schedule”. Overall in FY 2014, CHAP performed well on four of nine applicable comparable measures. However, CHAP had a lower score and has opportunity for improvement on the measure, “responses to CMS on or before specified due date”. CHAP also had a lower score for the measure, “facility notification letters submitted with attachments.” CHAP performed well on two of the three applicable new FY 2014 ASSURE Database performance measures, “timely electronic

submission of no-match data follow-up" and "evidence of no-match reconciliation", but showed opportunity for improvement on the measure "denied initial surveys with conditions". CHAP did not have any information regarding "timely uploading of Web-ASSURE import files ", as information reported in ASSURE is entered manually and not imported into the system. For all measures where CHAP demonstrated an opportunity for improvement or a lower score as compared to FY 2013, CMS worked with CHAP to determine possible causes and provided guidance on improving future scores.

Center for Improvement in Healthcare Quality (CIHQ)

Table 37
Performance Measure Results (Percentage) for CIHQ
Comparable Measures for FYs 2013-2014

	FY 2013	FY 2014
Number of CCNs present (not missing more than 180 days)	*N/A	100
Number of pending surveys (not pending more than 180 days)	*N/A	100
Timely triennial surveys	N/A	N/A
Letters submitted with attachments	*N/A	100
No duplicate notices submitted	*N/A	100
AO conducted survey as reported on survey schedule	*N/A	100
Timely submission of schedule changes and proper in-corporation into the next monthly schedule.	*N/A	100
Number of surveys performed matches number reported in ASSURE	*N/A	85
Responses to CMS on or before specified due date	*N/A	100

N/A: CIHQ received initial approval July 26, 2013. No renewal surveys were due to be conducted in FYs 2013 or 2014.
*N/A: FY 2013 measures not reported due to timing of initial approval.

Table 38
Performance Measure Results (Percentage) for CIHQ
FY 2014
(Not Comparable to FY 2013 Measures)

	FY 2014
Denied initial surveys with condition level citations	N/A
Timely uploading of Web-ASSURE import files	*N/A
Timely electronic submission of no-match data follow-up	**N/A
Evidence of no-match reconciliation	**N/A

NA: Not applicable due to sample size less than five.
*N/A: Data is manually entered into ASSURE.
**N/A: There were no "no-match" records during the reporting period.

CIHQ did not have any information for calculation of any of the FY 2013 comparable performance measures or new FY 2014 performance measure scores. In FY 2014, CIHQ performed well on all applicable measures with one exception. CIHQ had an opportunity for improvement on the measure, "number of surveys performed matches number reported in ASSURE". CMS worked with CIHQ to determine possible causes and provided guidance on improving future scores for this measure.

DNV GL-Healthcare (DNV GL)

Table 39
Performance Measure Results (Percentage) for DNV GL
Comparable Measures for FYs 2013-2014

	FY 2013	FY 2014
Number of CCNs present (not missing more than 180 days)	100	100
Number of pending surveys (not pending more than 180 days)	100	100
Timely triennial surveys	99	99
Letters submitted with attachments	100	96
No duplicate notices submitted	98	100
AO conducted survey as reported on survey schedule	100	100
Timely submission of schedule changes and proper in-corporation into the next monthly schedule.	100	100
Number of surveys performed matches number reported in ASSURE	89	99
Responses to CMS on or before specified due date	100	42

Table 40
Performance Measure Results (Percentage) for DNV GL
FY 2014
(Not Comparable to FY 2013 Measures)

	FY 2014
Denied initial surveys with condition level citations	NA
Timely uploading of Web-ASSURE import files	**N/A
Timely electronic submission of no-match data follow-up	100
Evidence of no-match reconciliation	100

NA: Not applicable due to sample size less than five.
**N/A: Data is manually entered into ASSURE.

For the performance measures that can be compared to FY 2013 scores, DNV GL continued to perform well on all applicable measures. DNV GL also performed well on the measure, "no duplicate notices submitted". In summary, DNV GL performed well in five of the nine applicable comparable measures, and showed substantial improvement on the measure, "number of surveys performed matches number reported in ASSURE". However, DNV GL had an opportunity for improvement and a lower score on the measure, "responses to CMS on or before specified due date". DNV GL performed well on two of the three applicable new FY 2014 ASSURE Database performance measures, "timely electronic submission of no-match data follow-up" and "evidence of no-match reconciliation", but had an opportunity for improvement for the measure, "denied initial surveys with conditions". DNV GL did not have any information for calculating a score for the measure, "timely uploading of Web-ASSURE import files", as information reported in ASSURE is entered manually. For all measures where DNV GL demonstrated an opportunity for improvement or a lower score as compared to FY 2013, CMS worked with DNV GL to determine possible causes and provided guidance on improving future scores.

The Joint Commission (TJC)

Table 41
Performance Measure Results (Percentage) for TJC
Comparable Measures for FYs 2013-2014

	FY 2013	FY 2014
Number of CCNs present (not missing more than 180 days)	95	96
Number of pending surveys (not pending more than 180 days)	100	100
Timely triennial surveys	98	99
Letters submitted with attachments	97	86
No duplicate notices submitted	69	100
AO conducted survey as reported on survey schedule	100	100
Timely submission of schedule changes and proper in-corporation	100	100

	FY 2013	FY 2014
into the next monthly schedule.		
Number of surveys performed matches number reported in ASSURE	97	97
Responses to CMS on or before specified due date	100	94

Table 42
Performance Measure Results (Percentage) for TJC
FY 2014
(Not Comparable to FY 2013 Measures)

	FY 2014
Denied initial surveys with condition level citations	0
Timely uploading of Web-ASSURE import files	100
Timely electronic submission of no-match data follow-up	100
Evidence of no-match reconciliation	100

For the performance measures that can be compared to FY 2013 scores, TJC continues to perform well on the measures, "number of pending surveys (not pending more than 180 days)", "AO conducted survey as reported on survey schedule" and "timely submission of schedule changes and proper incorporation into the next monthly schedule". In FY 2014, TJC also performed well and demonstrated substantial improvement on the measure, "no duplicate notices submitted". In summary, TJC performed well on four of the nine applicable comparable performance measures. However, TJC had a lower score and opportunity for improvement for the measure, "facility notification letters submitted with attachments". TJC performed well on three of the four new FY 2014 ASSURE Database performance measures, "timely uploading of Web-ASSURE import files", "timely electronic submission of no-match data follow-up" and "evidence of no-match reconciliation". However, TJC had an opportunity for improvement for the measure, "denied initial surveys with conditions". For all measures where TJC demonstrated an opportunity for improvement or a lower score as compared to FY 2013, CMS worked with the AO to determine possible causes and provided guidance on improving future scores.

SECTION 6: AO Self-Reported Program Improvements

Information presented in this section was self-reported by the AOs. CMS has not independently verified the statements made by individual AOs for accuracy.

The American Association for Accreditation of Ambulatory Surgery Facilities (AAAASF)

AAAASF Growth

AAAASF provided information on the various initiatives implemented during the past year to enhance the effectiveness of AAAASF's accreditation process and improve patient safety and quality. These initiatives include increased growth in all three of its CMS-approved programs. To date, AAAASF has nearly 500 active Medicare providers and suppliers. The RHC and OPT programs continue to grow rapidly at approximately 10 new applications per month. In 2014, AAAASF submitted a renewal application for continued deemed status for the AAAASF OPT program and is in the midst of the renewal process. The RHC renewal process is scheduled to take place in 2015. The AAAASF Board of Director's has continued to demonstrate its sensitivity to the changing needs of the Deemed programs. In FY 2014, AAAASF added another member to the accreditation team, and created new roles for clinical staff and survey schedulers to improve efficiency.

By creating a Compliance Specialist, AAAASF has shifted the detailed survey file review to a dedicated clinician, allowing the accreditation staff to focus on Medicare processes and providing better technical assistance to providers and suppliers. The Compliance Specialist is a clinical professional providing expert evaluation of the findings and corrective actions documented throughout the survey process. The clinical focus of the compliance reviews, free up AAAASF accreditation staff to conduct even more detailed completeness reviews. AAAASF has also added a CMS Survey Scheduler to focus on scheduling unannounced Medicare surveys. The scheduler prepares survey materials and ensures pre-survey materials are complete while maintaining cost efficiency.

AAAASF continues to host auditors from the OPT and RHC communities on its Board of Directors to ensure the programs have the direct attention of Board-Level Leadership. The accreditation staff has developed valuable relationships with the auditors as subject matter experts and surveyor training faculty.

The Importance of Peer Review

AAAASF updated Peer Review data now contains nearly 12 million procedures conducted in accredited facilities. This data provides vital statistical information to study patient safety indicators and drive standards revisions. AAAASF continues to work with the Board Auditors to create meaningful peer review programs for RHC and OPT. AAAASF is currently testing the next generation of the online Peer Review reporting system in parallel to the current data reporting period. This system will collect more points of information and is structured to facilitate improved data analysis.

Data Tracking Systems

AAAASF has revised crosswalks for all three deeming programs to reflect a more accurate relationship between all AAAASF standards and the CMS CFRs. The revisions also ensure consistency with CMS' publication of a final rule entitled, "Medicare and Medicaid Programs; Regulatory Provisions to Promote Program Efficiency, Transparency, and Burden Reduction; Part II". In 2014, CMS also released updated data tables containing CMS standards; the revised crosswalks reflect the most recent release of CMS data which corrected several omissions and duplications.

The new Director of Information Technology, joined AAAASF in 2014 and is dedicated to improving the accreditation process with new tools and performance tracking, and has greatly improved the integration and AAAASF's data upload to the ASSURE website. The Director of IT has enhanced the efficiency and capacity of the accreditation team with new tools to forecast workloads, identify and correct data entry errors, and improve our understanding of facility performance.

The AAAASF staff enjoys improved communications with Medicare ROs and SAs. Regions and States have become much more proactive at contacting AAAASF when questions arise in the course of the deeming process. CMS representatives at all levels have been extremely responsive to inquiries from AAAASF regarding facility enrollment information and providing guidance during unique situations.

AAAASF continues to perform well in performance measures due in large part to internal upgrades. The monthly ASSURE upload provides more regular interaction with CMS data and systems, any data issues are readily apparent without a significant lag in time. As a result AAAASF has used the regular feedback to make dramatic improvements in various areas of data capture and tracking. One area of note is the development of an enhanced report which analyzes all citations for their relationship to CMS conditions. This tool is incredibly helpful in determining whether several low level deficiencies, when considered together, constitute condition-level noncompliance.

AAAASF has also revised all required CMS notification letters for all three Medicare programs to more accurately represent CMS elements.

AAAASF continued its commitment to improved online resources. AAAASF's e-Weekly newsletter has improved communications with accredited providers/suppliers as well as surveyors and consultants. The e-Weekly is distributed to all accredited facilities as well as those who sign up at the AAAASF website. It provides recipients with information relevant to health care and working in an accredited environment. There are dedicated sections that provide content specific to each provider and supplier type, including RHC and OPT.

Surveyor Education

AAAASF conducted two surveyor trainings and issued two online training supplements for the ASC program in 2014. Additionally, AAAASF issued two RHC online surveyor training supplements and one OPT supplement. The trainings emphasized improved surveyor documentation, more detailed surveyor instructions, and the various levels of review AAAASF conducts. The trainings also highlighted improved record review worksheets and clarified the proper methodology for selecting records. AAAASF is planning additional surveyor training outreach in 2015 for all programs to reinforce existing requirements and introduce additional

updates.

Surveyor training includes a combination of lecture, interactive workshops, and a practical evaluation with an experienced survey team during an on-site survey. Mentoring surveyors provide evaluation on trainee performance for QA and training improvement.

QA

The QA Committee meets on a quarterly basis to examine various aspects of overall surveyor performance in AAAASF. The quarterly meetings address any acute surveyor performance concerns such as any negative comments about surveyor performance from providers/suppliers, accreditation staff, consultants, or other surveyors. The QA Committee examines a number of metrics to indicate individual surveyor performance and track the trends in the overall performance of the surveyor community. During quarterly meetings, the committee also considers any instances of discrepant findings between routine surveys and validation surveys conducted by either CMS or AAAASF to determine surveyor performance. In addition, the committee performs an annual review of each surveyor's performance in the Medicare Deemed Programs.

The committee carries out a case review for surveyors where metric warrant more detailed study or when AAAASF receives a complaint. Final disposition of a surveyor review requires QA Committee action.

In 2014, AAAASF enhanced its internal QA program through a variety of means. The Medicare accreditation staff and management team conduct quarterly meetings to review CMS performance measure scores and scoring trends, and workshop challenging survey processing and evaluation questions. Compliance personnel attend the quarterly meetings when agenda items warrant. AAAASF reinforces any updates or CMS directives during its quarterly meeting.

AAAASF also conducts real time quality checks throughout the accreditation process. At several stages, survey files are checked by compliance personnel. Staff additionally conducts a checklist review when closing each file. Finally, AAAASF management conducts random quarterly file reviews based on a sample of surveys conducted in the period to ensure the file meets all requirements within all required timeframes.

Another new internal QA process AAAASF instituted in 2014 consists of a staff tracer. At least once per year, management personnel observe each staff member in conducting their part of the accreditation process. This process ensures that staff follows only approved processes and procedures.

Future Focus

The AAAASF Board of Directors has committed significant resources toward continued growth in the Medicare arena. AAAASF has dedicated many staff and resources to educate the provider groups and engages State and regional contacts. Our staff and Board representatives are scheduled to attend congresses in all deemed provider/supplier types and will be presenting on the accreditation process and standards throughout the year. AAAASF hopes to achieve a collaborative approach to the certification of deemed providers through continued outreach to the provider/supplier community, government offices, and fiscal intermediaries.

Accreditation Association for Ambulatory Health Care (AAAHC)

AAAHC provided information on the various initiatives implemented during the past year to enhance the effectiveness of AAAHC's accreditation process and improve patient safety and quality. These initiatives include:

From October 2013 to September 2014, AAAHC has continued to review and modify the AAAHC Medicare Deemed Status program to improve the customer experience.

Process Improvements

Effective in 2012, AAAHC implemented a three-year term of accreditation. Previously, accreditable facilities could be granted accreditation terms of six months, one year, and three years. This policy change streamlined our process and included an interim survey process, which allows for oversight within the three-year term.

When any deficiencies are cited through the AAAHC Medicare Deemed Status survey, an ASC is required to submit an acceptable plan of correction (POC). Depending on the severity of the deficiencies, an ASC may be required to undergo an interim survey, as a means of reviewing compliance during the accreditation cycle. AAAHC continues to refine this accreditation model, tracking data to assess operational challenges in the delivery of survey findings, reviewing recurring factors that lead to follow-up surveys, and developing educational opportunities to address those common obstacles within the three-year term.

Throughout the last two years, AAAHC worked tirelessly to implement a new survey process to review LSC requirements and physical plant requirements during the on-site survey. Specialized Life Safety Surveyors were recruited, targeting those with expertise and experience in reviewing physical plant and Life Safety requirements. Ongoing review and monitoring of feedback from surveyed organizations and surveyors relative to this survey process are used to improve the program.

System Improvements

Every year AAAHC reviews its electronic reporting systems to ensure that complete information is consistently reported to CMS. We have updated our data systems to address changes in the environment and to assist the implementation of the web-based ASSURE reporting system. We continue to monitor our internal database systems to ensure that errors are addressed promptly.

AAAHC continues to receive positive feedback about its electronic POC process. Customers enjoy improved access in completing its POC through a web-based system. This system streamlines the electronic capture of documentation and supporting evidence and provides better access to data mining.

In addition to reviewing electronic reporting and database systems, AAAHC reviews its staffing needs on a regular basis. Throughout its history, the AAAHC has ensured staff availability to answer questions and concerns directly, instead of relying on automated systems. AAAHC continues to strive for improvements in customer service and in 2014, used customer service training to support staff fulfillment of customer service needs.

Performance Measures

AAAHC is proud of its record of consistent high scores for the performance measures set by the CMS. Outside of the CMS performance measures, AAAHC surveys organizations after the on-site survey to determine customer satisfaction. We continue to enjoy high satisfaction ratings from accredited organizations. We use the data collected on both the CMS performance measures and our own customer surveys to search for ways to improve the accreditation and survey process.

Education

AAAHC maintains resources to help ASCs understand and meet CMS requirements. We communicate to ASCs through newsletters, e-mail blasts, and our website. Program updates are posted on the AAAHC homepage or under the section News and Resources. AAAHC produces Connection—a bimonthly e-newsletter that focuses on a single topic of interest. Topics range from single standards to larger health care issues, such as safe injection practices.

AAAHC continues to provide quarterly face-to-face education programs with focused sessions on issues related to the CMS CfCs. During this past year, AAAHC improved its on-site educational seminars in many ways, including:

- Using the collected data to provide targeted education on commonly found deficiencies.
- Including time for organizations to network with one another.
- Partnering with Association for Professionals in Infection Control (APIC) to provide infection prevention specific education to attendees.
- Adding a "chat room" where attendees can ask AAAHC staff and faculty questions related to the accreditation process and requirements.

In addition, AAAHC produces a webinar series aimed at supplementing the quarterly on-site education. Previous topics for this series have included: Top Deficiencies, Quality Improvement, LSC and Credentialing and Privileging.

AAAHC Surveyors are required to fulfill annual requirements that include participation in web-based learning experiences. On-site training is required on a biennial basis to maintain surveyor privileges. AAAHC has developed an online learning management system to provide access to available resources for ASCs, as well as surveyor specific resources and educational tools that provide in-depth information on CMS requirements. Weekly e-mail communications and online training provide updates on CMS requirements, as needed.

New Resources

On December 2014, AAAHC released the second annual Accreditation Association Electronic National Evaluation and Information Dataset (AENEID) report on Top AAAHC Standard Deficiencies. AAAHC, in conjunction with the Institute for Quality Improvement, developed Patient Safety Toolkits with a focus on frequently cited areas, such as emergency management, deep vein thrombosis (DVT) management, and surgical checklists. These toolkits are available to accredited facilities for free.

During the on-site educational seminars, data from the AENEID and ASSURE systems are used to correlate the top-cited AAAHC and CMS CfCs. This allows interested attendees a chance to learn

about common obstacles and challenges within AAAHC Standards and the CMS CfCs.

Disparity Rate Analysis

AAAHC conducts ongoing, in-depth analysis of validation and Accreditation/Deemed Status Survey findings. The analysis compares data received from validation surveys conducted by SAs with AAAHC survey documents. Through this analysis, AAAHC continues to identify opportunities to reduce disparities and improve survey processes and education. AAAHC is proud to note the reduction of its disparity rate by almost half. Surveyors are given additional training and information related to these disparity issues. ASCs and patients realize the benefit of this improvement through the survey process.

AAAHC Recognition

AAAHC has been accrediting health plans since 1983 and has been recognized by CMS for Medicare Advantage plans since 2002 and more recently, we received recognition from The Center for Consumer Information & Insurance Oversight to accredit qualified health plans. We continue to receive recognition as an AO for the US Air Force, US Coast Guard, and Federally Qualified Health Centers.

Accreditation Commission for Health Care (ACHC)

ACHC provided information on the various initiatives implemented during the past year to enhance the effectiveness of ACHC's accreditation process and improve patient safety and quality. These initiatives include:

Home Health Deeming Authority

The CMS approved ACHC for continued recognition as a national AO for home health agencies that wish to participate in the Medicare or Medicaid programs. The status reflects ACHC's commitment to providing the highest-quality accreditation services with standards that meet or exceed Medicare CoPs. The status will remain in effect through February 24, 2021. This six year authorization of ACHC as a CMS-approved national AO signifies the maximum term achievable.

Ongoing Compliance and Certification Interconnection System Operation (ISO) 9001:2008

ACHC's Quality Management System (QMS) promotes accuracy and consistency throughout all organizational operations. The QMS is audited through on-site visits annually by an outside registrar. The ISO quality policy statement commits ACHC to developing and improving healthcare accreditation programs and services, meeting customer and regulatory requirements, enhancing employee skills and efficiencies, continual improvement of quality management systems/processes, sustaining fiscal growth and improving market presence.

CMS Acknowledgement of ACHC Surveyors

ACHC quality is centered on the exceptional survey experience that is provided to all organizations. In a letter to ACHC on August 29, 2014, the CMS technical review team commended the ACHC

surveyors; “ACHC’s surveyor conducted an effective, efficient, and comprehensive survey. Her systematic approach facilitated the evaluation of standards compliance, quality of care, treatment provided, and patient safety within the organization. The surveyor was knowledgeable and developed collegial relationships with staff and administrators. She identified and documented areas that required additional information, evidence, and analysis to determine compliance. She handled difficult situations with professionalism, diplomacy and grace. She identified numerous teachable moments to interact with staff and assist with improving the quality of care provided to their patients.”

Educational Resources

As a nationally-recognized AO, ACHC places great value on continuing education in regard to achieving and maintaining accreditation. As such, workshops are regularly offered throughout the year to provide healthcare organizations the opportunity to familiarize themselves with ACHC compliance requirements, learn about industry best practices, and enhance the overall quality of patient care. ACHC also offers program-specific resources including *ACHC Accreditation Guide to Success* workbooks, compliance checklists, and regular multimedia updates.

The American Osteopathic Association/Healthcare Facilities Accreditation Program (AOA/HFAP)

The AOA/HFAP provided information on the various initiatives implemented during the past year to enhance the effectiveness of AOA/HFAP’s accreditation process and improve patient safety and quality. These initiatives include:

Staffing and Resources

- HFAP Life Safety Surveyors: HFAP expanded the survey team to include an LSC expert for accreditation and re-accreditation surveys. To meet this demand, a total of 10 experienced LSC specialists met eligibility criteria and were approved by the Bureau of Healthcare Facilities Accreditation Program (BHFA). A rigorous two-day orientation was provided by the HFAP Engineering Advisor with expertise in LSC compliance. Ongoing training has been provided to ensure ongoing surveyor awareness of CMS updates.

- HFAP Surveyor Training: The monthly HFAP Surveyor Newsletter, one method of surveyor education, serves as a formal vehicle to communicate new, modified, or troublesome accreditation requirements. Surveyor post-tests are retained as evidence of completed education. Additional training was provided to the HFAP surveyors regarding the Alternate Equipment Management (AEM) program initiated by CMS.

Accreditation Manual Improvements

- Accreditation Requirements for Acute Care Hospitals Manual: The Acute Care Hospital manual was revised to incorporate the May 2014 CMS Final Rule for Burden Reduction II. Additional updates reflect CMS mandates published in the Survey and Certification memorandum #14-07 AEM and Interpretative Guideline changes published in 2013 and 2014.

- Accreditation Requirements for CAHs Manual: The CAH manual underwent extensive revisions that meet or exceed CMS regulations, and went into effect January 2014. Additional updates incorporated the May 2014 CMS Final Rule for Burden Reduction II and mandates published in the Survey and Certification memorandum #14-14 AEM.

- Waiver Requests and Equivalency Requests: Revisions were made to the HFAP process to approve waiver requests and equivalency requests. Through the guidance by CMS, definitive written instructions were created that provides direction for healthcare organizations seeking waivers or equivalencies to LSC deficiencies. Once received in the HFAP office, these requests are reviewed by staff, and if HFAP agrees, they will send the request on to the respective CMS RO for their review and approval. A webinar was presented to the HFAP accredited organizations to educate them on the new process for approval.

Implementation of Standardized Tools for Facility Responses

- The Official HFAP Website: The HFAP Website was expanded to provide client access to the online version of the 2014 CAH Accreditation Requirements Manual. Furthermore, through this electronic update, survey deficiency reports for CAHs were automated, thus eliminating paper documents.

- Hospital Application Submission Timeframe: HFAP expanded its process to notify facilities one year in advance of their expiration date. With this change, facilities are now required to submit their applications nine months in advance of the expiration date. HFAP facilities are informed that surveyors can arrive anywhere between 120–180 days prior to the expiration date. Not only does this ensure the element of surprise for the facility, but also allows ample time to resolve any unforeseen circumstances that may arise, such as surveyor availability, challenges with travel, or any other issues.

Accreditation Surveys

- HFAP Life Safety Surveys: HFAP expanded the survey team to include a LSC expert for accreditation and re-accreditation surveys. During acute care hospital and CAH surveys, these LSC surveyors evaluate facility compliance with LSC and the current National Fire Protection Association (NFPA) regulations. The LSC surveyor inspections include comprehensive tours of the physical plant as well as a review of fire-safety documentation.

- CAHs: To reduce the cost of accreditation and reaccreditation surveys, the HFAP surveyor complement was analyzed to identify opportunities for improving efficiency. The outcome of this assessment resulted in significant changes; notably, the duration of CAH surveys has been reduced from three to two days.

Post Survey Processes: POCs

Upon receipt of a survey deficiency report, within 10 days, facilities are required to submit their POC to the HFAP. The process for reviewing these POCs was analyzed to identify opportunities for streamlining the review of these important facility documents. Strategies were implemented in accordance with QAPI methods. The outcome of this project has improved the efficiency of

securing approval for these POCs and more importantly, reduced the turnaround time for returning the approved POCs to the respective facility.

BHFA: Membership and Training

Membership rotation took place in accordance with AOA policy. New members with appropriate qualifications were added. At a meeting in Chicago, the entire BHFA membership (i.e., new and returning members) received education and training, including a review of CMS requirements, the survey process, and roles and responsibilities for accreditation/certification decisions.

Complaint Process

HFAP CO completed an evaluation of its internal processes for the review of complaints, which identified opportunities for improvement. Strategies were implemented regarding how each concern was reviewed and triaged, the validation of the triage score, and the determination as to whether an on-site survey was indicated. For any potential condition-level noncompliance, improved processes included the preparation of an agenda which lists specific conditions to be investigated, as well as other related areas of concern. These revisions have improved the communication and instructions provided to the surveyor to ensure an efficient and comprehensive investigation. Finally, these improvements have ensured more timely closure with written communications to the complainant.

Community Health Accreditation Program (CHAP)

CHAP provided information on the various initiatives implemented during the past year to enhance the effectiveness of CHAP's accreditation process and improve patient safety and quality. These initiatives include:

Standardization and Reliability

Consistency and validity of results are important elements of the accreditation process. Although the CMS performance data indicate CHAP outcomes are within acceptable limits, CHAP continually seeks opportunities for quality improvement in its accreditation processes. In 2014, CHAP developed and implemented several programs to measure and enhance consistency and reliability in the survey process, application of standards in measuring organizational performance and analysis of provider's corrective action plans (CAPs).

CHAP launched a pilot program, in 2014, to standardize the survey process and ultimately increase the consistency of accreditation outcomes. With input from surveyors garnered through a series of workshops, processes and tools were developed to measure and further standardize documentation review and analysis of survey findings. Additionally, a performance measurement tool was created to assess the validity of surveyor application of accreditation standards. Initial thresholds for compliance have been determined and the collection of data to garner a baseline understanding of current trends is ongoing. Analysis of the information collected and additional training and education will be provided to surveyors in mid-2015. The Reliability project will continue on an ongoing basis, expanding to other aspects of the accreditation process in 2015.

Performance data regarding the analysis and use of provider POCs – for deficient survey findings – was aggregated in 2014 and used in the ongoing effort to improve the consistency of accreditation outcomes. A secondary outcome of efforts to standardize the review of provider POCs was that the related data was used to improve the quality of submitted POCs.

Surveyor Training and Provider Education

CHAP surveyors participated in on-site training and a series of web-based courses throughout 2014. The surveyor education focused on improving the accuracy and consistency of data collection and documentation, enhancing competencies in the assessment and analyses of survey findings and increasing the accuracy of site visit documentation.

CHAP also hosted several educational offerings for CHAP accredited providers and members of the home and community-based health care industry at large in 2014. Accreditation intensive web-courses and several series of articles were provided to CHAP accredited agencies to assist providers in developing a systematic approach to improving quality of care and services. Additionally, live webcasts, post-event recordings and on-demand trainings for topics such as trends in the Office of the General Inspector (OIG) fraud enforcement and alternative sanctions for home health agencies have been offered to the public to assist providers in understanding changing regulations and mandates.

Support of Alliance for Home Health Quality and Innovation's (AHHQI) Future of Home Health Project

In 2014, CHAP also served as a platinum sponsor and active participant in the AHHQI Future of Home Health Project. The project is a research-based strategic planning effort on the future of home health care in America. In September 2014, CHAP sponsored an ad hoc committee at the Institutes of Medicine's National Academies two-day public workshop. The workshop was designed to:

1. Provide an overview of the current state of home health care (defined broadly), with an emphasis on Medicare-certified home health care providers, and inform understanding of the role home health care will play in the future of the health care system as a whole;
2. Examine and explore innovative care delivery models;
3. Discuss how to facilitate the role of home health care in achieving the Triple Aim of improving quality of patient care, improving population health and reducing overall cost of care; and
4. Consider specific needs including: infrastructure, workforce, research and measurement and technology. Attention will also be paid to policy reforms and communication strategies needed to recognize the value of home health care.

CHAP continues to sponsor and participate in the Future of Home Health Project to serve as a partner for members of the home and community-based health care industry in navigating the future of health care.

Center for Improvement in Healthcare Quality (CIHQ)

CIHQ provided information on the various initiatives implemented during the past year to enhance

the effectiveness of CIHQ's accreditation process and improve patient safety and quality. These initiatives include:

Identified Opportunity for Improvement

Based on feedback from our accredited hospitals, it was identified that our online CAP submission process needed to be reviewed, revised and improved.

Goal

To develop and implement changes to the CAP submission software system on the client's extranet site in order to facilitate ease of submission by accredited hospitals and to assure that the system was set up to trigger complete action plans that address all observations/deficiencies noted in the accreditation survey report.

Actions Taken to Implement the Process

1) Current CIHQ accredited hospitals, specifically individuals that were responsible for entering data into the CAP section of their CIHQ extranet site were interviewed in order to obtain specific information related to the ease of use for the online CAP submission software.
2) The interviews resulted in the following opportunities for improvement:
    a. The system was not designed to require a unique and complete CAP including a monitoring plan for each observation noted as part of the finding.
    b. The system was also not designed to allow the user to track which observations were being appealed vs. those that were to have CAPs entered.
    The system was also not designed to allow the user to easily track which CAPs had been entered and which ones were left unanswered.
3) The information technology department and survey staff at CIHQ took the feedback and essentially reconstructed our online CAP submission software component of our website including the following components:
    a. A mechanism to allow the user to easily see which findings were appealed vs. those that require a CAP to be entered.
    b. Once entered a mechanism was developed and implemented that would allow the user to tell which observations had been entered as appeal or CAPs and which ones had not been entered.
    c. Instructions for completing and submitting both CAPs and appeals were incorporated directly into the user screen for quick reference.
    d. The document entitled, "GUIDELINES FOR SUBMITTING A CORRECTIVE ACTION PLAN" was revised in June of 2014 to include instructions for using the improved software submission system.
    e. The revised guideline document was subsequently sent to each newly accredited organization via e-mail with an offer to provide a telephone tutorial by a CIHQ staff member should the facility deem that value added.
4) The same clients interviewed at the beginning of the project were asked to beta test the revised online CAP submission software.
5) The beta test resulted in a much improved product and the feedback obtained from the accredited hospitals indicated that the goal had been achieved.

6) Subsequent accredited hospitals have required little to no assistance in entering their CAP's and appeals.

Identified Opportunity for Improvement

A need for a mechanism or vehicle to communicate information to our accredited hospitals on some stable frequency was identified.

Goal

To develop and implement a communication vehicle for our accredited hospitals in order to keep them informed of changes to CIHQ or CMS regulations as well as survey procedure changes on an ongoing basis.

Actions Taken to Implement the Process

1) A team of senior leadership and staff was developed to identify the most efficient way to routinely communicate with accredited hospitals.
2) The team recognized that CIHQ currently publish Accreditation Alerts when there are changes to standards or survey procedures; however, it was felt that there needed to be a secondary mechanism to communicate with our accredited hospitals on a routine basis as part of the "partnership" business model that is integral to the CIHQ Hospital Accreditation Program.
3) The team developed and implemented a newsletter that would be published each month and would include the following static items:
    a. Celebration of newly accredited hospitals
    b. Tutorial component as to the use of and location of a tool, policy or form located in the resource library on the accredited hospital extranet site
    c. New documents added to the resource library in the last 45 days
    d. Tutorial component to the location of an item in the reference library that an organization may find added value
4) The newsletter would also include an overview of any accreditation alerts published the previous month with regard to standard or survey procedure changes.
5) The newsletters are sent to the main contact at each accredited hospital each month and then posted to their extranet site for 45 days.
6) Additionally, the newsletters will be archived for 12 months at a time should an organization wish to view a historical copy of the newsletter.

Identified Opportunity for Improvement

The CMS letter dated 11/24/2014 regarding the approval of time-limited and standard LSC waivers, a need was identified to develop instructional guidance along with template forms to be used in the waiver application process as defined by CMS.

Goal

To develop guideline and template waiver application forms for accredited hospitals to use in order to assure that adequate information is received when there is a need for CIHQ to apply for a waiver with an accredited hospital's CMS RO when a standard or time-limited waiver is needed for a LSC

deficiency.

Actions Taken to Implement the Process

1) A team of senior leadership and staff was developed to research the requirements regarding the application process for both a standard and time-limited waiver.
2) Once the requirements were established the team developed both a policy and template forms to be used to apply for either a standard or time-limited waiver.
3) The policy includes detailed specific instructions for the accredited organization to follow in order to assure that the required information can be provided by CIHQ to the RO on behalf of the organization.
4) The policy and template forms were approved by senior leadership in December 2014.
5) The approved documents were posted to the extranet site of all accredited organizations as well as to the extranet site of those organizations that have extranet sites established and are scheduled or ready to be scheduled for survey.

DNV GL-Healthcare (DNV GL)

DNV GL provided information on the various initiatives implemented during the past year to enhance the effectiveness of DNV GL's accreditation process and improve patient safety and quality. These initiatives include:

Effectiveness of the Annual Surveys

A unique aspect of the DNV GL accreditation process is that annual surveys are conducted in addition to the initial and reaccreditation surveys. This process has helped to facilitate compliance and improvements within the hospital to have on-site surveys throughout the accreditation cycle. One aspect we have introduced is a discussion of the innovative practices and other improvement actions the hospital has addressed. The annual survey process has proven to be very effective to enhance the accountability to keep hospitals more vigilant in meeting the regulatory requirements and our accreditation standards. This is a staple for ISO 9001 QMS certification to facilitate organizational improvement.

Introduction of the Stroke Ready Certification for CAHs and RHCs

The Acute Stroke Ready (ASR) Certification Program has been developed by DNV GL and integrates requirements related to the CMS CoPs, the Guidelines of the Brain Attack Coalition and Recommendations of the American Stroke Association. ASRs are designed to be a part of a larger stroke system of care which will include all levels of stroke care. The stroke ready certification will mean that a hospital is equipped to evaluate, stabilize and provide emergency care to patients with acute stroke symptoms. The intent of the ASR is to provide initial diagnostic services, stabilization, emergent care and therapies to patients with an acute stroke who are seen in the emergency department. In most cases, the ASR would be in a remote location and not in a densely populated urban or suburban area where there might be a nearby Primary or Comprehensive Stroke Center.

Managing Infection Risk

Developed first and only management standard on Biorisk – CWA 15793, sponsored by 24 countries (co-shared with U.S. Department of Agriculture). Based on this standard, DNV GL has approved the first of what will hope to be many hospitals achieving the Managing Infection Risk Management Certification. This is a program for designation of excellence to effectively reduce the risk of healthcare acquired infections (HAIs). This also coincides with the CMS Partnership for Patients to place more focus on the area of infection prevention and control. With the recent impact of the Ebola virus and the efforts to mitigate the risks of exposure to so many, it is prudent to further take this certification program to hospitals as a means of enhancing the confidence of those served by the hospitals.

Partnership with another AO

DNV GL and the ACHC have established a partnership allowing us to offer accreditation services to large hospitals and health systems who are jointly seeking accreditation for their hospital and ancillary services. Delivering accreditation programs designed to ensure adherence to State regulations and requirements as well as creating standards for accreditation that are relevant to the services provided.

Through our alliance with ACHC, hospitals are now able to achieve accreditation simultaneously for a wide variety of ancillary services, including home health, hospice, private duty, behavioral health, pharmacy, sleep and durable medical equipment prosthetics, orthotics and supplies (DMEPOS). ACHC has CMS deeming authority for various programs and has been a leader in the national accreditation industry for more than 27 years.

Customer Satisfaction Results

The customer satisfaction results have been overwhelmingly positive. This provides hospitals the means for providing direct feedback on the surveys. This is important to note as we have the responsibility as an AO with deeming authority to hold hospitals accountable for meeting our standards and the CMS CoPs, but this has also enabled us to build great relationships with our accredited hospitals to drive further improvement in patient care and patient safety. We have been able to lead this effort with assessing the overall effectiveness of the ISO 9001 QMS to create a means for improving the operations of the hospitals to facilitate better compliance.

Research and Innovation

DNV GL and Monday Morning Sustainia are supporting a global conversation on the future of healthcare. The need for change is clear with skyrocketing health spending, chronic disease pandemics, aging populations, global inequality, and many more. These numerous challenges have resulted in the unsustainability of healthcare systems around the world.

New approaches and readily available solutions are required to create healthcare that can enable people to live healthy, happy and independent lives, which at the same time prove more economically sustainable. We have started a global conversation on how we can co-create the safer, smarter and more sustainable healthcare systems of the future.

The next step of this initiative is to continue research and cooperation with health experts resulting in a second publication and the establishment of a global network of healthcare experts.

DNV GL continues to improve its internal processes based on communication and feedback from CMS. The CMS COs and ROs provide copies of the reports (Form 2567) for Validation Surveys completed of DNV GL accredited hospitals. This information is used to identify common findings and assist our surveyors to improve the consistency of the survey process. This has helped in identifying focus areas for survey and helping to identify issues to facilitate a better understanding of the CMS CoPs. This should be demonstrated in the improvement reflected in the disparity rate for FY 2014 Validation Surveys conducted.

The Compliance Team (TCT)

TCT RHC accreditation program received initial approval July 18, 2014; therefore, TCT does not have any self-initiatives to report this FY.

The Joint Commission (TJC)

TJC provided information on the various initiatives implemented during the past year to enhance the effectiveness of TJC's accreditation process and improve patient safety and quality. These initiatives include:

Continued Emphasis on Healthcare Associated Infections

TJC has merged its two online infection prevention resource portals into one convenient, expanded tool: the Infection Prevention and HAI Portal. The HAI Portal contains information accessible by all accredited organizations from TJC, TJC Center for Transforming Healthcare, and TJC Resources in one place. In addition, it offers links to other nationally recognized resources on infection prevention issues, including:

- The 2014 "Compendium of Strategies to Prevention Healthcare-Associated Infections in Acute Care Hospitals";
- TJC's Ebola Preparedness Resource Web Page;
- Resources on Emerging Issues such as Influenza and Enteroviruses;
- Disinfection and Sterilization Resources; and
- Resources Specific for Different or Various Healthcare Settings.

TJC strives to provide the best possible resources for healthcare professionals in a way that is easy for them to access. Our new Infection Prevention and HAI Portal accomplishes this by offering one simple place to find the most up-to-date information on these very important infection issues.

http://www.jointcommission.org/hai.aspx

Sentinel Event Alert #52: Preventing Infection from the Misuse of Vials

In June 2014, TJC released a *Sentinel Event Alert*, a complimentary patient safety publication, titled *Preventing Infection from the Misuse of Vials.* This issue was developed to educate health care organizations and health care professionals about preventing infection from the misuse of vials. The misuse of single-dose/single-use and multiple-dose vials has caused harm to individual patients through occurrences and outbreaks of blood borne pathogens and associated infections, including

hepatitis B and C virus, meningitis, and epidural abscesses. Specifically, this publication encourages health care organizations and professionals to educate staff on:

- Safe injection and infection control practices;
- Correct aseptic technique;
- Hand hygiene;
- One-time-only use of needles and syringes; and
- Safe infection control practices when transporting, storing, preparing, and administering medications.

TJC worked with the Centers for Disease Control & Prevention (CDC) to develop this issue of Sentinel Event Alert.

Sentinel Event Alert #53: Managing Risk during Transition to a New ISO Tubing Connector Standards

In August 2014, TJC released a *Sentinel Event Alert*, a complimentary patient safety publication, titled *Managing Risk during Transition to a New ISO Tubing Connector Standards.* This issue focuses on the continued risk of tubing misconnections that can cause severe patient injury and death, since tubes with different functions can easily be connected using luer connections, or connections can be "rigged" using adapters, tubing or catheters. New ISO tubing connector standards are being developed for manufacturers that will make it nearly impossible to connect one delivery system to another delivery system that serves a completely different function. TJC urges organizations to begin planning for the upcoming period of transition, which will introduce changes and new risks into the health care environment. The *Sentinel Event Alert* delineates suggested actions to prepare for the launch of the new ISO standards and help prevent tubing misconnections.

Collaborating with the CDC to Prepare Healthcare Organizations to Handle Infectious Disease

TJC worked with the CDC to prepare our nation's healthcare organizations for infectious disease, such as Ebola. Resources for all hospitals have been developed to provide guidance for preparedness. This has been accomplished by cross-walking the CDC resources with TJC standards to ensure compliance and the safe delivery of care. In addition, a resource was developed that presents the scenario of the first infectious disease patient walking through the door. This is an exercise-based resource that guides the healthcare organization to simulate how this patient will be handled during the first 96 hours in an inpatient setting. This guidance reviews staff/team response, use of personal protective equipment (PPE), isolation capabilities, specimen collection and analysis, waste management, and communication.

Introduction of Quick Safety: Ebola Response and Preparedness Portal

TJC in collaboration with the CDC is working to improve overall infection control across health care facilities that could impact not only Ebola, but also other events like flu, health care safety infections, and drug resistant infections. TJC has developed an Ebola Response and Preparedness Portal that contains the latest preparedness and response resources from TJC standards, CDC guidance, as well as other guidance from federal partners.

http://www.jointcommission.org/topics/ebola_preparedness_resources.aspx

Continued Recognition of the Top Performer on Key Quality Measures™ Program

Continued recognition of the *Top Performer on Key Quality Measures™ Program* for hospitals and CAHs that attain and sustain excellence in accountability measure performance. Nearly all of TJC's accountability measures have been recognized for inclusion in the CMS' Value-Based Purchasing program. In TJC's *2014 Annual Report on Quality and Safety*, 1,224 (36.9 percent) TJC accredited hospitals attained and sustained excellence in accountability measure performance for the previous year, 2013. This represents an increase of 11 percent from 2012 in terms of the total number of hospitals achieving this distinction, including a total of 712 hospitals that achieved the distinction for a second straight year, 314 hospitals that achieved the distinction for the third consecutive year, and 147 hospitals that have achieved the distinction for the fourth consecutive year.

Development of New Memory Care Requirements for Nursing Care Centers

Development of new memory care requirements designed to help accredited nursing care centers enable patients and residents with dementia to remain engaged in their environment at the level of their cognitive ability and function at their highest level for as long as possible. The new requirements encompass five key areas:

1) Staff collaboration and coordination of care consistent with current advances in Dementia care practices;
2) Staff knowledge and competency to provide care to those with memory impairment;
3) The provision of activities that match the cognitive ability, memory, attention span, language, reasoning ability, and physical function of the individuals served;
4) Behavior management with an emphasis on the use of non-pharmacological interventions; and
5) Providing care in a safe and supportive PE that minimizes confusion and overstimulation.

New Emergency Management Portal

Initiation of a new emergency management portal available on TJC website at www.jointcommission.org/emergency_management.aspx. The portal was developed to provide valuable, relevant and timely information and resources to healthcare organizations and the communities that they serve. In addition to TJC requirements associated with emergency management and preparedness, the portal includes a variety of disaster resources, as well as information concerning codes and alerts, exercises and drills, public health readiness, and lessons learned from recent disasters or emergencies.

High Reliability Organizations

High-reliability science is the study of organizations in industries like commercial aviation and nuclear power that operate under hazardous conditions while maintaining safety levels that are far better than those of health care. Adopting and applying the lessons of this science to health care offer the promise of enabling hospitals to reach levels of quality and safety that are comparable to those of the best high-reliability organizations. TJC has combined the knowledge of healthcare organizations with knowledge from the published literature and from experts in high-reliability industries and leading safety scholars outside healthcare. We have developed a conceptual and practical framework for assessing hospitals' readiness for and progress towards high reliability. Through iterative testing with hospital leaders, we refined the framework and, for each of its

fourteen components, defined stages of maturity through which we believe hospitals must pass to achieve high reliability. We discovered that the ways that high-reliability organizations generate and maintain high levels of safety cannot be directly applied to today's hospitals; therefore, we defined a series of incremental changes that hospitals should undertake to progress toward high reliability. These changes involve the leadership's commitment to achieving zero patient harm, a fully functional culture of safety throughout the organization, and the widespread deployment of highly effective process improvement tools. Hospitals can make substantial progress toward high reliability by undertaking several specific organizational change initiatives. TJC and the South Carolina Hospital Association launched a multiyear high reliability collaborative project to improve quality and safety of patient care. In addition, TJC continues working with other organizations and experts in the field to further research and practical experience to refine the framework for high-reliability healthcare delivery system.

SECTION 7: CMS Improvements

The volume of facilities that participate in the Medicare programs through accreditation from a CMS-approved accreditation program continued to grow in FY 2014. Currently, 36 percent, over 12,000 facilities, of all Medicare-participating facilities that have an approved accreditation program option demonstrate compliance with the Medicare requirements and participate in the Medicare program via their deemed status. There are currently nine CMS-recognized AOs and 21 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 2014, CMS focused on a number of key areas in order to continue to refine and maintain an effective oversight infrastructure:

- CMS/AO Communication and Relationship Building
- AO Education
- AO Performance Management
- Deemed Facility Data

CMS/AO Communication and Relationship Building

Communications

CMS continues its periodic meetings with recognized national AOs, including quarterly teleconferences and an annual face-to-face meeting. 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; better assure ongoing deemed facility compliance with Medicare conditions; and provide information and education for AO staff. CMS Central and RO staff, and individual AOs communicate on a weekly, if not daily, basis, either by e-mail or telephone, to address a wide variety of issues, including, but not limited to: specific deemed facility deficiencies, certification issues, program operations, surveys, requirements, interpretation of regulations, and data.

Consultation

CMS increased opportunities for AOs as well as other stakeholders to provide input into the development of sub-regulatory guidance concerning Medicare standards and survey processes. CMS has committed to ongoing consultation in an effort to improve the resulting guidance.

AO 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 at the annual CMS-AO meeting as well as periodically at the request of individual AOs. AOs are also provided the opportunity to send representatives to SA Surveyor Training. The CMS AO annual meeting continues to include breakout sessions by program type and interactive sessions. Also, in FY 2014, CMS provided

updates to the AO resource manual. This manual contains a wide variety of information on CMS requirements and expectations of AO performance.

AO Performance Management

Deeming Application, Standards, and Survey Process Reviews

Deeming application, standards, and survey process reviews are conducted by a team of trained analysts to ensure consistent application of a standardized rigorous review methodology. All findings are subject to detailed supervisory review to enhance reliability and consistency. As a result, AO applications, standards, and survey processes are reviewed comprehensively and consistently, and areas for improvement are being identified and communicated in writing to the AOs for correction before applications may be approved.

In FY 2014, the team completed five deeming application reviews (four renewals and one initial application). Other deeming program review activity included four one-year performance reviews, 26 standard and survey process reviews. CMS also identified and addressed 11 issues outside an application review that arose in case-specific instances and which suggested problems with the manner in which an AO had implemented its CMS-approved accreditation program. Through this case-based process, CMS facilitates resolution of issues and improved AO performance and oversight of deemed facilities. (See Section 1 for discussion of CMS review of AO accreditation programs)

AO Performance Measures

CMS continues to refine and improve the current methods for measuring AO performance in assuring compliance with the Medicare requirements. Measures are calculated and shared with individual AOs on a quarterly basis. Measures are reviewed, evaluated and updated on an annual basis. (See Section 5 for discussion of FY 2014 AO Performance Measures)

Standards Update in Response to Changes in CMS Requirements

The final rule entitled, "Medicare Program, Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and FY 2014 Rates; Quality Reporting Requirements for Specific Providers, Hospital CoPs, Payment Policies Related to Patient Status", published in the *Federal Register* August 19, 2013 (78 FR 50496), contained regulation revisions for the hospital requirement for nursing services at §482.23 and the CAH requirements for number of beds and length of stay at §485.620 and provision of services at §485.635. In accordance with the requirements at §488.4(b)(3)(iv), CMS requested and reviewed AOA/HFAP's, CIHQ's, DNV GL's, and TJC's standards, surveyor tools, documents and relevant surveyor training to ensure their accreditation program requirements continued to meet or exceed those of Medicare.

The final rule entitled, "Medicare and Medicaid Programs; Regulatory Provisions To Promote Program Efficiency, Transparency, and Burden Reduction; Part II", published in the *Federal Register* May 12, 2014, contained extensive regulation revisions for hospitals, psychiatric hospitals, CAHs, RHCs, and ASCs (79 FR 27106). In accordance with the requirements at §488.4(b)(3)(iv), CMS requested and reviewed AAAHC's, AAAASF's, AOA/HFAP's, CIHQ's, DNV GL's , TCT's,

and TJC's standards, surveyor tools, documents and relevant surveyor training to ensure their accreditation program requirements continued to meet or exceed those of Medicare.

The final rule entitled, "Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and FY 2015 Rates; Quality Reporting Requirements for Specific Providers; Reasonable Compensation Equivalents for Physician Services in Excluded Hospitals and Certain Teaching Hospitals; Provider Administrative Appeals and Judicial Review; Enforcement Provisions for Organ Transplant Centers; and Electronic Health Record (EHR) Incentive Program", published in the *Federal Register* August 22, 2014, contained revised location requirements for CAHs (79 FR 49854). In accordance with the requirements at §488.4(b)(3)(iv), CMS requested and reviewed AOA/HFAP's, DNV GL's, and TJC's standards, surveyor tools, documents and relevant surveyor training to ensure their accreditation program requirements continued to meet or exceed those of Medicare.

Data Exchange

CMS continues to focus on obtaining complete, accurate and timely data from AOs on facilities accredited under their CMS-approved accreditation programs. This has been a major challenge for both CMS and the AOs. Web-ASSURE, a CMS electronic database designed to inventory and track AO actions for deemed facilities, enables the AOs to provide demographic and survey activity information for deemed facilities to CMS monthly and on an ongoing basis. It provides both CMS and the AOs with the means to collect, analyze, and manage data regarding deemed facilities, and supports CMS oversight of the AOs and their CMS-approved accreditation programs.

In 2014, CMS implemented changes to the Web-ASSURE database to enhance the ability of the system to capture and present data in a more complete and accurate manner. In addition, numerous new features and updates were added to the system, based on stakeholder feedback, to improve communication between the AOs and CMS through the use of this data, improve CMS oversight, and make the system more user-friendly. These new features include the ability for Web-ASSURE to:

- Disseminate broadcast communication to an AO when a facility record has been matched to a national record. The AO retains control as to who within their organization would receive such communication.
- Set the Medicare CCN automatically in the system, when a record has been matched to a national record.
- Support the reporting of Medicaid-only participating facilities.
- Differentiate between a facility that is seeking initial participation in Medicare via accreditation by a CMS-approved AO or whether the facility is already participating in Medicare, but is seeking accreditation through a CMS-approved AO for the first time.
- Display both a facility's full Legal Business Name and Doing Business As Name.
- Eliminate the inclusion of withdrawn, denied and inactive records from the export file of facilities not yet matched to a record in the national database.
- Provide the end-user with links directly to the following resources: Certification and Survey Provider Enhanced Reporting (CASPER), Web-ASSURE CASPER Report Guides, and ASSURE End-User Tutorial Videos.
- Update program-specific regulation tables as regulatory changes are implemented to ensure the accurate capture and reporting of CMS-related deficiencies cited by an AO.

- Improve the format and usability of the Web-ASSURE upload error report for AO end-users who use the direct upload feature in the system.

AO Validation Surveys

A large and increasing number of providers achieve their Medicare participation by means of CMS deeming their eligibility as a result of accreditation by a CMS-approved accrediting body. As a result, CMS has sought to further strengthen the oversight of the AOs through a variety of methods, including increases to the sample sizes used in the validation surveys. Those validation surveys also form the essence of the statutorily-required annual Report to Congress on AO performance. The proposed increase in the AO validation survey budget for FY2016 and FY2017 is representative of those efforts.

There are currently 9 CMS-approved accreditation organizations (excluding CLIA AOs), and most AOs accredit multiple provider types. The percentage of Medicare-participating providers that achieve Medicare certification via deemed status varies substantially by provider type, but the percentage in each type has been slowly increasing over time.

Based on FY 2014 data, the percentage that participate in Medicare via deemed status are:

- 80% of all Medicare-participating hospitals (3,629 facilities)
- 77% of all Medicare-participating psychiatric hospitals (425 facilities)
- 33% of all Medicare-participating CAHs (439 facilities)
- 37% of all Medicare-participating HHAs (4652 facilities)
- 38% of all Medicare-participating hospices (1562 facilities)
- 28% of all Medicare-participating ASCs (1507 facilities)
- 5% of all Medicare-participating OPTs (97 facilities)
- 3% of all Medicare-participating rural health clinics (140 facilities)

Clinical Laboratory Improvement Amendments (CLIA) Validation Program

Introduction

The 1988 CLIA legislation expanded survey and certification of clinical laboratories from Medicare-participating and interstate commerce laboratories to all facilities testing human specimens for health purposes, regardless of location. CMS regulates all laboratory testing (whether provided to beneficiaries of CMS programs or to others), including those performed in physicians' offices, for a total of 236,882 facilities at the beginning of CY2014. The CLIA standards are based on the complexity of testing; thus, the more complex the test is to perform, the more stringent the requirements. There are three categories of tests: waived, moderate and high complexity. Waived laboratories are not subject to the quality standards or routine oversight. Laboratories which perform moderate and high complexity testing are subject to routine onsite 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 18,959 laboratories on a biennial basis. CMS-approved accrediting organizations conduct onsite surveys of an additional 16,081 laboratories biennially. 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 accrediting organizations, exempt states and proficiency testing providers, certificate generation, enforcement and data system design; (2) the CDC provides research and - technical support, and coordinates the Secretary's Clinical Laboratory Improvement Advisory Committee (CLIAC); and (3) the Food and Drug Administration (FDA) performs test categorization.

This report on the Clinical Laboratory Improvement Validation Program covers the evaluations of FY 2014 performance by the seven accreditation organizations approved by CMS under the Clinical Laboratory Improvement Amendments of 1988 (CLIA). The seven organizations are:

- American Association of Blood Banks (AABB)
- American Association for Laboratory Accreditation (A2LA)
- American Osteopathic Association (AOA)
- American Society for Histocompatibility and Immunogenetics (ASHI)
- College of American Pathologists (CAP)
- Commission on Office Laboratory Accreditation (COLA)
- The Joint Commission (TJC)

CMS appreciates the cooperation of all of the organizations in providing their inspection schedules and results. While an annual performance evaluation of each approved accreditation organization is required by law, we also see this as an opportunity to present information about, and dialogue with, each organization as part of our mutual interest in improving the quality of testing performed by clinical laboratories across the Nation.

Legislative Authority and Mandate

Section 353 of the Public Health Service Act, as amended by CLIA, requires any laboratory that performs testing on human specimens to meet the requirements established by HHS and have in effect an applicable certificate. Section 353 further provides that a laboratory meeting the standards of an approved accreditation organization may obtain a CLIA Certificate of Accreditation. Under the CLIA Certificate of Accreditation, the laboratory is not routinely subject to direct Federal oversight by CMS. Instead, the laboratory receives an inspection by the accreditation organization 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 quality assurance and quality control programs, records, equipment, personnel, proficiency testing, and others to assure accurate and reliable laboratory examinations and procedures.
In section 353(e)(2)(D), the Secretary is required to evaluate each approved accreditation organization by inspecting a sample of the laboratories they accredit and "such other means as the Secretary determines appropriate." In addition, section 353(e)(3) requires the Secretary to submit to Congress an annual report on the results of the evaluation. This report is submitted to satisfy that requirement.

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

- Laboratory-specific basis, insight into the effectiveness of the accreditation organization's standards and accreditation process; and
- 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 C.F.R. §493.575 provide that if the validation inspection results over a one year period indicate a rate of disparity[10] of 20 percent or more between the findings in the accreditation organization's results and the findings of the CLIA validation surveys, CMS will re-evaluate whether the accreditation organization continues to meet the criteria for an approved accreditation organization (also called "deeming authority"). Section 493.575 further provides that CMS has the discretion to conduct a review of an accreditation organization program if validation review findings, irrespective of the rate of disparity, indicate such widespread or systematic problems in the organization's accreditation process that the requirements are no longer equivalent to CLIA requirements.

Validation Reviews

The validation review methodology focuses on the actual implementation of an organization's

[10] The methodology for the CLIA Rate of Disparity is calculated the same as Figure 2 on page 35. The only difference is CLIA performs a 90-day validation instead of a 60-day.

accreditation program described in its request for approval. The accreditation organization's standards, as a whole, were approved by CMS as being equivalent to or more stringent than, the CLIA condition-level requirements[11], as a whole. This equivalency is the basis for granting deeming authority.

In evaluating an organization's performance, it is important to examine whether the organization's inspection findings are similar to the CLIA validation survey findings. It is also important to examine whether the organization's inspection process sufficiently identifies, brings about correction, and monitors for sustained correction, laboratory practices and outcomes that do not meet their accreditation standards, so that equivalency of the accreditation program is maintained.

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

Number of Validation Surveys Performed

As directed by the CLIA statute, the number of validation surveys should be sufficient to "allow a reasonable estimate of the performance" of each accreditation organization. A representative sample of more than 16,000 accredited laboratories received a validation survey in 2014. 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 accreditation organization it designates for CLIA compliance, irrespective of the number of accreditations it attains.

Nationwide, fewer than 500 of the accredited laboratories used AABB, AOA, or ASHI accreditation for CLIA purposes. Given these proportions, very few validation surveys are performed in laboratories accredited by those organizations. The overwhelming majority of accredited laboratories in the CLIA program used their accreditation by COLA, CAP or TJC, thus the sample sizes for these organizations were larger. The sample sizes are roughly proportionate to each organization's representation in the universe of accredited laboratories; however, true proportionality is not always possible due to the complexities of scheduling.
The number of validation surveys performed for each organization is specified below in the summary findings for the organization.

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

Results of the Validation Reviews of Each Accreditation Organization

American Association of Blood Banks (AABB)

Rate of disparity: zero percent

In FY 2014, approximately 225 laboratories used their AABB accreditation for CLIA program purposes. Validation surveys were conducted in seven AABB accredited laboratories. No condition-level deficiencies were cited in any of the validation surveys. When a validation survey results in compliance with the CLIA condition-level requirements, as is the case with the AABB accredited laboratories this year, the result is a disparity rating of zero (no disparity). We commend the AABB for its history of zero percent disparity in 15 out of the past 19 validation reviews.

American Association for Laboratory Accreditation (A2LA)

Rate of disparity: see below

On March 25, 2014, A2LA was the seventh accreditation organization to receive deeming authority by CMS. No laboratories were accredited by A2LA for CLIA purposes during FY14, therefore no CLIA validation surveys were performed for this accreditation organization.

American Osteopathic Association (AOA)

Rate of disparity: zero percent

For CLIA purposes, approximately 130 laboratories used their AOA accreditation. Validation surveys were conducted in six AOA accredited laboratories. No condition-level deficiencies were cited in any of the validation surveys. When a validation survey results in compliance with the CLIA condition-level requirements, as is the case with the AOA accredited laboratories this year, the result is a disparity rating of zero (no disparity). We commend the AOA for its history of zero percent disparity in 15 out of the past 19 validation reviews.

American Society for Histocompatibility and Immunogenetics (ASHI)

Rate of disparity: zero percent

Approximately 121 laboratories used their ASHI accreditation for CLIA purposes. A validation survey was conducted in eight ASHI accredited laboratories. No condition-level deficiencies were cited in any of the validation surveys. When a validation survey results in compliance with the CLIA condition-level requirements, as is the case with the ASHI accredited laboratories this year, the result is a disparity rating of zero (no disparity). We commend the ASHI for its history of zero percent disparity in 18 out of the past 19 validation reviews.

Commission on Office Laboratory Accreditation (COLA)

Rate of disparity: eight percent

A total of 168 validation surveys were conducted in COLA accredited laboratories. One survey was removed from the review pool for administrative reasons. Of the remaining 167, twenty laboratories were cited with condition-level deficiencies. In six of those laboratories, COLA findings were comparable to all of the CLIA condition-level deficiencies cited. In the remaining 14 laboratories, however, COLA noted comparable findings to only some or none of the CLIA condition-level deficiencies cited; thus, there were 14 disparate cases yielding a disparity rate of eight percent.

College of American Pathologists (CAP)

Rate of disparity: 14 percent

A total of 91 validation surveys were conducted in CAP accredited laboratories. Three surveys were removed from the review pool for administrative reasons. Of the remaining 88 validation surveys, 12 laboratories were cited with CLIA condition-level deficiencies. In all 12, the CAP noted comparable findings to only some or none of the CLIA condition-level deficiencies cited; thus, there were 12 disparate cases for a disparity rate of 14 percent.

The Joint Commission (TJC)

Rate of disparity: 13 percent

During this validation period, a total of 56 validation surveys were conducted in TJC accredited laboratories. One survey was removed from the validation review pool for administrative reasons. Of the remaining 55 validation surveys, 7 laboratories were cited with CLIA condition-level deficiencies. In all 7 laboratories, TJC noted comparable findings to only some or none of the CLIA condition-level deficiencies cited; thus, there were 7 disparate cases yielding a disparity rate of 13 percent.

CLIA Table 1: Validation Survey Results for Clinical Laboratories- FY2014

Number of	AABB	AOA	ASHI	COLA	CAP	TJC	Total
Accredited Labs	225	130	121	6,612	5,968	2,347	15,403
Validation Surveys	7	6	8	167	88	55	331
Surveys with condition-level deficiencies	0	0	0	20	12	7	39
Surveys with one or more condition-level deficiencies missed by AO	0	0	0	14	12	7	33
Disparity Rate	**0%**	**0%**	**0%**	**8.4%**	**13.6%**	**12.7%**	**10.0%**

Conclusion

CMS has performed this statutorily mandated validation review in order to evaluate and report to Congress on the performance of the seven laboratory accreditation organizations 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 accreditation organization's standards and accreditation process on a laboratory-specific basis.

CMS recognizes that similarity of accreditation organization findings to CLIA validation survey findings is an important measure of the organization's capability to ensure equivalency and effectiveness of oversight. Another important measure is an organization's capability to 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 accreditation organization'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 we hope to further improve the level of laboratory oversight and ultimately, patient care.