

**Department of Health and Human Services**

**OFFICE OF  
INSPECTOR GENERAL**

**Quality Oversight of  
Ambulatory Surgical Centers**

**The Role of Certification and Accreditation**  
*Supplemental Report 1*



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**FEBRUARY 2002**  
**OEI-01-00-00451**

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# EXECUTIVE SUMMARY

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## PURPOSE

To assess the role of State agency certification and accreditation in the quality oversight of ambulatory surgical centers in the Medicare program.

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## BACKGROUND

In 2000, Medicare paid \$1.6 billion for 4.3 million procedures performed in ambulatory surgical centers (ASCs). ASCs are generally free-standing facilities and may bill Medicare only for surgical procedures that the Centers for Medicare & Medicaid Services (CMS) has determined can be performed safely outside of the hospital. While ambulatory surgery has been shown to have good surgical outcomes, routine procedures can result in serious complications and death. Over 3,000 ASCs participate in the Medicare program.

Quality oversight of ASCs revolves around Medicare's minimum health and safety standards, called the Conditions of Coverage. CMS requires ASCs to become Medicare-certified or privately accredited to show that they meet the Conditions. Certification is carried out by State agencies and accreditation by CMS-approved accreditors. The focus of both certification by State agencies and accreditation is routine inspections, called surveys. While ASCs are free to choose which route they take, the overwhelming majority elect State agency certification.

This report is the first of two that supplement the main report of this inquiry, *A System in Neglect*. Our companion report, Supplemental Report 2: *Holding State Agencies and Accreditors Accountable*, assesses how State agencies and accreditors are held accountable for their performance overseeing ASCs. Our inquiry relies on claims and survey data, survey observations, and reviews of relevant laws and documents.

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## IMPORTANCE OF QUALITY OVERSIGHT

### **Medicare ASCs are experiencing explosive growth**

From 1990 to 2000, the number of ASCs doubled and the annual volume of procedures they perform tripled—making ASCs one of the fastest growing providers in Medicare.

### **Scope and complexity of procedures are on the rise**

From 1990 to 2000, CMS approved over 800 new procedures for ASCs. Major procedures now comprise over a quarter of approved procedures. In this time, the annual volume of major procedures performed by ASCs jumped from 12,000 to over 101,000.

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## **FINDINGS ON STATE AGENCY CERTIFICATION**

### **State agency certification allows many ASCs to fall through the cracks**

Nearly a third of ASCs certified by State agencies have gone 5 or more years without a survey; over 130 have gone 10 years. From 1990 to 2000, elapsed time between recertification surveys grew from 1.8 to 4.4 years. Nearly half of complaints against ASCs certified by State agencies remain unresolved—some for as long as 5 years. ASCs consistently rank near the bottom of CMS’ survey budget priorities.

### **The Conditions of Coverage fall short**

The Conditions have not been updated since 1982. They are one-size-fits-all and fail to distinguish among ASCs performing surgery of varying risks and complexities.

### **State agency surveys focus entirely on compliance and fail to include continuous quality improvement**

Surveys focus on gathering evidence to verify compliance with the Conditions. They do little toward improving the quality of ASCs beyond enforcing minimum requirements.

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## **FINDINGS ON ACCREDITATION**

### **Accreditation provides regular presence in ASCs**

Each of the accreditors has policies to survey ASCs every 3 years. ASCs expect on-site presence at regular intervals.

### **Accreditors update their standards regularly and adjust them to match the levels of surgery performed by individual ASCs**

Each accreditor has a process in place to regularly update its standards and adjusts them to match the risk and complexity of surgery performed by individual ASCs.

### **Accreditation surveys focus on helping ASCs continuously improve but pay less attention to verifying compliance**

Surveyors spend considerable effort on helping ASCs continuously improve their performance. However, the educational nature of surveys, large number of standards, and limited time on-site result in less attention to compliance.

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## **RECOMMENDATIONS**

### **CMS should determine a minimum cycle for surveying ASCs certified by State agencies**

Take into consideration the nature and risks of care ASCs deliver. Consider a strategic approach that addresses survey cycles for all types of providers certified by State agencies. Consider using analysis of claims data, complaint history, and accreditation status to help identify survey priorities.

**CMS should update the Conditions of Coverage for ASCs**

Add sections that deal with patient rights and continuous quality improvement. Make the Conditions adjustable to match the levels of surgery performed by different ASCs.

**CMS should ensure that State agency certification and accreditation strike an appropriate balance between compliance and continuous quality improvement**

Monitor State agencies and accreditors to ensure that they protect the public from poor performing ASCs while encouraging the rest to go beyond minimal health and safety standards. Our companion report, Supplemental Report 2:  *Holding State Agencies and Accreditors Accountable*, has recommendations for improving CMS' oversight of State agencies and accreditors.

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# INTRODUCTION

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## PURPOSE

To assess the role of State agency certification and accreditation in the quality oversight of ambulatory surgical centers in the Medicare program.

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## BACKGROUND

### Ambulatory Surgical Centers in the Medicare Program

Medicare began covering services provided by ambulatory surgical centers (ASCs) in 1982. In 2000, Medicare paid \$1.6 billion for 4.3 million procedures performed in ASCs. Currently, over 3,000 ASCs participate in the Medicare program.<sup>1</sup>

Although ASCs have operating rooms and recovery rooms, they are not hospitals. However, medical advances enable many of the same procedures that hospitals perform to be performed on an ambulatory basis in an ASC. In addition to ASCs, ambulatory surgery is also performed in physician offices and hospital outpatient departments. However, unlike hospital outpatient departments, ASCs are generally free-standing facilities that provide surgical services to patients not requiring hospitalization.<sup>2</sup> An ASC may only bill Medicare for surgical procedures that the Centers for Medicare & Medicaid Services (CMS) has determined can be performed safely outside of the hospital.

While ambulatory surgery has been shown to have good surgical outcomes, even routine procedures can result in serious complications and death.<sup>3</sup> For example, a patient undergoing a routine Medicare-covered gynecologic procedure died in an ASC from complications during surgery; a patient whose bladder was perforated during surgery in an ASC was transported while bleeding to the nearest emergency room; a patient undergoing one of the most common procedures in Medicare, cataract extraction, went into cardiac arrest and died on the operating table in an ASC. While these adverse events could happen in any setting, the risk of such complications and the fact that more elderly patients with poorer health conditions are becoming candidates for ambulatory surgery illustrate the necessity for strong quality oversight of ASCs.<sup>4</sup> Yet, since the inception of the ASC program in 1982, CMS' approach to oversight remains unchanged. Despite the rapid evolution of ambulatory surgery and the growth in ASCs, there has been little assessment of the adequacy of its quality oversight.

### Quality Oversight of Ambulatory Surgical Centers

Quality oversight of ASCs in the Medicare program revolves around Medicare's

Conditions of Coverage.<sup>5</sup> The Conditions are minimum health and safety requirements that ASCs must meet in order to be eligible for Medicare reimbursement. They cover topics ranging from the credentialing and privileging of physicians to the governing body and management of a facility. The Conditions are established in the regulations by CMS.

CMS relies on State agency certification and private accreditation to ensure that ASCs meet the Conditions. Facilities must be certified by State survey and certification agencies or accredited to participate in Medicare. They are free to choose which route they take. State agency certification is available to ASCs free of charge, while they must pay a fee to become accredited. Over 90 percent of ASCs choose to be certified by State agencies. Yet the number of facilities choosing accreditation is growing.<sup>6</sup> Some ASCs that are certified by State agencies are also accredited for reasons other than Medicare certification.

The emphasis of both State agency certification and accreditation is routine inspections of ASCs, called surveys. Generally, surveys are conducted to add new ASCs to the Medicare program, reevaluate those already in the program, and respond to complaints or adverse events. State agency surveys follow CMS' survey protocol, which is based on the Conditions. Accreditation surveys, however, follow accreditors' own survey protocols and standards. Thus, only accreditors whose standards meet or exceed the Conditions have authority to approve ASCs for participation in the Medicare program.<sup>7</sup>

Medicare certification is carried out by State survey and certification agencies under agreement with CMS. CMS has approved three accreditors to survey ASCs for the Medicare program: the American Association for Accreditation of Ambulatory Surgical Facilities, the Accreditation Association for Ambulatory Health Care, and the Joint Commission on Accreditation of Healthcare Organizations.<sup>8</sup> (See the Profile of State Agency Certification and Accreditation on page 8 for more information on State agency certification and the three approved accreditors.)

## **This Inquiry and This Report**

This inquiry focuses on the oversight of ASCs and is part of a larger plan to assess the quality oversight of ambulatory surgery in the Medicare program. We chose to evaluate the oversight of ASCs first because they are one of the fastest growing settings for ambulatory surgery in Medicare.

This report is the first of two that supplement the main report of this inquiry, *A System in Neglect*, which also includes the full text of the comments we received on the draft reports. Supplemental Report 2: *Holding State Agencies and Accreditors Accountable*, assesses how State agencies and accreditors are held accountable for their performance overseeing ASCs.

Our inquiry draws on a variety of sources. We analyzed data from CMS' Online Survey Certification and Reporting System and the Medicare Part B file, as well as survey data



from the three accreditors. We observed surveys of ASCs conducted by the accreditors and State agencies. We reviewed policy manuals from the accreditors, CMS' State Operations and Regional Operations manuals, laws, regulations, and articles from newspapers, journals, newsletters, and magazines. In addition, through interviews both in-person and over the phone, we gathered information from representatives of CMS central and regional offices, State agencies, professional associations, and the American Association for Accreditation of Ambulatory Surgical Facilities, the Accreditation Association for Ambulatory Health Care, and the Joint Commission on Accreditation of Healthcare Organizations. For a more detailed description of the data sources we used for this inquiry, please see Appendix A.

We conducted this inspection in accordance with the *Quality Standards for Inspections* issued by the President's Council on Integrity and Efficiency.

# PROFILE OF STATE AGENCY CERTIFICATION AND ACCREDITATION

The table below profiles some key characteristics of Medicare certification by State survey and certification agencies and the three accreditors: Accreditation Association for Ambulatory Health Care (AAAHC), the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), and the American Association for Accreditation of Ambulatory Surgery Facilities (AAAASF).

Characteristics	Oversight Mechanism			
	State Agencies	AAAHC	JCAHO	AAAASF
<b>Number of Medicare ASCs as of Spring 2001</b>	2,980	249	55	2
<b>Cost to ASC</b>	None.	Ranges from \$1,500 plus per year.	Ranges from \$1,500 plus per year.	Ranges from \$1,500 plus per year.
<b>Standards</b>	One size fits all, last revised in 1982.	Adjustable to match type of surgery performed; ongoing revision.	Adjustable to match type of surgery performed; ongoing revision.	Adjustable to match type of surgery performed; ongoing revision.
<b>Survey</b>	Unannounced. No minimum survey cycle. Many ASCs go 5 years without a survey.	Unannounced.* Every 3 years; 6 months or 1 year for certain ASCs.	Unannounced.* Every 3 years. Moving toward every 18 months.	Unannounced.* Every 3 years plus self-evaluation every year.
<b>Type of Surveyors</b>	Team rarely includes a physician.	Team always includes a physician.	Team always includes a physician.	Team always includes a physician.
<b>Surveyor Training</b>	Offered ad hoc; 2 day training in 1999; previous training in 1987.	Attend 2 ½ day training every 2 years.	Initial 2 week training and preceptorship, annual training, distance learning.	Attend 1 day training every 3 years.
<b>Public Information</b>	Survey results available only through State agencies or CMS regional office.	Information limited to a list of accredited ASCs by phone and on website.	Accreditation history and most recent survey report available by phone and on website.	Information limited to a list of accredited ASCs by phone and on website.
<b>Standardized Performance Data</b>	None. Performance data not linked to certification.	None. Performance data not linked to accreditation.	None.** Performance data not linked to accreditation.	None. Performance data not linked to accreditation.

\* The accreditors do request a surgical/business schedule for several months surrounding a survey date to ensure that the ASC will be open and caring for patients at time of survey.

\*\* JCAHO is moving towards the use of outcome/performance data to assess compliance with specific standards.

# IMPORTANCE OF QUALITY OVERSIGHT

## Medicare ASCs are experiencing explosive growth

The growth of ASCs outpaces almost all other settings in Medicare. Currently 3,266 ASCs take part in the Medicare program (with about 30 percent located in California, Florida, and Texas). From 1990 to 2000, the number of ASCs increased by close to 200 facilities a year while the number of hospitals decreased slightly. In fact, over the past 5 years, the ASC growth rate outpaces all other settings in Medicare except for comprehensive rehabilitation facilities and rural health clinics.

As the number of ASCs has increased, so too has the number of surgical procedures that they perform. In 1990, 1.3 million procedures took place within Medicare ASCs. By 2000, the number of procedures increased over 220 percent to 4.3 million, accounting for over \$1.6 billion in reimbursement. This growth far outpaces that of Medicare's two other main surgical settings, hospital outpatient departments, which increased by 78 percent, and inpatient hospitals, which increased by 38 percent. Experts project that procedures performed in ASCs will continue to grow steadily between 2000 and 2006.<sup>9</sup>

## Scope and complexity of procedures are on the rise

The procedures taking place in ASCs have not only increased in volume, but have also increased in scope. In 1990, CMS' list of procedures approved for ASCs included 1,500 procedures. The current list, last approved in 1995, includes nearly 2,300 procedures.<sup>10</sup> While it has always included many minor procedures such as draining of a major joint, biopsy of the prostate, and determining urinary bladder pressure, the number of major procedures on the list has grown substantially. CMS defines major procedures as those involving high levels of anesthesia and invasiveness. In fact, 632 major procedures are now approved for ASCs, representing over a quarter of the list. A proposed update to the list, introduced in 1998 but not yet implemented, includes over 2,500 procedures, and will increase the number of major procedures to 743.<sup>11</sup> See Appendix B for descriptions of a major, minor, and an eye procedure commonly performed in Medicare ASCs.

These changes in the list of approved procedures resulted in a dramatic increase in the volume of major procedures performed in ASCs. From 1990 to 2000, the annual volume of major procedures taking place in ASCs grew by 730 percent, from 12,000 to over 101,000 procedures, while those in outpatient departments and hospitals grew by 392 and 57 percent respectively. Thus, Medicare beneficiaries are increasingly going to ASCs for complex procedures involving higher levels of invasiveness and anesthesia. Procedures such as laparoscopic repair of inguinal hernia, shoulder arthroscopy, and arthroscopic

repair of the Anterior Cruciate Ligament, all of which require general anesthesia and were once performed only in inpatient hospitals, are now commonly performed in ASCs.

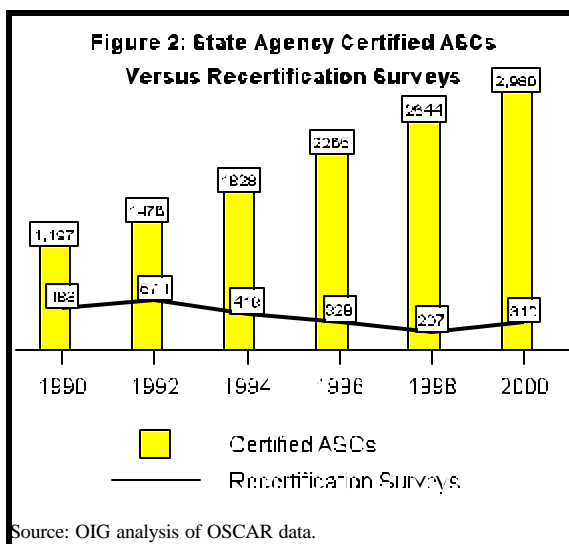
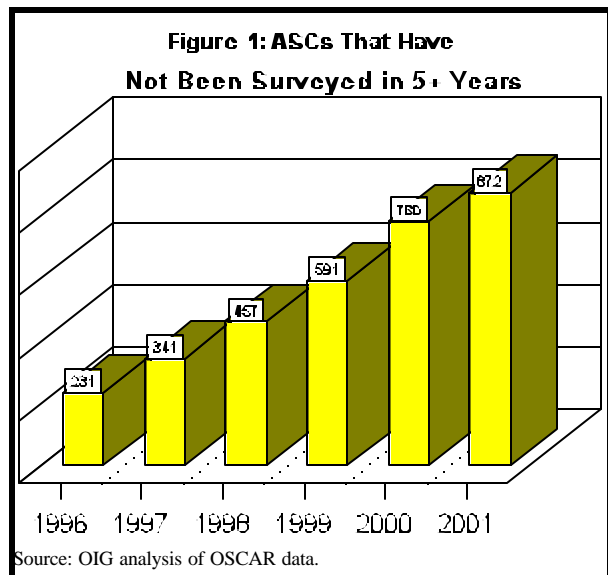
# STATE AGENCY CERTIFICATION

## State agency certification allows many ASCs to fall through the cracks

Over 90 percent of ASCs choose state agency certification as their route to participate in the Medicare program, making it Medicare’s primary tool of oversight for ASCs. Yet, despite significant growth in ASCs, the level of state agency surveys has changed little.

### Recertification surveys are not keeping up

Nearly a third of ASCs certified by State agencies (872) have gone 5 or more years and over 130 have gone 10 or more years without a recertification survey (see figure 1).<sup>12</sup> From 1990 to 2000, the elapsed time between recertification surveys of ASCs already in the program more than doubled, from 1.8 years to 4.4 years. Periodic surveys are important for ensuring that ASCs continue to meet minimum standards for health and safety. This concept is reinforced by the Joint Commission, where a movement is underway to increase the frequency of reaccreditation surveys from once every 3 years to once every 1.5 years.<sup>13</sup>



ASCs certified by State agencies are going so long between surveys because the level of recertification surveys has failed to match ASC growth. Between 1990 and 2000, the number of ASCs certified by State agencies more than doubled from 1,197 to 2,966, but the level of State agency surveys has changed little—hovering at an average of 610 surveys per year.<sup>14</sup> Of these, an increasing portion has been used to survey new ASCs entering the Medicare program rather than to recertify existing ASCs. For example, in 1990, State

agencies conducted 30 surveys to add new ASCs to the program and 483 surveys to recertify the 1,197 ASCs that were already in the program.<sup>15</sup> Yet, in 2000, State agencies performed 287 surveys to add new ASCs and 310 surveys to recertify the 2,966 ASCs already in the program (see Figure 2 for the overall trend).

## Complaint surveys lack follow through

Complaints serve as possible warning signs of deficiencies in patient care and safety. CMS considers surveys in response to complaints and serious incidents as priorities in its budget and instructions to State agencies.

In the past 5 years, State agencies conducted 141 surveys in response to complaints. However, the follow-through on deficiencies (resurveys and plans of correction) identified during these surveys was limited.<sup>16</sup> For example, as of 2001, 47 percent of complaints in CMS' data system are unresolved.<sup>17</sup> In some cases, complaints remain unresolved for as many as 5 years. In fact, 17 percent of unresolved complaint surveys uncovered deficiencies serious enough to warrant terminating the ASC from Medicare.<sup>18</sup> The large number of unresolved cases shows that after a complaint survey, facilities are frequently left unmonitored without a resurvey or without a requirement for them to resolve their deficiencies (see box above).

### **One ASC That Slipped Through The Cracks**

*A State agency received a complaint against an ASC in 1999 from a woman whose mother, a Medicare beneficiary, underwent a routine cataract extraction there. The beneficiary died during surgery. In response to the complaint, the State agency surveyed the ASC and found it to be out of compliance with 5 of the 10 Medicare Conditions, including missing emergency equipment, uncredentialed staff participating in surgery, and falsified medical records. The surveyors suspected that the ASC's lack of emergency equipment was related to the death of the beneficiary. Although the ASC submitted a plan of correction, CMS rejected it and instead, in October of 1999, gave the facility 23 days to resolve deficiencies or be terminated from the Medicare program. Yet neither the facility nor CMS has taken any action toward resolving these deficiencies. Despite its unresolved deficiencies related to patient safety, the facility continues to perform surgeries and treat Medicare patients.*

Finally, we acknowledge that poor follow-through indicated by CMS' data system could be the result of lags in data entry of updates to complaint cases. However, we reviewed the paper records for 18 cases and found that they agreed with the data system records.

## ASCs are a low priority in CMS' survey and certification budget

Over the last 5 years, ASCs have consistently ranked near the bottom of CMS' survey priorities.<sup>19</sup> ASCs compete for survey funding with over 25,000 other facilities in the Medicare program.<sup>20</sup> In their last place priority category, called "other," ASCs still compete with over 10,000 facilities in the Medicare program, including hospices, rural health clinics, and psychiatric hospitals.<sup>21</sup> By statute, CMS must survey nursing homes and home health agencies at regular intervals. Home health agencies must be surveyed every 3 years while nursing homes must be surveyed every 12-15 months.<sup>22</sup> ASCs,

however, lack such a mandated survey cycle. Thus, they drop even lower in survey priority.

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## The Medicare Conditions of Coverage fall short

The Conditions set the overall tone and approach of CMS' oversight model for any given provider type in the Medicare program. They drive the structure and content of State agency surveys and set a baseline that the standards of CMS-approved accreditors must meet or exceed. Indeed, the effectiveness of Medicare's entire system of quality oversight depends upon having Conditions that are adequate in light of the nature and risks of care delivered by a given provider type. CMS is in the process of updating the Conditions for several provider types, including hospitals.

### They are outdated

CMS has not updated the Conditions for ASCs since the inception of the ASC program in 1982.<sup>23</sup> Thus Medicare's approach to overseeing ASCs has failed to keep pace with important advances in quality oversight. We note that CMS did attempt to update the Conditions in 1996, but the effort never reached conclusion. Below we highlight two key areas where the Conditions have fallen behind.

**The Conditions do not address patient rights.** The Conditions fail to address important patient protections such as complaint processes, safeguarding patient privacy, and making available information on treatment options. Yet, in its Strategic Plan CMS cites a renewed commitment 'to beneficiaries as the ultimate focus of all CMS activities, expenditures, and policies.'<sup>24</sup> Indeed, CMS has added patient rights to the Conditions for several other provider types, including hospitals and nursing homes, but it has not yet done so for ASCs.<sup>25</sup>

**The Conditions do not address continuous quality improvement.** The Conditions offer little commitment to continuous quality improvement. While CMS speaks to the importance of continuous quality improvement in its interpretive guidelines to ASC surveyors, the Conditions themselves do not require ASCs to conduct continuous quality improvement efforts. Nor do they require the use of standardized performance measures for assessing performance and directing quality improvement efforts. However, CMS has begun to require nursing homes, home health agencies, and hospitals to report standardized performance measures which can be used to direct continuous improvement.<sup>26</sup>

### They cannot adjust to match the levels of surgery that different ASCs offer

Nearly half of ASCs are single-specialty facilities, performing only one type of procedure, such as pain management injections, eye surgery, endoscopy, or orthopedic surgery.<sup>27</sup> Yet, the Conditions fail to distinguish among ASCs performing surgery of varying risk and complexity. Instead, they take a one-size-fits-all approach that appears geared toward

large, multi-specialty ASCs that use general anesthesia. They cannot adjust to reflect the degree of invasiveness or type of anesthesia, among other factors, that vary among ASCs. This could overburden some ASCs while leaving others with a set of standards that may not effectively address key aspects of their operations.

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## State agency surveys focus entirely on compliance and fail to include continuous quality improvement

State agency surveys revolve around ensuring compliance with the 10 requirements that comprise the Conditions of Coverage. Surveyors use a standard protocol called the Interpretive Guidelines that CMS derives directly from the Conditions. These guidelines serve as a road map to focus the survey, suggesting probes for ascertaining compliance with each requirement. In our observations, surveyors did not veer from these guidelines. Further focusing their review, they often collapsed the guidelines into 1 - 3 page checklists of evidence necessary to complete the survey. To verify that they had an accurate picture of compliance, surveyors would cross-reference evidence from different sources. For example, they often cross-referenced evidence through the surgical log to verify that surgeons practiced within their privileges, that peer review dealt with problem cases, and that the ASC followed its bylaws.

### **A State Agency Survey We Observed**

*The ASC was a large multi-specialty facility with 5 operating rooms and over 25 staff. On the day of the survey, two nurses from the State agency arrived at the facility unannounced. The survey began at 9AM with a 15 minute conference with the surveyors and the facility administrator. At this time the lead surveyor provided the facility administrator with a list of documents she would need to review: bylaws, surgical log, and personnel lists. She used these documents to develop a list of medical record and personnel files for review. The second surveyor went on a 1.5 hour tour of the facility, and then a 1.5 hour tour of the operating rooms. At this time, a representative of the State Insurance and Fire Safety Commission arrived to do a 2-hour life safety inspection of the facility, measuring doorways and checking smoke barriers. Meanwhile, the second surveyor reviewed medical records and other documents. Next, the surveyors reconvened and together completed a review of medical records, credentialing, and the facility's quality assurance program, consistently probing in areas where they found problems by requiring additional documents and asking additional questions. Surveyors frequently asked ASC staff to explain how hypothetical situations would unfold at the facility--such as emergency situations and application/reapplications for privileges for a doctor joining the staff. The next morning, surveyors held an exit conference to describe the deficiencies they found.*

The State agency survey is characterized by a challenging, direct approach in which surveyors aim to enforce minimums, rather than educate toward continuous quality improvement.<sup>28</sup> This approach is ingrained in State agency surveys. It is delineated in CMS' policy, which states that the role of the surveyor is, "to assess the quality of care and services and relate those findings to statutory and regulatory requirements."<sup>29</sup> The policy goes on to explain that the surveyor's role is not to educate, advise, or consult with the facility on ways to improve the quality of care. This is reinforced by the Conditions in their failure to require ASCs to address continuous quality improvement. Thus State



agency surveys focus on assessing compliance with the Conditions and do little toward improving the quality of ASCs beyond Medicare’s minimum requirements. For example, at exit conferences of State agency surveys, surveyors run down a list of what is out of compliance and refuse to discuss strategies a facility could use to improve its level of care. As one surveyor told us, “CMS specifically tells its surveyors not to act as educators or give advice. My role is to simply make sure everyone is safe.”

# ACCREDITATION

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## **Accreditation provides regular presence in ASCs, but covers a small proportion of facilities**

Each of the accreditors has policies to survey ASCs every 3 years. In fact, data from the two accreditors with more than 3 years of experience accrediting Medicare ASCs show that both survey facilities every 3 years.<sup>30</sup> Routine on-site presence at ASCs provides oversight that is important to ensuring patient safety and reducing risk. Even though the surveys are unannounced, ASCs who voluntarily chose to be accredited expect such an on-site presence at regular intervals. This usually means that at a minimum, the facility must update policy manuals, recheck credentials and privileges, and perform staff training to retain accreditation.

For some facilities, the survey cycle is shorter than every 3 years. For example, the Accreditation Association for Ambulatory Health Care accredits facilities where it finds patient safety concerns for shorter periods (6 and 12 months).<sup>31</sup> This means these ASCs will be resurveyed sooner, so it can follow up on problem areas. Currently, the Joint Commission has a program in place to survey 5 percent of their facilities within a year of the ASCs' accreditation. In addition, to increase its on-site presence, the Joint Commission is moving toward surveying ASCs every 18 months.<sup>32</sup> Finally, the American Association for Accreditation of Ambulatory Surgical Facilities requires its facilities to complete a self-evaluation in the years between the on-site surveys. On this form, facilities must evaluate their compliance with its standards.<sup>33</sup>

Finally, while each of the accreditors reserves the right to survey ASCs in response to complaints, these surveys do not play a prominent role in their approach to oversight. As of February 2001, the accreditors have received a total of 10 complaints against ASCs and conducted surveys in response to 2 of them.<sup>34</sup>

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## **Accreditors update their standards regularly and adjust them to match the levels of surgery performed by individual ASCs**

Each accreditor has a process in place to regularly update its standards. For example, in consultation with the ASC industry, the Accreditation Association for Ambulatory Health Care updates its standards on a yearly basis. Similarly, the Joint Commission revises its standards at a minimum of one year and the American Association for Accreditation of Ambulatory Surgical Facilities last revised its standards 2 years ago.

This approach enables the accreditors to keep up with advances in ambulatory surgery and with important developments in quality oversight. For example, each of the

accreditors developed standards concerning malignant hyperthermia, a recently recognized complication triggered by commonly used general anesthetics. Furthermore, each of the accreditors also developed standards for several focal areas within health care, such as patient rights and quality improvement, while the Joint Commission also added a test standard for pain management.

Furthermore, each of the accreditors builds adjustability into its standards to reflect the diverse surgical procedures offered within ASCs. The accreditors are able to scale these standards on the basis of the types of procedures performed in the ASCs, the complexity of services offered, and the levels of anesthesia used. For example, the American Association for Accreditation of Ambulatory Surgical Facility's standards accommodate three levels of surgery based on the types of anesthesia used. Similarly, the Accreditation Association for Ambulatory Health Care applies a modular approach, using eight sets of core standards that apply to all facilities and several sets of adjunct standards that are used only for specific services offered by each facility, such as anesthesia services and surgical services. The Joint Commission also applies its standards so that their surveys are individualized according to the services provided at each ASC.

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## Accreditation surveys focus on helping ASCs continuously improve but pay less attention to verifying compliance

By its nature, accreditation focuses on continuous quality improvement through peer-to-peer interaction around the standards of the accreditors.<sup>35</sup> Each of the accreditors describes its process as a consultative one, sending at least one physician as part of every survey team. These survey teams spend considerable effort educating physicians and staff on ways to continuously improve their facility's performance. Indeed, a trusting and instructional manner characterized the interaction within each of the accreditation surveys we observed. As one surveyor said, "I'm not here to find you doing things wrong. We're here to find things you can do

### **An Accreditation Survey We Observed**

*The ASC was a two-operating room facility that specialized in ophthalmology and pain management, but had recently added podiatry and orthopedics to its services. The survey team of two, one of whom was a physician, arrived unannounced at 8:30 am and began with a tour of the facility. During the tour, the surveyors asked the Head Nurse a series of questions about the ASC's operating policies and took notice of the layout and equipment within the facility. After the tour, they reviewed the bylaws, staff and quality assurance minutes, the surgical log, and other documents. They also reviewed a sample of 25 medical records chosen by the ASC staff based on criteria provided by the survey team. After the survey concluded for the day, the surveyors visited the office of one of the physician-owners of the ASC, where they talked informally about the local health care market. Upon returning to the facility the following morning, the surveyors changed into surgical dress and did an in-depth tour and inspection of the facility. During the tour, they observed surgery, assessed sterile technique, security of narcotics, and the presence of required emergency equipment. Following the tour, the surveyors briefly discussed the survey findings with each other and then, at 11:30 am, held an exit conference with the facility staff. During the exit conference, a positive tone prevailed as surveyors reviewed a handful of problems they found and praised staff for things the facility was doing well, which they called 'Wows.'*

better. Since you asked us here, we presume you're doing things well.” Insights passed along by surveyors ranged from those having to do with quality of care and patient safety to business and financial operations. In addition, surveyors often praised staff, particularly when they felt that a facility had done well within important areas.

However, while working within this instructional manner, accreditation surveyors must also assess compliance with hundreds of standards for each ASC, often within surveys that last less than 2 days.<sup>36</sup> This results in surveyors paying less attention to verifying compliance with accreditation standards. For example, we observed that accreditation surveyors rarely used the surgical log to verify that surgeons practiced within the scope of their privileges or that adverse events were flagged for quality review. Instead, they relied on conversations with staff or review of a limited sample of medical records. This tact may result in superficial review of serious problems. For example, during a survey of an endoscopy center that we observed, staff disclosed that they had used the crash cart two times in the last 6 months, one of which was for a ‘code blue’ situation. Yet, in response, the surveyor did not check the facility’s quality assurance minutes or peer review worksheets to see that it examined the cases appropriately. Instead, he simply stressed the importance of using a quality assurance process to analyze such cases for evidence of a pattern of problems.

# RECOMMENDATIONS

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## **CMS should determine an appropriate minimum cycle for surveying ASCs certified by State agencies**

Over the past 10 years, State agencies' oversight has weakened dramatically while the number of ASCs certified by State agencies and the scope of services they provide has increased dramatically. Currently, only nursing homes and home health agencies have a minimum survey cycle to ensure that they receive routine on-site surveys. ASCs, along with all other Medicare provider types, lack such a cycle. In determining a minimum survey cycle for ASCs, CMS should consider the nature and risks of care ASCs deliver.<sup>37</sup> CMS should consider a strategic approach that addresses survey cycles for ASCs within the overall context of adequately surveying all types of providers certified by State agencies. In addition, it should consider how its analysis of certain data could help it prioritize surveys across ASCs. For example, it could draw on volume of Medicare procedures, complaint history, and whether an ASC is accredited for reasons other than Medicare certification. CMS should also consider whether the financial demands presented by the rising number of Medicare-certified providers warrant establishing user fees, which would require legislative change. Such steps might enable CMS to better manage and plan for growth in the number of State agency surveys required to adequately oversee certified providers.

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## **CMS should update the Conditions of Coverage for ASCs**

CMS has not updated the Conditions of Coverage for ASCs since it began covering procedures performed in ASCs in 1982. Several times since, however, CMS has increased the number of ASC-approved procedures as medical advances have enabled ASCs to perform increasingly varied and complex types of surgery. Yet, the effectiveness of Medicare's quality oversight system depends upon having Conditions that are adequate in light of the nature and risks of care ASCs deliver. The Conditions are of central importance because they set the overall tone and approach of CMS' oversight model, thus driving the structure and content of State agency surveys. They also set a baseline which the standards of Medicare-deemed accreditors must meet or exceed. Indeed, CMS is in the process of updating the Conditions for several provider types, including hospitals.

### **At a minimum, add sections that deal with patient rights and continuous quality improvement**

As ASCs continue to gain importance within the Medicare program, it is important that CMS ensures that they provide a core set of patient rights to Medicare beneficiaries. Adding a section to the Conditions that addresses issues such as how ASCs will respect

patients' dignity and resolve patient complaints would be an important step in this direction. Indeed, such a step would reflect with CMS' renewed focus on beneficiaries within its strategic plan and goals aimed at strengthening beneficiary satisfaction and protections.

Similarly, addressing continuous quality improvement is also in line with several goals of CMS' strategic plan including those for enhancing quality of care and improving program administration. CMS should ensure that the Conditions require ASCs to conduct continuous quality improvement efforts. Over the longer term, we urge CMS to explore developing performance measures for ASCs. ASCs could use the measures to direct continuous quality improvement efforts while CMS could use them to monitor ASCs' performance and to adjust the frequency and focus of surveys. We note that CMS already has a similar initiative underway using indicators reported by nursing homes and home health agencies. Both the Medicare Payment Advisory Commission and Congress have recently called on CMS to explore the expanded use of quality indicators.<sup>38</sup>

### **Make the Conditions adjustable to match the levels of surgery performed by different ASCs**

In updating the Conditions, CMS should move away from its current one-size-fits-all model and instead consider an adjustable approach that would enable them to be tailored to individual ASCs.<sup>39</sup> Such an approach might take into account anesthesia, invasiveness, and other factors that drive the riskiness of procedures done by a given ASC. This would improve the effectiveness and efficiency of State agency certification as well as minimize the regulatory burden by focusing the standards and the State agency survey on the level of services offered by each ASC. For example, an ASC that specializes in pain management would have a set of standards different from that of an ASC offering general surgery.

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### **CMS should ensure that State agency certification and accreditation strike an appropriate balance between compliance and continuous quality improvement**

While compliance typifies the regulatory approach taken by State agencies, continuous quality improvement is central to the collegial approach of accreditors. Both have important roles to play in quality oversight. In previous work, the OIG has highlighted work done by the National Roundtable on Health Care Quality and others that suggests that both approaches have value, but not so much that one should dominate at the expense of the other.<sup>40</sup> Balance between the approaches would protect the public from poorly performing ASCs while encouraging the rest to improve beyond minimal health and safety standards. Yet, quality oversight of ASCs provided by State agencies and accreditors engages almost exclusively in one approach or the other.

Adding continuous quality improvement to the Conditions would be a good first step toward bringing balance to quality oversight of ASCs. The challenge for CMS lies in

monitoring and working closely with State agencies and accreditors to ensure that their work reflects an appropriate balance. However, in our companion report, Supplemental Report 2: *Holding State Agencies and Accreditors Accountable*, we find that CMS does little to oversee State agencies' and accreditors' performance. In that report, we offer recommendations for ways that CMS can improve its oversight of State agencies and accreditors.

## Methodology

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### Center for Medicare & Medicaid Services

**Data.** We obtained dates of State agency surveys from CMS' Online Survey Certification and Reporting System (OSCAR). CMS authorizes States to update and maintain this database with survey information. We used OSCAR to gather basic demographic information on ASCs certified by State agencies as well as explore the accuracy of data in OSCAR on those ASCs that are accredited. We extracted survey data pertaining to the frequency of State agency surveys between 1990 and 2000. In addition, we used OSCAR to identify ASCs that had a complaint survey between 1995 and 2000. We analyzed these data sets using the SAS software program. We are satisfied that our information is as accurate as CMS' OSCAR system.

Additionally, we obtained other descriptive information using OIG-generated random samples of 1 percent of Medicare's Part B claims from 1990 and 2000. We used these samples to determine the total number of procedures taking place in ASCs, to sum reimbursement, to identify the top procedures, and to find what Medicare approved procedures are being performed in ASCs. Also, by applying the Berenson-Eggers Type of Service codes to the samples, we determined the number of major procedures taking place in ASCs. We conducted all of our analysis of Medicare claims data using SAS software. We are satisfied that our information is as accurate as the Part B 1 percent sample files.

**Documents.** We reviewed a variety of documents from CMS, including:

- Budget call letters for each year from 1995 to 2001
- Regional Office and State Operations Manuals
- ASC Conditions of Coverage and Interpretive Guidelines
- Strategic plan
- Data compendium from 1995 to 1999
- Internal policy memos from the central and regional offices
- Correspondence with the accreditors.

Finally, we reviewed 18 ASC complaint files from both State agencies and CMS regional offices from the years 1995 to 2000. We chose complaint files for review based on information obtained from OSCAR on date of complaint survey, number of complaints, and follow-up action taken. Additionally, we reviewed documents pertaining to CMS' evaluation of the accreditors' performance, as well as the findings of CMS oversight surveyors at site visits with the accreditors.



**Interviews.** We interviewed CMS employees involved with the ASC program at both central and regional offices.

### **State Survey Agencies**

We interviewed State surveyors and State health agency officials involved in the certification of ASCs. We obtained a variety of documents from State agency certification surveys including checklists used by surveyors and final survey findings including deficiencies found and plans of correction.

### **Accreditors**

We interviewed officials from all three accreditors. We also reviewed documents from the three organizations, including mission statements, accreditation manuals, policies, and ASC survey reports, communication from CMS, and complaint files. We requested and received aggregate data from these organizations reflecting their survey activity and findings over the last 3 years. In addition, we attended surveyor training sessions for the American Association for Accreditation of Ambulatory Surgery Facilities and Accreditation Association for Ambulatory Health Care.

### **Survey Observation**

We observed a total of nine ASC surveys in seven states during the course of this study. Four were State agency surveys and five were accreditation surveys.

### **Other Sources**

Other sources of information that we used for this report include relevant laws and regulations. We also reviewed a variety of articles from newspapers, peer reviewed journals, medical text books, and medical web sites. Finally, we interviewed stakeholders, including consumer advocates, members of several professional associations, practicing physicians, and practicing lawyers.

## Description of Three ASC Procedures

	<b>Injection for Pain Management (CPT 62311)</b>	<b>Cataract Removal with Lens Insertion (CPT 66984)</b>	<b>Knee Arthroscopy with Meniscectomy (CPT 29881)</b>
<b>Procedure Description</b>	Diagnostic and/or therapeutic medication is injected into the lumbar/sacral spinal area.	A cataract is broken-up and removed, either manually or by the use of ultrasonic pulses. Once the cataract is removed, a new lens is put in place.	An arthroscope and other instruments are inserted through small incisions made in the knee joint. The condition of the knee joint is evaluated and any damaged tissue is removed and/or repaired.
<b>Anesthesia</b>	! Local anesthesia. ! IV sedation (rare).	! Topical anesthetic eye drops with or without IV sedation. ! Nerve block with or without IV sedation.	! IV sedation with local anesthetic for knee. ! General anesthesia with nerve block.
<b>Average Surgery time</b>	<10 minutes	19 minutes	30 minutes
<b>Average Recovery time</b>	<30 minutes	29.5 minutes	90 minutes
<b>Number of procedures 1990 (Ranking)</b>	9,800 (14)	521,600 (1)	5,700 (21)
<b>2000 (Ranking)</b>	159,500 (6)	1,349,400 (1)	22,200 (21)

### **Injection of diagnostic or therapeutic substance into the lumbar/sacral area**

The procedure begins with a consultation period to determine if the injection is warranted for the patient. This will vary between 10 and 30 minutes, depending upon how complex the patient’s history and examination are.<sup>41</sup>

This procedure, which generally takes 10 minutes to complete, involves injecting medication into the epidural space, which is the vertical “tunnel” surrounding the spinal canal and extends from the base of the skull to the sacrum. Normally, the patient will not require IV sedation for this procedure, rather, local anesthetic is placed at the site of injection. By injecting the medication into the epidural space, it is able to wash over the nerve roots which have just left the spinal cord and are, for a short space, enclosed within the epidural space. The medication used most frequently is a steroid with or without local anesthetics or opioids (such as morphine). Occasionally, anti-spasmodic medication, such as Baclofen, is also injected into the epidural space. There are also occasions in

which steroids are not used. In the case of obese patients and patients who have undergone surgery and, consequently, have scar tissue in the area of this procedure, the procedure may take substantially longer, though normally not longer than 45 minutes.

There are some situations when medication is injected directly into the spinal canal. In this case, the medication is injected at or below the level of the first lumbar vertebrae. There is also a “caudal” approach in which medication is injected into the epidural space at the lowest end of the spine.

Depending upon whether local anesthesia was placed at the site of injection, the recovery for this procedure usually takes 30 minutes. On rare occasions, when this procedure is done as a diagnostic event, it is necessary to keep the patient on-site for physician evaluation and pain relief over the course of several hours.

### **Cataract removal with lens insertion**

Prior to the procedure, an ophthalmologist takes several measurements of the eye, such as an ultrasound and other non-invasive means, to evaluate the curvature of the eye. Also, the general health of the patient is evaluated prior to the surgery to determine the patient’s fitness for the procedure. Most patients with comorbidities are able to undergo this procedure.<sup>42</sup>

Typically the eye will be anesthetized using topical anesthetic eye drops or a nerve block. Often, patients are also given IV sedation to help them relax throughout the procedure.

With the help of a microscope, the edge of the cornea is incised in order to get to the cataract that has formed on the lens. Manual removal of the cataract calls for a small incision of the cornea, while use of ultrasound to break up the cataract requires an even smaller incision. The cataract is then either manually or ultrasonically crushed into small pieces, which are then either manually removed or vacuumed out of the eye.

Once the pieces of the cataract are removed, the lens is inserted through the incision in the cornea. Oftentimes, no sutures are needed to close the incision. A patch is placed over the eye and is removed the next day at the postoperative examination. Antibiotic and anti-inflammatory eye drops are prescribed and the eye is completely healed in about 10 weeks.

### **Knee arthroscopy with meniscectomy**

The patient can be placed under local, spinal, or general anesthesia, however, it is recommended that the patient be given general anesthesia. After the patient is anesthetized, a tourniquet is put into place about the thigh. A leg-holding device is also

put in place to assist in stressing the knee to open up the different compartments that require exploration for diagnostic or operative procedures.<sup>43</sup>

Prior to surgery, the leg, from ankle to tourniquet, is thoroughly scrubbed and prepared for surgery. The patient's leg is then draped to isolate the knee. The patient can be placed in either one of two positions; laying down with either the surgically prepared leg angled off the side of the table, or with both legs dangling off the end of the table at 90 degrees.

Next, the patient is ready for the incisions through which the arthroscope and other instruments will be inserted. First, the surgeon uses a skin-marking pen to mark several landmarks, including all standard and optional incisions, and the outlines of ligaments, tendons and joint lines. Next, before any incisions are made for insertion of the scope and other instruments, the knee joint must be distended in order ensure the view of the arthroscope is not obscured. Distention involves inserting a tube, called an inflow cannula, into the knee joint through a small incision. This tube is connected to a fluid bag situated four to five feet above the patient. Constant inflow of this fluid into the knee joint assures the surgeon has a proper view of the joint. Once the knee is fully distended, the surgeon should check the initial landscape markings of the knee to ensure the incisions will be made in the proper areas.

The surgeon can now make the small incisions at the standard incision sites and, if need be, at the optional incision sites as well. Once the small incisions are made the surgeon inserts the arthroscope which enables the surgeon to see inside the knee joint. While manually manipulating the knee joint by moving the leg, the surgeon probes the entire knee joint in order to determine where the damage is and what course of action should be taken. In the case of a meniscectomy, there is a tear in the meniscus, which is the disc shaped cartilage in the knee joint, and the damaged portion of the meniscal cartilage must be removed. The surgeon then inserts either basket forceps, scissors, or an arthroscopic knife into another portal to remove the damaged meniscal cartilage. Once the damaged cartilage is removed, the remaining meniscal cartilage is probed to ensure there are no additional tears and that it is balanced and stable. Finally, the knee joint is thoroughly lavaged and suctioned in order to remove any small cartilage particles that may have dropped into the joint during the removal procedure, and the small incisions are sutured.

## Endnotes

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1. CMS' Online Survey Certification and Reporting System (OSCAR), March 5, 2001.
2. 42 C.F.R., sec. 416.2.
3. Mark A. Warner et al., "Major Morbidity and Mortality Within 1 Month of Ambulatory Surgery and Anesthesia," *Journal of the American Medical Association* 270 (September 22, 1993) 12: 1437-1441.
- G. Mezei & F. Chung, "Return hospital visits and hospital readmissions after ambulatory surgery," *Annals of Surgery* 230 (November 1999) 5: 721-727.
- Rebecca Twersky et al., "What happens after discharge? Return hospital visits after ambulatory surgery," *Anesthesia & Analgesia* 84 (February 1997) 2: 319-324.
4. Margaret Jean Hall et al., "Ambulatory Surgery in the United States, 1996," Advance Data: National Center for Health Statistics, Centers for Disease Control 300 (August 12, 1998).
- Mark A. Warner et al., "Major Morbidity and Mortality Within 1 Month of Ambulatory Surgery and Anesthesia," *Journal of the American Medical Association* 270 (September 22, 1993) 12: 1437-1441.
5. Social Security Act, sec. 1832 (a) (2) (F)(i).
6. Based on data provided to OIG by the three accreditors.
7. Social Security Act, sec. 1865, 42 U.S.C. 1395bb.
8. CMS announced in the Federal Register (50 Fed. Reg. 66, 14906, March 14, 2001) that the American Osteopathic Association (AOA) applied for recognition as a national accreditation program for ASCs for the Medicare program. As of the date this report was issued the AOA had not yet been approved to accredit Medicare ASCs. The Joint Commission on the Accreditation of Health Care Organizations and the Accreditation Association for Ambulatory Health Care have been approved since December 19, 1996 ( 245 Fed. Reg. 61, 67042, Dec. 19, 1996). The American Association for Accreditation of Ambulatory Surgical Facilities has had approval since December 2, 1998 (231 Fed. Reg. 63, 66554, Dec. 2, 1998).
9. SMG Marketing Group Inc "Freestanding Outpatient Surgery Centers (FOSCs)." Copyright 2000.
10. CMS approves procedures to be performed in ASCs based on 42 C.F.R., sec. 416.65 These standards limit ASC procedures to those that do not generally result in extensive blood loss, that do not require major or prolonged invasion of body cavities, that do not directly involve major blood vessels, or that are not generally emergency or life-threatening in nature.

11. Section 1833(i)(1) of the Social Security Act requires that the ASC list be reviewed and updated at least biennially. The current list of procedures approved for ASCs was last reviewed and updated in 1995. CMS has not updated this list in over 6 years and has missed its last three scheduled update deadlines.
12. We count the number of ASCs that have not had a survey in 5 or more years in a given year using the midyear, July 1, as the point of reference for each year.
13. JCAHO website information: *Accreditation Process Improvement Initiative* [www.jcaho.org](http://www.jcaho.org).
14. Year 2000 data is from December 2000. According to OSCAR, as of May 2001, 3,234 ASCs participate in the Medicare program, of those, 2,966 are certified.
15. Initial surveys and recertification surveys do not total to overall number of surveys for this year because State agencies performed two “other” types of surveys.
16. Between 1995 and 2000 State agencies and CMS regional offices have received 159 complaints and performed unannounced surveys in response to all but 3 of them This is the total number of complaints that the CMS Regional Office and State Agency entered into OSCAR. It is not known how many actual complaints were received that were either not entered into OSCAR or not investigated.
17. OIG analysis of OSCAR data. Complaint files are considered to be unresolved if they are listed in OSCAR as “pending.” We obtained a total of 18 complaint files to check against OSCAR. We found that the provider files marked pending in OSCAR have not had a follow-up survey or action against them since the complaint survey was performed.
18. Medicare surveyors have three options when they investigate complaints and find deficiencies. They can place a facility on a 23-day or 90-day termination track, or ask the facility to submit a written plan of correction. The termination tracks require facilities to correct deficiencies within a specified time limit or risk termination from the Medicare program. Facilities placed on termination tracks are usually those where the most serious problems exist. If an ASC is out of compliance with the Conditions to such an extent that patients are in jeopardy, surveyors use a 23-day termination notice. For ASCs with condition-level deficiencies but no finding of patient jeopardy; surveyors use a 90-day termination notice. ASCs that are not placed on a termination track, but have non condition-level deficiencies can be given a plan of correction whereby the facility sends the State agency a written notice stating the date the deficiencies were corrected, how they were corrected, and in some cases, documentation that the deficiencies were corrected. Only facilities with condition-level deficiencies can be placed on a termination track. The path to termination is not direct. The survey process allows ASCs to correct condition-level deficiencies before the deadline for termination from the Medicare program.

19. Ranking of Survey Type on CMS Budget Call Letter FY 1997-2001

<b>FY Year</b>	<b>Rank of Initial Surveys</b>	<b>Rank of Recertification Surveys</b>
2001	11 out of 11	10 out of 11
2000	8 out of 8	7 out of 8
1999	11 out of 12	10 out of 12
1998	8 out of 9	7 out of 9
1997	8 out of 9	7 out of 9

20. Other facility types in the Medicare program include: Nonaccredited hospitals, skilled nursing facilities, nonaccredited home health agencies, hospices, outpatient physical therapy centers, comprehensive outpatient rehabilitation centers, x-ray facilities, end-stage renal dialysis facilities, rural health clinics, organ procurement organizations, and community mental health centers.

21. From CMS' FY 2001 budget. Our analysis of 2000 Medicare Part B and OSCAR data revealed 515 ASCs certified by State agencies that made no Medicare claims in 2000 (16% of all ASCs that take part in the Medicare program). Further analysis would be needed to determine whether these 515 are newly certified by State agencies and therefore unlikely to have 2000 claims.

22. 42 U.S.C. Sec. 1396r All skilled nursing facilities and nursing facilities are subject to a standard survey not later than 15 months after the previous standard survey, with a Statewide average interval between standard surveys of not more than 12 months. Home health agencies are subject to a standard survey not later than 36 months after the previous standard survey (42 U.S.C. Sec. 1395bbb). The frequency for surveys of HHAs within this 36 month interval shall be commensurate with the need to assure delivery of quality home health services.

23. CMS has updated the conditions for several other providers such as hospitals, home health agencies, and ESRD, however, none have been officially approved. CMS does have plans to update the ASC conditions.

24. CMS Strategic Plan, p. 10, September, 1988.

25. See 64 Fed. Reg. 36,088, July 2, 1999 and 62 Fed Reg. 11,026, March 10, 1997 respectively.

26. CMS has implemented the Minimum Data Set in nursing homes and the Outcome and Assessment Information Set in home health agencies. In addition, CMS calls for quality indicators within its proposed update of the Conditions of Participation for hospitals.

27. SMG Report. Page 20.

28. Office of Inspector General, *The External Review of Hospital Quality: A Call for Greater Accountability* (July 1999).
29. CMS State Operations Manual section 4018.
30. Data from 1997, the first year the Joint Commission on the Accreditation of Health Care Organizations and the Accreditation Association for Ambulatory Health Care surveyed facilities for the Medicare program shows that 26 ASCs applied to have a Medicare survey through the Joint Commission in the year 1997. In 2000, the Joint Commission resurveyed a third of those facilities. AAAHC had 149 ASCs in the Medicare program in 1997. Three years later, AAAHC resurveyed a third of those ASCs. The American Association for Accreditation of Ambulatory Surgical Facilities (AAAASF) has been approved for Medicare since December 2, 1998 (231 Fed. Reg. 63, 66554, Dec. 2, 1998). AAAASF surveyed its first Medicare ASC in 2000. Therefore, survey data is not available for 1998 and 1999.
31. AAAHC has three survey options for their facilities. Facilities with minor or without any deficiencies will be resurveyed in 3 years. However, facilities with some deficiencies that AAAHC considers to be more serious or part of a pattern of partial compliance will be given shorter periods of accreditation, 6-months to 1 year, meaning these facilities must submit a plan to correct deficiencies and be resurveyed in order to gain 3 year accreditation. In fact, in 1998, 34 percent of ASCs surveyed by AAAHC received either a 6 month or 1 year accreditation decision and in 1999, 44 percent of ASCs received this decision. Through these shorter accreditation periods, which result in more frequent on-site presence, AAAHC helps to ensure that facilities with the most serious problems are not allowed to go 3 years in between surveys.
32. Joint Commission web page “Accreditation Process Improvement Initiative” May 5, 2001. Currently, the Joint Commission conducts random unannounced surveys on 5 percent of accredited ASCs per year, 9-30 months after a facility’s last accreditation survey. On these surveys areas of specific concern about the provider based on prior surveys, complaints, and sentinel events are covered as well as elements that vary year to year. Some examples are: performance improvement, credentialing and privileging, and medication use.
33. If ASCs report on the self-evaluation form that they do not meet AAAASF standards they are subject to the same 30-day corrective process as would occur after an on-site survey, including the possibility of on-site follow-up surveys.
34. See our companion report, *Holding the System Accountable*, for further discussion of complaint mechanisms.
35. For more on the nature of accreditation, see Office of Inspector General, *The External Review of Hospital Quality: A Call for Greater Accountability* (July 1999) and Michael S. Hamm, *The Fundamentals of Accreditation* (Washington, D.C.: American Society of Association Executives, 1997) 3.



36. State agency certification has 10 conditions of coverage and about 50 standards for ASCs, whereas all three accreditors have over 200 standards for ASCs. In fact, AAAASF has over 300 standards.

37. CMS could also consider whether particular ASCs are, in fact, treating Medicare beneficiaries. Our analysis revealed 515 ASCs certified by State agencies that made no Medicare claims in 2000 (16% of all ASCs that take part in the Medicare program). Further analysis would be needed to determine whether these 515 are newly certified by State agencies and therefore unlikely to have 2000 claims.

38. In its 2000 Report to the Congress, Medpac recommended that CMS expand its indicator-driven survey process for nursing homes and home health agencies to other providers in the Medicare program. In the Benefits Improvement and Protection Act of 2000, Congress directed the Secretary to work with Medpac and the Agency for Healthcare Research and Quality to examine and report on the development of standard instruments for patient assessment across settings.

39. This may require legislative change.

40. Department of Health and Human Services, Office of Inspector General, *The External Review of Hospital Quality*, OEI-01-97-00050; Office of Inspector General, *The External Quality Review of Dialysis Facilities*, OEI-01-99-00050; Mark R. Chasin et al, “*The Urgent Need to Improve Health Care Quality: Institute of Medicine National Roundtable on Health Care Quality*,” *Journal of the American Medical Association* 280 (September 16, 1998) 11: 1000-1005.

41. Personal contact with Douglas Merrill, M.D. ASA Committee on Pain, Chair, 06/08/01.

42. We obtained this information from several sources, including:

- personal observations of this procedure,
- Accreditation Association for Ambulatory Health Care, Inc. Institute for Quality Improvement, 1999 Performance Measurement Study, *Cataract Extraction with Lens Insertion*,
- <http://www.adam.com/b2b/products/demos/ency/ENCY/ARTICLE/002957.htm>, accessed 06/12/01 and,
- [wysiwig://222/http://www.healthanswers.com/library/MedEnc/enc/832.asp](http://www.healthanswers.com/library/MedEnc/enc/832.asp), accessed 06/12/01

43. We obtained this information from several sources, including:

- Accreditation Association for Ambulatory Health Care, Inc. Institute for Quality Improvement, 1999 Performance Measurement Study, *Knee Arthroscopy with Meniscectomy*,
- S. Terry Canale, M.D., *Campbell’s Operative Orthopaedics: Ninth edition, Vol 2* (St. Louis: Mosby, 1998), 1470 - 1501.
- [http://www.webmd.lycos.com/content/asset/adam\\_surgery\\_synovectomy](http://www.webmd.lycos.com/content/asset/adam_surgery_synovectomy), accessed 07/11/01.

**APPENDIX C**