
BACKGROUND

The shift of surgical procedures to outpatient settings has given rise to an increase in the number of ambulatory surgery centers (ASCs) over the past few decades. From 2006 to 2017, the number of ASCs grew by 25 percent, from 4,490 to 5,603 ASCs.^{1,2} Medicare payments to ASCs totaled \$4.6 billion in 2017.³

The Centers for Medicare & Medicaid Services' (CMS) primary oversight tool for ensuring the health and safety of patients at ASCs is the survey and certification process. The Office of Inspector General (OIG) examined Medicare's quality oversight of ASCs in a series of reports in 2002 and found that nearly a third of ASCs certified by State agencies went 5 or more years without a survey.^{4,5,6} At that time, CMS did not set a minimum requirement for how often State agencies needed to survey ASCs. Since those reports, outbreaks of healthcare-associated infections have raised concerns about infection control at these facilities.^{7,8}

OIG has not assessed the frequency of ASC State certification surveys since 2002. This data brief provides an updated analysis of how States are meeting CMS requirements for State ASC surveys, including insights into the findings of those surveys. This information contributes to OIG's body of work on Medicare's quality oversight.

Ambulatory Surgery Centers that Participate in Medicare

An ASC is a distinct entity that exclusively provides surgical services to patients who do not require hospitalization. ASCs perform only services that ordinarily would not take more than 24 hours (including pre-operative and recovery time) and that CMS judges can be safely performed on an ambulatory basis.^{9,10} Services provided in ASCs range in complexity from simple surgeries, such as biopsies, to surgeries performed under general anesthesia, such as inserting a permanent pacemaker. Cataract surgeries, upper gastrointestinal endoscopies, and colonoscopies with biopsy are among the most commonly performed procedures in ASCs.¹¹

CMS has established baseline health and safety requirements, called Medicare Conditions for Coverage (CfCs), that ASCs must meet to be eligible for participation in Medicare. The 14 CfCs cover topics ranging from credentialing and privileging of surgeons to infection control and ASCs' quality improvement programs.¹² Each CfC covers a broad area (e.g., surgical services or infection control) and then is further defined by a set of specific standards that ASCs must meet. See Appendix A for a full list of the 14 CfCs.

Certification Surveys

To participate in Medicare, ASCs must demonstrate that they meet the CfCs. Most ASCs do this by undergoing an onsite inspection, called a certification survey, conducted by their respective State survey and certification agencies on behalf of CMS.¹³ (In this report, we refer to these State agencies as States.)

Alternatively, ASCs can elect to be accredited by a CMS-approved accreditation organization instead of undergoing inspection by their respective States.¹⁴

These ASCs are referred to as deemed facilities, and make up a little under a third of all ASCs.

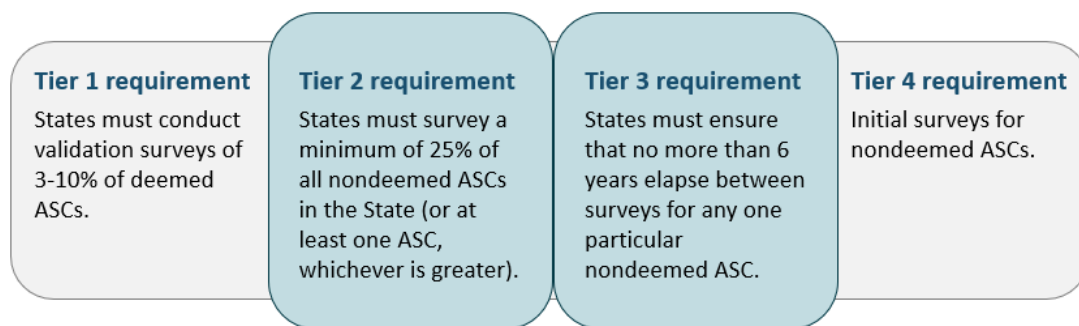
Nondeemed and Deemed ASCs

Nondeemed ASCs are certified by their respective State agencies. The majority of ASCs are nondeemed.

Deemed ASCs demonstrate that they meet the CfCs by becoming accredited by a CMS-approved accreditor.

To direct States in prioritizing their certification responsibilities, CMS sets performance standards for States in overseeing ASCs.¹⁵ CMS organizes these requirements by level of priority, with Tier 1 as the highest priority (see Exhibit 2).

Exhibit 2: CMS Table of Survey Frequencies and Priorities, Fiscal Year (FY) 2017



Source: CMS, FY 2017 Mission & Priority Document.

Tier 1 addresses accreditors' surveys of deemed ASCs by requiring State validation surveys of a sample of deemed ASCs. This report focuses on CMS's Tier 2 and Tier 3 requirements, which both concern nondeemed ASCs and constitute CMS's top two priority requirements for nondeemed ASCs. The majority of ASCs—about two-thirds—are nondeemed, underscoring the importance of the States' oversight roles.

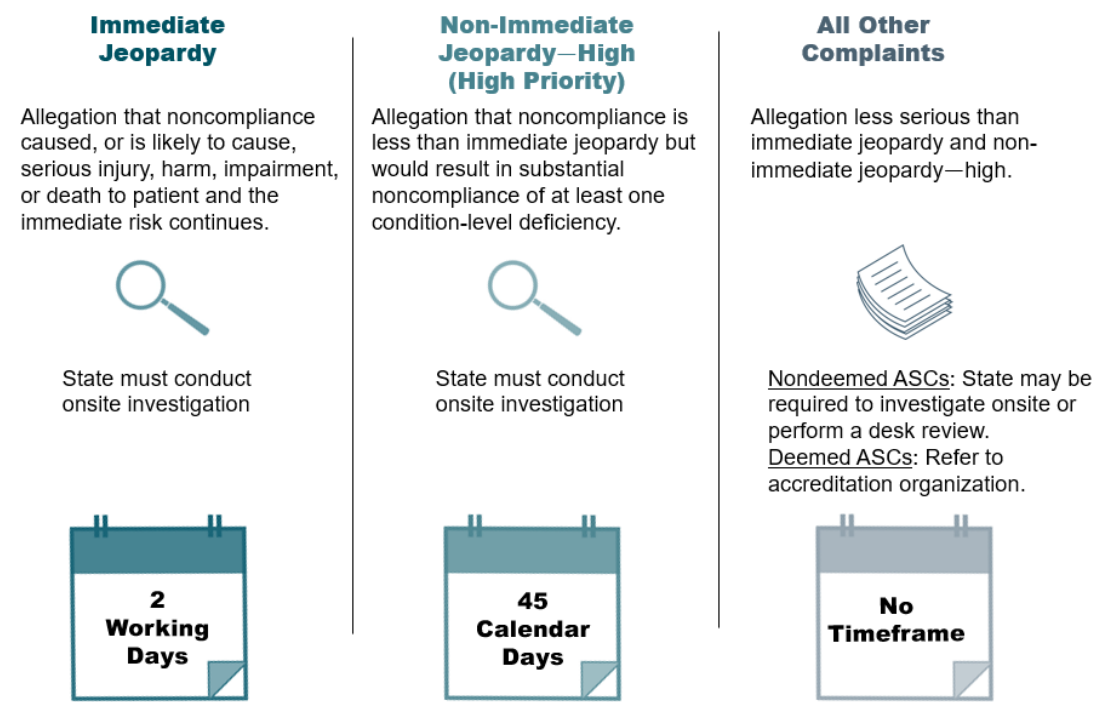
When a State conducts a certification survey, it may find that an ASC does not meet one or more requirements. If the State finds the ASC is out of compliance, it must determine whether the lack of compliance is at the standard level (less serious) or the condition level (more serious) by considering how serious the deficiency is in terms of its potential or actual harm to patients and the extent of noncompliance. If the State finds that substantial noncompliance with multiple standards of a CfC adds up to pervasive noncompliance, or if it determines that noncompliance with one or more standards poses a serious threat to patient health and safety, it will cite the ASC with a condition-level deficiency.¹⁶

After conducting a certification survey of an ASC, the State communicates its determination of compliance or noncompliance with CfCs to the surveyed ASC. In instances of noncompliance, the ASC must submit a plan to achieve compliance for each cited deficiency.

Complaint Investigations

Patients and others can file complaints with CMS regional offices or States alleging poor care or other problems at ASCs.¹⁷ CMS requires States to conduct onsite investigations for the most serious complaints. The required timeframes for investigations depend on the seriousness of the allegation. See Exhibit 3 for complaint priority levels and required timeframes.¹⁸ States may conduct complaint surveys of any ASC in Medicare, including deemed ASCs.¹⁹

Exhibit 3: Priority Levels of Complaints Regarding ASCs



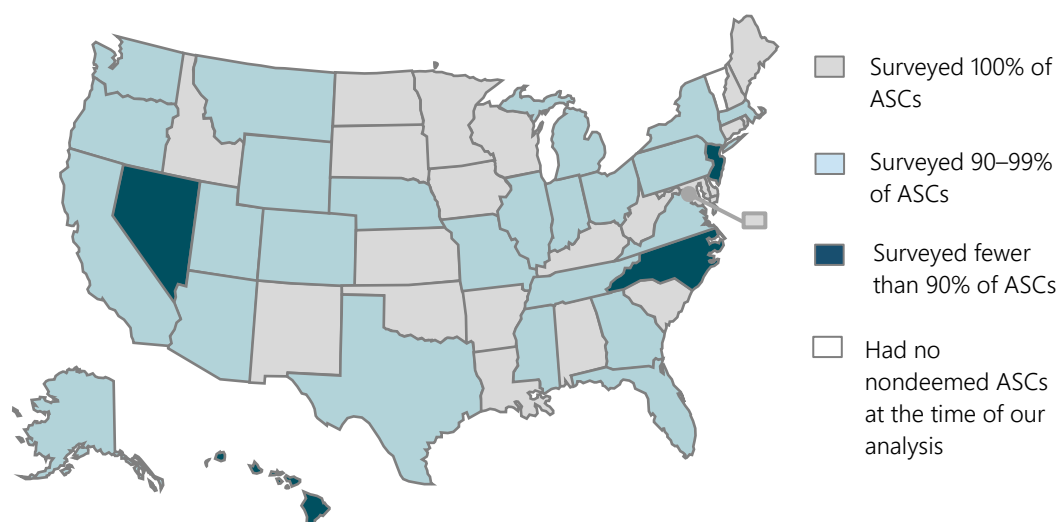
Source: CMS *State Operations Manual*, ch. 5, “Complaint Procedures” (Revised 155, 06-10-16).

Previous Work

In 2002, OIG issued three reports on the quality oversight of ASCs in Medicare.^{20, 21, 22} These reports assessed States' and accreditation organizations' oversight of ASCs and how CMS held them accountable to Medicare and the public. OIG found problems with the oversight of ASCs, including ASCs that went for extended periods between State certification surveys and CMS's doing little to hold States and accreditors accountable. CMS implemented OIG's recommendations to establish a minimum survey cycle for ASCs; update the CfCs; and improve accountability of States and accreditation organizations.

In 2009, the Government Accountability Office (GAO) recommended that CMS improve its data collection on infection control practices at ASCs following a series of high-profile cases of healthcare-associated infections at ASCs.²³ CMS agreed with GAO's recommendation.

Exhibit 5: In FY 2017, 22 States had surveyed all of their nondeemed ASCs within the past 6 years.



Source: OIG analysis of CASPER and ASSURE datasets, 2019.

A few States fell short across both requirements. Eleven States failed to meet both the requirement to survey 25 percent of nondeemed ASCs each year and the requirement to let no more than 6 years elapse between surveys for any nondeemed ASC. Notably, three of those States—Hawaii, Nevada, and New Jersey—missed both requirements by clear margins. See Appendix B for percentages of ASCs that States surveyed.

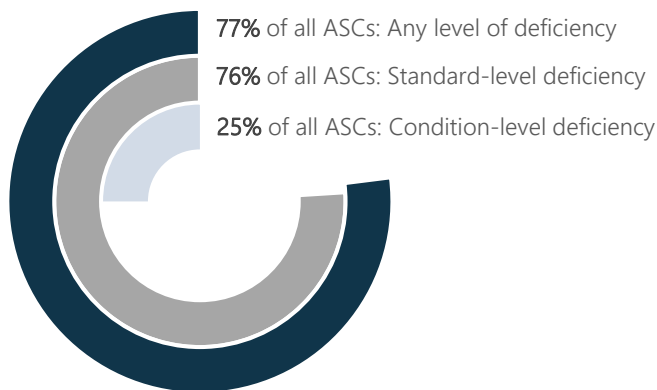
States cited about three-quarters of nondeemed ASCs with at least one deficiency in their most recent survey; one-quarter of ASCs had serious deficiencies

When States conduct their certification surveys, they often identify deficiencies that can affect patient care. During their most recent surveys for the nondeemed ASCs in our review, States cited 77 percent with one or more condition-level or standard-level deficiencies.

As part of these surveys, States cited 25 percent of nondeemed ASCs with one or more of the more serious (condition-level) deficiencies. A condition-level deficiency indicates that substantial noncompliance with multiple standards of a CfC adds up to pervasive noncompliance, or that noncompliance with one or more standards poses a serious threat to patient health and safety. See Appendix A for a full list of ASC survey CfCs.

More commonly, States cited nondeemed ASCs with standard-level deficiencies. Most ASCs (76 percent) had one or more standard-level deficiencies, which indicate that an ASC was noncompliant with one or more standards within a CfC, but not to the degree of a condition-level deficiency. See Exhibit 6 for a breakdown of nondeemed ASCs cited with deficiencies in their respective most recent surveys.

Exhibit 6: States cited three-quarters (77 percent) of nondeemed ASCs with a deficiency in ASCs' most recent certification surveys.



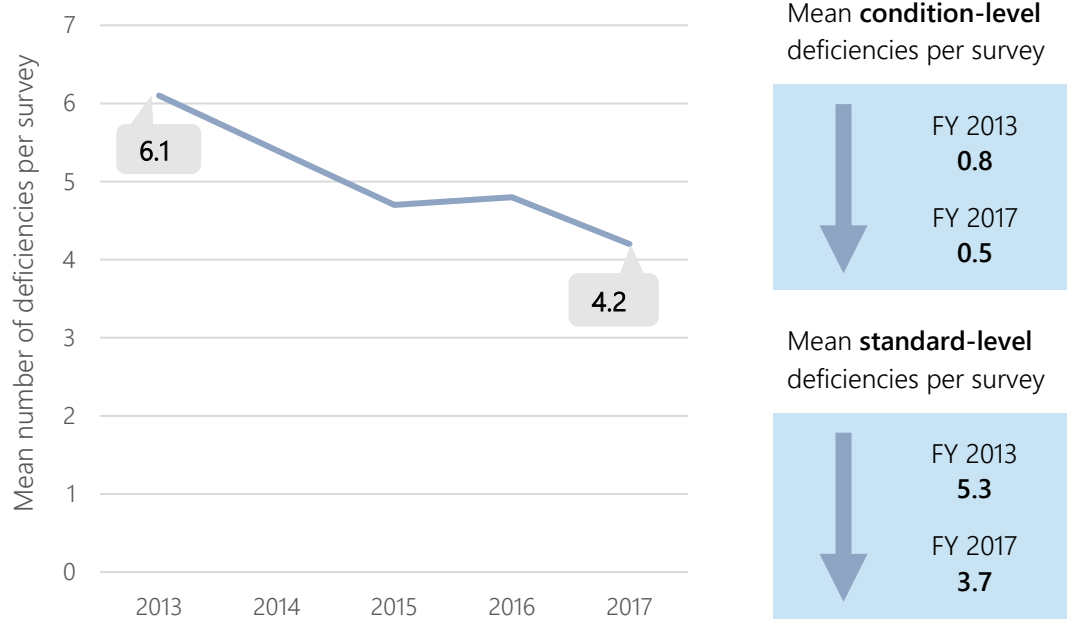
NOTE: A State can cite both a standard-level and condition-level deficiency in a single survey.

Source: OIG analysis of CASPER dataset, 2019.

The average number of deficiencies per survey decreased from FY 2013 through FY 2017; infection control deficiencies remained the most prevalent

From FY 2013 through FY 2017, the mean number of total deficiencies per certification survey decreased from 6.1 to 4.2 for nondeemed ASCs.²⁵ Both condition-level and standard-level deficiencies per survey decreased (see Exhibit 7). These decreases could reflect improvements in ASC performance and/or changes in how States assessed compliance.

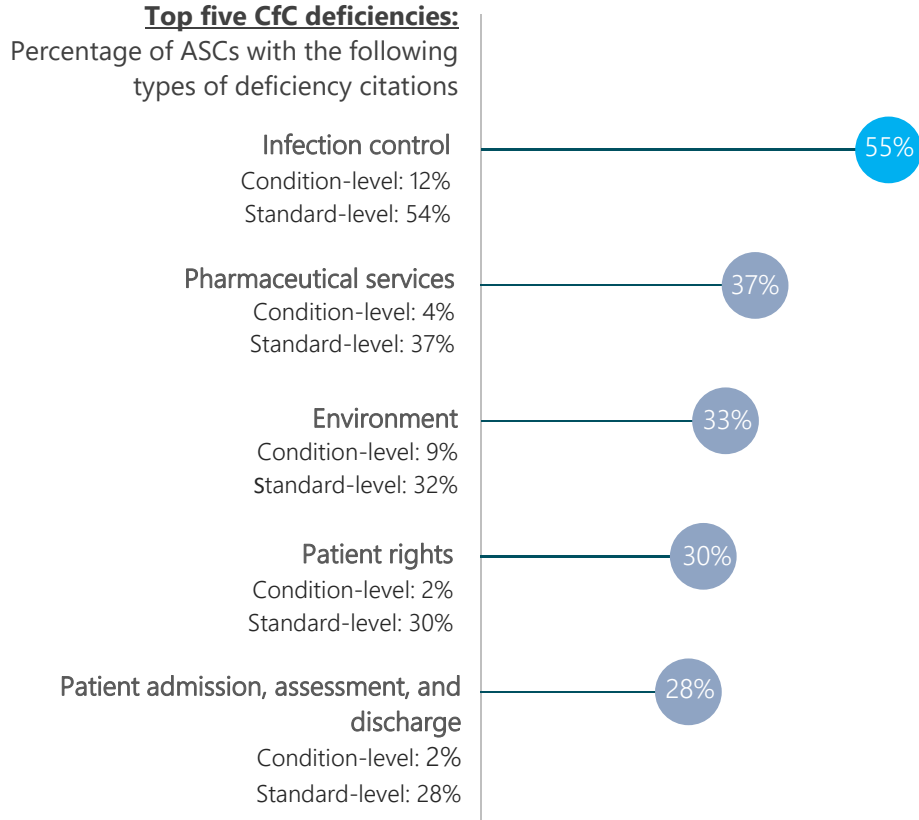
Exhibit 7: From FY 2013 through FY 2017, the mean number of deficiencies per survey decreased from 6.1 to 4.2.



Source: OIG analysis of CASPER dataset, 2019.

ASCs appear to struggle with maintaining compliance with infection control requirements. States cited slightly more than half (55 percent) of all nondeemed ASCs with one or more infection control deficiencies in the ASCs’ most recent certification surveys. States cited ASCs with infection control deficiencies much more frequently than other kinds of deficiencies (see Exhibit 8). One example of an infection control deficiency would be failure to ensure that surgical equipment is sanitized properly.

Exhibit 8: States cited over half of nondeemed ASCs with **infection control deficiencies in ASCs' most recent certification surveys.**



NOTE: A State can cite multiple CfC deficiencies and both condition-level and standard-level deficiencies in a single survey.

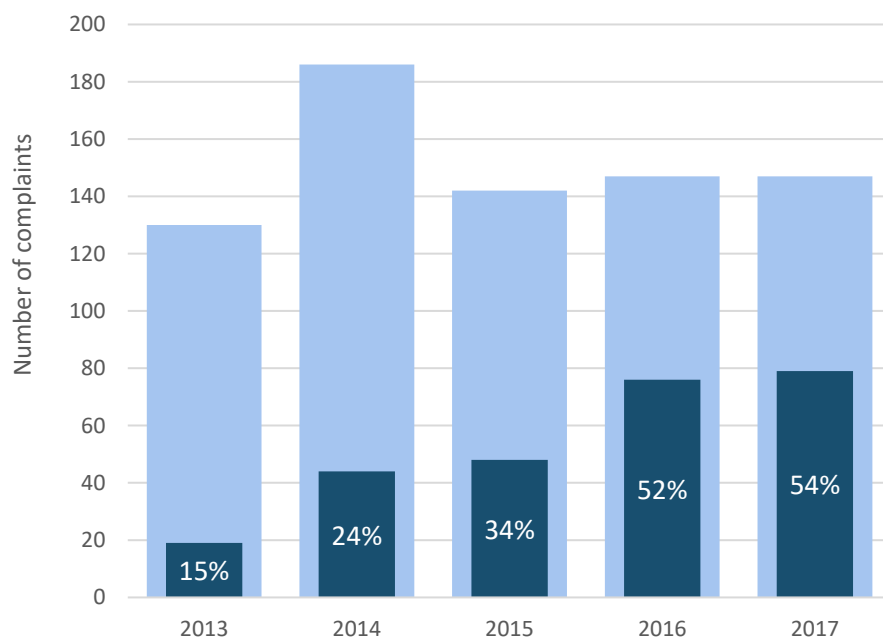
Source: OIG analysis of CASPER dataset, 2019.

Infection control remained the most commonly cited category of deficiency (both at the standard level and at the condition level) in certification surveys of nondeemed ASCs from FY 2013 through FY 2017. Between 19 and 22 percent of all deficiencies cited each year concerned infection control. In comparison, for 4 of these 5 years, the next most frequently cited category was patient rights, which accounted for 12 to 16 percent of deficiencies each year.

From FY 2013 through FY 2017, States received complaints for fewer than 4 percent of ASCs each year, but the share of those complaints requiring an onsite survey more than tripled

Complaints serve as warning signs of possible shortfalls in patient care and safety. From FY 2013 through FY 2017, States received 752 complaints about ASCs, ranging from 130 complaints in FY 2013 to 186 complaints in FY 2014. See Exhibit C-1 in Appendix C for total number of complaints per State over this time. However, the proportion of the most serious complaints—those that the State categorized as immediate jeopardy and non-immediate jeopardy-high, thus requiring an onsite survey—increased over this time (see Exhibit 9).

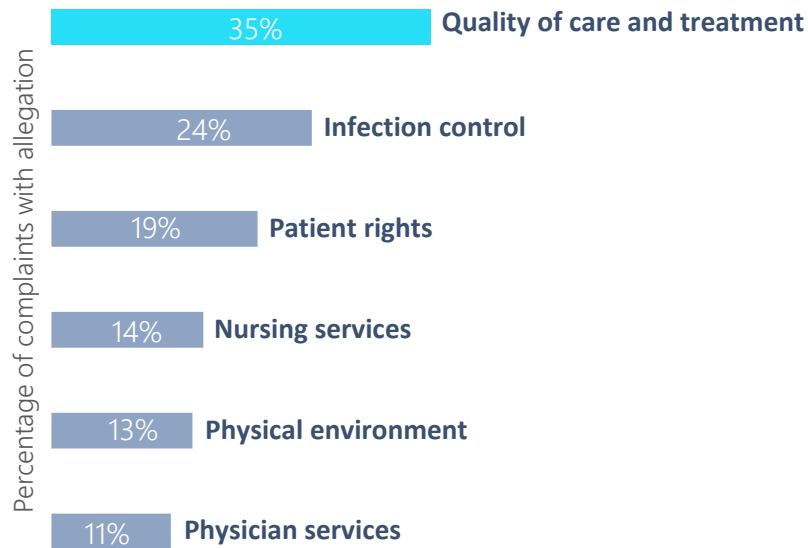
Exhibit 9: The proportion of Immediate Jeopardy and Non-Immediate Jeopardy - High complaints within total complaints increased from 15 percent to 54 percent from FY 2013 through FY 2017.



Source: OIG analysis of ACTS dataset, 2019.

Between FY 2013 and FY 2017, the most common complaints about ASCs related to quality of care and treatment and to infection control (see Exhibit 10).

Exhibit 10: The most common complaint allegations from FY 2013 through FY 2017 relate to **quality of care and treatment.**



Source: OIG analysis of ACTS dataset, 2019.

States substantiated allegations for almost half of the complaints that they investigated. Specifically, States investigated 632 of the 752 total complaints they received between FY 2013 and FY 2017 and substantiated 1 or more allegations for 47 percent of them.²⁶ The proportion of complaints with substantiated allegations ranged from a high of 51 percent in 2015 to a low of 42 percent in 2017. When States substantiate a complaint, they may or may not cite deficiencies related to the complaint.²⁷ An example of a substantiated complaint with a deficiency includes an ASC's being cited for a standard-level deficiency in infection control when State surveyors confirmed that it was not mopping the surgical suites after each patient. A more serious example is State surveyors' citing an ASC for numerous condition-level deficiencies when they confirmed that it failed to properly assess patients pre-operatively, did not have medical records for some patients, and did not follow its own procedures, among other problems.

States largely appeared to investigate the second most serious type of complaints—those categorized as non-immediate jeopardy-high—within 45 days, as required. Of the 206 complaints in this category, States investigated at least 90 percent (185 complaints) on time (see Exhibit 11). States were late in investigating at least 6 percent (12 complaints). We cannot determine from the data whether the remaining 4 percent (nine complaints) were investigated within the required 45-day timeframe. See Appendix C-2 for the total number of the most serious complaints that were investigated late per State from FY 2013 through FY 2017.

Data limitations prevent us from determining definitively how often States met requirements to investigate the most serious complaints—immediate jeopardy—within 2 days. Of the 60 total immediate jeopardy complaints, States investigated at least 72 percent (43 complaints) on time and at least 12 percent (7 complaints) late. We cannot determine whether the remaining 17 percent (10 complaints) were investigated on time (see Exhibit 11).

Exhibit 11: Between FY 2013 and FY 2017, States largely appeared to investigate the most serious complaints timely.

	<u>Non-Immediate Jeopardy - High:</u> Must be investigated within 45 calendar days	<u>Immediate Jeopardy:</u> Must be investigated within 2 calendar days*
On time	185 (90 percent)	43 (72 percent)
Late	12 (6 percent)	7 (12 percent)
Unknown	9 (4 percent)	10 (17 percent)

* In this column, the percentages sum to 101 percent because of rounding.
Source: OIG analysis of ACTS data, 2019.

CONCLUSION

State agencies play critical roles in ensuring the health and safety of Medicare beneficiaries who receive medical procedures, including invasive surgeries, from ASCs. These roles include conducting certification surveys and assessing and investigating complaints. Periodic surveys are an essential tool for ensuring that ASCs meet the minimum standards for health and safety. CMS requires that States survey at least 25 percent of nondeemed ASCs each year and that no more than 6 years elapse between surveys for each ASC. Most States met or came close to meeting these minimum requirements. However, States cited deficiencies at about three-quarters of nondeemed ASCs in their most recent surveys and almost a quarter of ASCs had serious (condition-level) deficiencies. Deficiencies were most frequently related to standards for infection control. These findings underscore the importance of timely surveys so that deficiencies do not go unaddressed even longer.

Although States received complaints about relatively few ASCs each year (fewer than 4 percent), States categorized a rising proportion of those complaints as serious (i.e., immediate jeopardy or non-immediate jeopardy high). States appear to be generally meeting requirements to investigate the second most serious type of complaint (non-immediate jeopardy high) within 45 days. However, States did not meet the 2-day requirement for investigating the most serious type of complaints (immediate jeopardy) complaints for at least 12 percent, and possibly as many as 28 percent, of these complaints. The data limitations that prevented us from determining timeliness more precisely are also concerning, as CMS needs to be able to oversee and enforce timeliness requirements.

CMS has made progress in strengthening oversight of ASCs and addressing vulnerabilities previously identified by OIG and GAO, and more can be done. Meeting CMS's requirement for States to annually survey 25 percent of nondeemed ASCs deserves attention because of the extended time frame—6 years—of CMS's other requirement. That 6-year timespan allows ASCs the potential to transition in and out of compliance, or worse, remain out of compliance for substantial amounts of time. The results of this new analysis can support CMS in further strengthening its oversight, particularly of the few States that are falling short of meeting its requirements. It can also help CMS focus on ASCs' recurring challenges in meeting health and safety requirements, especially for infection control.

METHODOLOGY

Scope

This data brief examines the extent to which Medicare investigated complaints about ASCs between FY 2013 and FY 2017; cited deficiencies in certification surveys conducted between 1992 and 2018; and met the following requirements for certification surveys: (1) surveying a minimum of 25 percent of nondeemed ASCs per State in FY 2017 (CMS's Tier 2 requirement); and (2) ensuring that 100 percent of ASC were surveyed in the 6-year time period between FY 2012 and FY 2017 (CMS's Tier 3 requirement).

Methods

We relied on three sources for this data brief: State ASC certification survey records entered into the Certification and Survey Provider Enhanced Reporting (CASPER) system; CMS's Accrediting Organization System for Storing User Recorded Experiences (ASSURE) system; and data on complaints from the ASPEN [Automated Survey Processing Environment] Complaints Tracking System (ACTS) system.

CASPER Data

CMS provided us with data from CASPER, including records from 50 States and the District of Columbia. We excluded ASC data from Guam, Puerto Rico, and the Virgin Islands in our analysis.

We limited State certification analyses to health surveys for active ASCs, which we defined as ASCs that were still providing services at the time CMS provided us with CASPER data. We primarily used the deemed status information in ASSURE to determine whether an ASC was deemed. However, if the ASC was listed in ASSURE as both deemed and nondeemed or if it was not listed in ASSURE, we used the deemed status information in CASPER to determine its status. This gave us a final dataset that included 3,735 nondeemed ASCs and 1,851 deemed ASCs. Vermont did not have any nondeemed ASCs at the time of our analysis.

For analyses assessing the percentage of ASCs that States surveyed in FY 2017 and the 6-year period between FY 2012 and FY 2017, our denominator consisted of all nonterminated ASCs with a "begin service date" earlier than October 1, 2016.

We analyzed these data to determine national and State-level ASC certification survey trends. We calculated: (1) the percentage of ASCs surveyed in FY 2017; (2) the percentage of ASCs surveyed during FY 2012 to FY 2017; (3) the mean deficiencies per State in the most recent certification survey; (4) the percentage of ASCs cited with deficiencies, including broken down by CfC, in ASCs' most recent surveys; (5) mean number of deficiencies

per survey between FY 2013 and FY 2017; and (6) the percentage of CfC deficiencies within total deficiencies between FY 2013 and FY 2017.

ACTS Data

CMS provided us with data on all deemed and nondeemed ASC complaints from FY 2013 through FY 2017. Our final dataset included 2,904 records from 45 States. (Hawaii, Montana, Nebraska, New Mexico, Vermont, and the District of Columbia did not have any complaints.) Complaints can include multiple allegations; each record represents one allegation.

We analyzed these data to determine national and State trends for ASC complaints between FY 2013 and FY 2017. We calculated (1) the number of ASC complaints that States received; (2) the percentage of complaints that States prioritized as Immediate Jeopardy and Non-Immediate Jeopardy-High; (3) the percentage of Immediate Jeopardy and Non-Immediate Jeopardy-High complaints that States investigated onsite within required timeframes; and (4) the percentage of Immediate Jeopardy and Non-Immediate Jeopardy-High complaints that States substantiated.

To determine whether States investigated complaints within required timeframes, we excluded weekends and Federal holidays and calculated the number of days that elapsed between the complaint receipt date (or, for deemed ASCs, the CMS regional office approval date) and the onsite investigation date. We did not exclude State-only holidays from our analysis.

Limitations

We did not assess the extent to which the data in CASPER, ASSURE, or ACTS are complete. We also did not independently verify the accuracy of the records. We based our analysis on CASPER, ASSURE, and ACTS data and not on information collected directly from States.

Standards

We conducted this study in accordance with the *Quality Standards for Inspection and Evaluation* issued by the Council of the Inspectors General on Integrity and Efficiency.

APPENDIX A: Ambulatory Surgery Centers, CMS Survey Conditions for Coverage*

§416.40

Compliance with State Licensure Law

The ASC must comply with State licensure requirements.

§416.41

Governing Body and Management

The ASC must have a governing body that assumes full legal responsibility for determining, implementing, and monitoring policies governing the ASC's total operation. The governing body has oversight and accountability for the quality assessment and performance improvement program, ensures that facility policies and programs are administered so as to provide quality health care in a safe environment, and develops and maintains a disaster preparedness plan.

§416.42

Surgical Services

Surgical procedures must be performed in a safe manner by qualified physicians who have been granted clinical privileges by the governing body of the ASC in accordance with approved policies and procedures of the ASC.

§416.43

Quality Assessment and Performance Improvement

The ASC must develop, implement, and maintain an ongoing, data-driven quality assessment and performance improvement (QAPI) program.

§416.44

Environment

The ASC must have a safe and sanitary environment, properly constructed, equipped, and maintained to protect the health and safety of patients.

§416.45

Medical Staff

The medical staff of the ASC must be accountable to the governing body.

§416.46

Nursing Service

The nursing services of the ASC must be directed and staffed to assure that the nursing needs of all patients are met.

§416.47

Medical Records

The ASC must maintain complete, comprehensive, and accurate medical records to ensure adequate patient care.

§416.48*Pharmaceutical Services*

The ASC must provide drugs and biologicals in a safe and effective manner, in accordance with accepted professional practice, and under the direction of an individual designated responsible for pharmaceutical services.

§416.49*Laboratory and Radiologic Services*

- (a) Standard: Laboratory services. If the ASC performs laboratory services, it must meet the requirements of [42 CFR Part 493]. If the ASC does not provide its own laboratory services, it must have procedures for obtaining routine and emergency laboratory services from a certified laboratory in accordance with [42 CFR Part 493]. The referral laboratory must be certified in the appropriate specialties and subspecialties of service to perform the referred tests in accordance with the requirements of [42 CFR Part 493].
- (b) Standard: (1) Radiological services, Radiological services may only be provided when integral to procedures offered by the ASC and must meet requirements specified in §482.26(b), (c)(2), and (d)(2) of [42 CFR]. (2) If radiologic services are utilized, the governing body must appoint an individual qualified in accordance with State law and ASC policies who is responsible for assuring all radiologic services are provided in accordance with the requirements of this section.
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§416.50*Patient Rights*

The ASC must inform the patient or the patient's representative or surrogate of the patient's rights and must protect and promote the exercise of these rights, as set forth in this section. The ASC must also post the written notice of patient rights in a place or places within the ASC likely to be noticed by patients waiting for treatment or by the patient's representative or surrogate, if applicable.

§416.51*Infection Control*

The ASC must maintain an infection control program that seeks to minimize infections and communicable diseases.

§416.52*Patient Admission, Assessment, and Discharge*

The ASC must ensure each patient has the appropriate pre-surgical and post-surgical assessments completed and that all elements of the discharge requirements are complete.

§416.54*Emergency Preparedness*

The ASC must comply with all applicable Federal, State, and local emergency preparedness requirements. The ASC must establish and maintain an emergency preparedness program that meets the requirements of this section.

* Description from 42 CFR § 416.40-416.54.

APPENDIX B: Number and Percentage of ASCs Surveyed per State, Fiscal Years 2017 and 2011 Through 2017

Exhibit B: Total Active, Nondeemed ASCs Surveyed (Certification Survey) in FY 2017 and Between 10/1/2011 and 9/30/2017, per State

	Total number of ASCs*	FY 2017 (CMS Tier 2 requirement**)		10/1/2011 to 9/30/2017 (CMS Tier 3 requirement***)	
		ASCs surveyed	Percentage surveyed †	ASCs surveyed	Percentage surveyed †
Alabama	26	9	35%	26	100%
Alaska	11	2	18%	10	91%
Arizona	104	33	32%	101	97%
Arkansas	52	13	25%	52	100%
California	414	75	18%	396	96%
Colorado	85	12	14%	83	98%
Connecticut	42	14	33%	42	100%
Delaware	12	3	25%	12	100%
District of Columbia	3	1 ‡	33%	3	100%
Florida	293	89	30%	286	98%
Georgia	238	68	29%	232	97%
Hawaii	14	0	0%	9	64%
Idaho	29	8	28%	29	100%
Illinois	78	21	27%	76	97%
Indiana	81	21	26%	79	98%
Iowa	9	3	33%	9	100%
Kansas	52	13	25%	52	100%
Kentucky	31	7	23%	31	100%
Louisiana	63	16	25%	63	100%
Maine	13	5	38%	13	100%
Maryland	293	138	47%	293	100%
Massachusetts	30	6	20%	28	93%
Michigan	56	14	25%	54	96%
Minnesota	47	15	32%	47	100%
Mississippi	54	13	24%	53	98%
Missouri	80	22	28%	78	98%
Montana	16	4	25%	15	94%
Nebraska	37	9	24%	36	97%
Nevada	44	4	9%	21	48%
New Hampshire	17	4	24%	17	100%
New Jersey	145	12	8%	123	85%
New Mexico	9	4	44%	9	100%
New York	41	7	17%	38	93%
North Carolina	88	21	24%	63	72%

Exhibit B (continued): Total Active, Nondeemed ASCs Surveyed (Certification Survey) in FY 2017 and Between 10/1/2011 and 9/30/2017, per State

	Total number of ASCs*	FY 2017 (CMS Tier 2 requirement**)		10/1/2011 to 9/30/2017 (CMS Tier 3 requirement***)	
		ASCs surveyed	Percentage surveyed	ASCs surveyed	Percentage surveyed
North Dakota	9	3	33%	9	100%
Ohio	102	33	32%	101	99%
Oklahoma	33	9	27%	33	100%
Oregon	66	19	29%	65	98%
Pennsylvania	216	62	29%	214	99%
Rhode Island	7	0 †	0%	7	100%
South Carolina	56	17	30%	56	100%
South Dakota	16	4	25%	16	100%
Tennessee	124	32	26%	122	98%
Texas	225	76	34%	218	97%
Utah	31	10	32%	30	97%
Vermont	0	N/A	N/A	N/A	N/A
Virginia	35	10	29%	34	97%
Washington	144	38	26%	141	98%
West Virginia	8	3	38%	8	100%
Wisconsin	28	4	14%	28	100%
Wyoming	15	5	33%	14	93%
All States	3,722	1,011	27%	3,575	96%

* Total number of ASCs active during all of FY 2017.

** CMS requires States to survey 25 percent of nondeemed ASCs per year.

*** CMS requires States to survey individual nondeemed ASCs at a minimum of every 6 years.

† Red text indicates that the State was noncompliant with the applicable Tier requirement by a clear margin. For the Tier 2 requirement, we considered this to be missing the 25-percent mark by two or more surveys. For the Tier 3 requirement, we considered this to be surveying fewer than 90 percent of ASCs.

†† Rhode Island and Washington, DC each have seven or fewer ASCs. To meet the Tier 2 requirement, according to the FY 2017 CMS Mission and Priority document, "States with only 7 or fewer ASCs must survey at least 1 ASC unless all nondeemed ASCs were surveyed within the prior two years." Further analysis by OIG indicates that Rhode Island did not meet this requirement.

APPENDIX C: Trends in ASC Complaints by State, Fiscal Years 2013 Through 2017

Exhibit C-1: Total Number of Complaints Received by States, FYs 2013 Through 2017

	Total number of complaints received				
	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Alabama	1	0	0	0	0
Alaska	2	0	0	0	1
Arizona	6	8	3	9	9
Arkansas	2	3	2	2	1
California	21	37	35	37	26
Colorado	3	3	4	3	1
Connecticut	0	0	0	0	0
Delaware	0	1	0	0	2
District of Columbia	0	0	0	0	0
Florida	15	25	14	7	14
Georgia	5	7	7	5	8
Hawaii	0	0	0	0	0
Idaho	1	1	1	1	1
Illinois	0	3	5	10	6
Indiana	4	2	3	2	3
Iowa	0	0	0	0	1
Kansas	2	3	2	3	2
Kentucky	2	0	0	1	1
Louisiana	3	2	1	0	1
Maine	3	1	0	0	0
Maryland	8	16	16	11	12
Massachusetts	0	1	1	0	1
Michigan	7	3	3	3	3
Minnesota	2	2	0	0	3
Mississippi	0	0	0	0	0
Missouri	5	7	2	5	7
Montana	0	0	0	1	0
Nebraska	0	0	1	0	0
Nevada	0	0	1	0	0
New Hampshire	0	0	1	0	1
New Jersey	13	14	8	13	5
New Mexico	0	0	0	0	0
New York	4	2	6	7	4
North Carolina	3	5	4	1	2
North Dakota	0	1	0	0	0
Ohio	5	2	1	2	3

Exhibit C-1 (continued): Total Number of Complaints Received by States, FYs 2013 Through 2017

	Total number of complaints				
	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Oklahoma	0	1	1	1	2
Oregon	0	3	1	1	4
Pennsylvania	4	1	1	4	3
Rhode Island	1	0	0	0	0
South Carolina	0	0	1	0	0
South Dakota	0	1	0	0	0
Tennessee	0	2	0	3	1
Texas	5	16	11	6	10
Utah	0	0	0	1	2
Vermont	0	0	0	0	0
Virginia	0	1	1	1	1
Washington	1	5	2	4	1
West Virginia	0	0	2	0	0
Wisconsin	1	4	1	3	2
Wyoming	1	3	0	0	3
Annual Total	130	186	142	147	147

Exhibit C-2: Total Number of Most Serious Complaints Investigated Late by State, Complaints Received FYs 2013 Through 2017

	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Arizona	2			2	
California				2	
Georgia				1	
Illinois			2	1	
New York			1		
North Carolina		1			
Tennessee		2		3	
Texas			1		1
Total	2	3	4	9	1

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ENDNOTES

- ¹ MedPAC, *Report to the Congress: Medicare Payment Policy*, ch. 5, "Ambulatory Surgical Center Services," March 2018.
- ² MedPAC, *Report to the Congress: Medicare Payment Policy*, ch. 5, "Ambulatory Surgical Center Services," March 2019.
- ³ Ibid.
- ⁴ OIG, *Quality Oversight of Ambulatory Surgical Centers: A System in Neglect*, OEI-01-00-00450, February 2002.
- ⁵ OIG, *Quality Oversight of Ambulatory Surgical Centers: The Role of Certification and Accreditation*, OEI-01-00-00451, February 2002.
- ⁶ OIG, *Quality Oversight of Ambulatory Surgical Centers: Holding State Agencies and Accreditors Accountable*, OEI-01-00-00452, February 2002.
- ⁷ Jennifer Steinhauer, "77 New Cases of Hepatitis Are Identified in Las Vegas," *The New York Times*, May 9, 2008.
- ⁸ Kalhan Rosenblatt, "More than 3,000 patients at New Jersey surgery center possibly exposed to HIV, hepatitis," *U.S. News*, December 25, 2018.
- ⁹ 42 CFR § 416.2 and CMS's *State Operations Manual*, Pub. No. 100-07, Appendix L, "Guidance for Surveyors: Ambulatory Surgical Centers," Part II, § 416.2, Tag Q-0002.
- ¹⁰ 42 CFR § 416.173 (requiring CMS to publish annually the list of covered surgical procedures for ASCs). Medicare covers 3,500 services provided in ASCs.
- ¹¹ MedPAC, *Report to the Congress: Medicare Payment Policy*, ch. 5, "Ambulatory Surgical Center Services," March 2019.
- ¹² 42 CFR pt. 416, subpt. C—Specific Conditions for Coverage.
- ¹³ 42 CFR §§ 416.26(b)(1) and 488.12(a)(1).
- ¹⁴ 42 CFR §§ 416.26(a) and 488.4(a). See also CMS, *FY 2017 Report to Congress: Review of Medicare's Program Oversight of Accrediting Organizations (AOs) and the Clinical Laboratory Improvement Amendments of 1988 Validation Program*. Accessed at <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/QSO19-01-RTC.pdf> on April 1, 2019.
- ¹⁵ CMS, *Admin Info: 18-01-ALL REVISED 10.27.2017: FY2017 Mission & Priority Document-Action*. See also 42 CFR §§ 488.20(a) and (b).
- ¹⁶ 42 CFR § 488.26. CMS, *State Operations Manual*, Appendix L, "Guidance for Surveyors: Ambulatory Surgical Centers," Part I, Task 4.
- ¹⁷ CMS, *State Operations Manual*, ch. 5, "Complaint Procedures," § 5010.
- ¹⁸ CMS, *State Operations Manual*, ch. 5, "Complaint Procedures," §§ 5075.1, 5075.2, 5075.3, 5075.4, and 5075.9.
- ¹⁹ Ibid., § 5100.1. For deemed ASCs, a State must receive authorization from the CMS regional office before the State conducts a complaint investigation.
- ²⁰ OIG, *Quality Oversight of Ambulatory Surgical Centers: A System in Neglect*, OEI-01-00-00450, February 2002.

²¹ OIG, *Quality Oversight of Ambulatory Surgical Centers: The Role of Certification and Accreditation*, OEI-01-00-00451, February 2002.

²² OIG, *Quality Oversight of Ambulatory Surgical Centers: Holding State Agencies and Accreditors Accountable*, OEI-01-00-00452, February 2002.

²³ GAO, *Health-Care-Associated Infections: HHS Action Needed to Obtain Nationally Representative Data on Risks in Ambulatory Surgical Centers*, GAO-09-213, February 2009.

²⁴ Due to data limitations, we are unable to assess how States met this requirement over time.

²⁵ In our analysis of deficiency citations in State certification surveys, we conducted both mean and median calculations. As part of this analysis, we determined that the deficiency citation data were not excessively influenced by extreme outliers. Therefore, we are presenting only mean calculations in this report.

²⁶ In certain circumstances, a State may not investigate a complaint. For example, a State may not investigate a complaint if the allegation does not involve Medicare/Medicaid participation requirements or if the State decides to refer the complainant to another agency or organization.

²⁷ CMS, *State Operations Manual*, Appendix L, "Guidance for Surveyors: Ambulatory Surgical Centers," Part I (Rev. 137, 04-01-15).