

**Department of Health and Human Services**

**OFFICE OF  
INSPECTOR GENERAL**

**Quality Oversight of  
Ambulatory Surgical Centers**

**Holding State Agencies and Accreditors Accountable**  
*Supplemental Report 2*



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# EXECUTIVE SUMMARY

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## PURPOSE

To assess how CMS holds State agencies and accreditors accountable for their performance overseeing 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 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, routine procedures can result in serious complications and death.

Quality oversight of ASCs revolves around Medicare's set of minimum health and safety requirements. CMS relies on States agencies (certification) and private accreditors (accreditation) to ensure that ASCs meet these requirements. CMS has approved three accreditors to oversee ASCs. The focus of both State agency certification and accreditation is on-site surveys of ASCs. CMS has not changed its approach to quality oversight since it began the ASC program in 1982.

This report is the second of two that supplement the main report of this inquiry, *A System in Neglect*. Our companion report, Supplemental Report 1: *The Role of Certification and Accreditation*, assesses how State agencies and accreditors oversee ASCs. Our inquiry relies on a variety of data including claims and survey data, observations of surveys, and reviews of literature, laws, and regulations.

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## FINDINGS

### **CMS does little to hold State agencies and accreditors accountable to the Medicare program**

**It does little to monitor their performance.** CMS does not use electronic data reporting to track basic metrics of performance. It rarely conducts Federal oversight surveys to monitor review done by State agency and accreditation surveyors. Its formal evaluations of State agencies and accreditors provide little insight on performance.

**It provides almost no feedback on their performance.** With little performance monitoring, CMS has little on which to base meaningful feedback to State agencies and accreditors. Routine, operational feedback to State agencies and accreditors is problematic, since policy emerges from one of several units within CMS.

## **CMS does little to hold State agencies and accreditors accountable to the public**

**Survey results are not readily accessible.** CMS does not publish the results of State agency surveys on the Medicare web site, the Medicare telephone hotline, or on-site at ASCs. Only one accreditor releases accreditation survey results to the public.

**State agency certification and accreditation provide few meaningful insights for comparing ASCs.** State agency survey reports lack comparative information on ASCs' performance relative to their past or their peers. Only one accreditor provides such information.

**Complaint processes have limited accessibility.** CMS does not provide prominent, clear instructions for complaining about poor care received in certified ASCs. Only one accreditor makes complaint instructions available on the web and over the telephone.

**CMS makes no information available on the performance of State agencies and accreditors.** CMS does not publish the results of its formal evaluations, summaries of complaint volumes against State agency certified/accredited ASCs, or other aggregate information that would allow comparison across State agencies and accreditation agencies.

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## **RECOMMENDATIONS**

### **CMS should hold State agencies and accreditors fully accountable to the Medicare program**

Increase performance monitoring and use it as the basis of feedback to State agencies and accreditors. Performance monitoring should include: 1) using electronic data reporting to track basic metrics of performance; 2) conducting periodic Federal oversight surveys to monitor the review done during State agency and accreditation surveys; 3) conducting formal, periodic evaluations of State agencies' and accreditors' performance.

### **CMS should do more to hold State agencies and accreditors accountable to the public**

Use the Medicare web site, the Medicare telephone hotline, and on-site postings to make performance information and complaint instructions for ASCs certified by State agencies more accessible to the public. Negotiate with the accreditors to increase accessibility of performance information and complaint instructions for accredited ASCs. Make performance reviews of State agencies and accreditors available to the public.

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# INTRODUCTION

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## PURPOSE

To assess how CMS holds State agencies and accreditors accountable for their performance overseeing 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.

### Growth of Ambulatory Surgical Centers

The number of ASCs in the Medicare program has grown more dramatically than other surgical settings, increasing at a rate of almost 200 facilities a year.<sup>3</sup> This growth is due to advances in medical technology, increased focus on patient convenience, and economic incentives created by changes in reimbursement systems. Furthermore, the growth of ASCs is projected to continue.<sup>4</sup> For further discussion of the growth of ASCs, see Supplemental Report 1: *The Role of Certification and Accreditation*.

While ambulatory surgery has been shown to have good outcomes, even routine procedures can result in serious complications and death.<sup>5</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 six blocks by wheelchair 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 importance of oversight of ASCs.<sup>6</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. 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 Medicare Conditions of Coverage. Facilities must be certified by State 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>7</sup> Some ASCs that are certified by State agencies are also accredited for reasons other than Medicare certification.

The focus 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>8</sup>

Medicare certification is carried out by State survey and certification agencies under agreement with CMS. CMS has given its approval to 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>9</sup>

## Holding State Agencies and Accreditors Accountable

CMS has three main mechanisms for monitoring the performance of State agencies and accreditors and holding them accountable to the Medicare program:

- **Electronic reporting of survey activity:** State agencies and accreditors electronically transmit the results of their surveys to CMS on an ongoing basis.<sup>10</sup> Such reporting identifies the provider, survey date, standards not met by the provider, follow-up activity, and other items for each State agency or accreditation survey. It is valuable because it offers a cost-effective way for CMS to monitor

State agencies' and accreditors' progress surveying facilities and allows it to detect emerging problems within their survey processes.

- **Federal oversight surveys:** Federal oversight surveys are a quality assurance mechanism whereby trained CMS staff either observe surveys unfold or validate recently surveyed facilities' compliance with the Conditions through resurvey. Federal oversight surveys can encompass State agency certified and accredited facilities. Observing surveys unfold is valuable because it allows CMS to gain insight about the nature and extent of on-site review conducted on Medicare's behalf by State agencies and accreditors. Validating recently surveyed facilities' compliance with the Conditions is CMS' traditional approach to Federal oversight surveys, but its value has been called into question by previous OIG work.<sup>11</sup>
- **Periodic, formal evaluations:** Periodic, formal evaluations are a mechanism whereby CMS verifies the State agencies' and accreditors' activities against established criteria and provides formal feedback on their performance. They also serve as the basis of CMS' decision whether or not to allow a State agency or accreditor to continue surveying facilities on behalf of Medicare.

As our health care system moves toward a consumer-oriented marketplace, public accountability takes on increasing importance. Public accountability leverages CMS' oversight by focusing the attention of the public, Medicare beneficiaries, and interest groups on the performance of ASCs and how well State agencies and accreditors ensure that ASCs provide quality care. Indeed, consumer orientation and its implications on CMS' programs comprise a major theme within CMS strategic plan.<sup>12</sup> Below are three main mechanisms for holding State agencies and accreditors accountable to the public:

- **Public release of information on the performance of ASCs:** Publishing information such as survey results, statistics on complaints against facilities, and outcomes data focuses public attention on how well State agencies and accreditors oversee ASCs. This information is also essential for Medicare consumers who wish to make informed decisions about where they receive their health care. While Medicare statute already dictates that the results of State agency surveys be available to the public, the CMS Administrator has recently reaffirmed CMS' commitment to enhancing the information available to the public on the Medicare program.<sup>13</sup>
- **Complaint processes:** Complaint processes provide Medicare consumers a forum to have their complaints about ASCs investigated by State agencies and accreditors. They can identify poor or even dangerous ASCs for intervention and follow-up. CMS' strategic plan highlights the importance of collecting and investigating complaints.<sup>14</sup>
- **Public release of information on the performance of State agencies and accreditors:** Through the release of the results of its periodic, formal evaluations of State agencies and accreditors, CMS can focus public attention on how well



they oversee ASCs. Public disclosure also helps Medicare beneficiaries and their families make informed decisions between using State agency certified or accredited ASCs.

## **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 second of two that supplement the main report of this inquiry, *A System in Neglect*, which also contains the full text of the comments we received on the draft reports. Supplemental Report 1: *The Role of Certification and Accreditation*, assesses how State agencies and accreditors oversee 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 the Accreditation of Health Care 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.

# FINDINGS

## **CMS does little to hold State agencies and accreditors accountable to the Medicare program**

### **It does little to monitor the performance of State agencies and accreditors**

**Electronic reporting of survey activity is underutilized.** Despite the efficiency of doing so, CMS makes minimal use of this reporting to monitor the performance of State agencies and accreditors. CMS central office staff responsible for the quality oversight system for ASCs reported to us that their monitoring is limited to reviewing quarterly summaries of the top deficiencies. While this may lend insight to what State agencies and accreditors are finding in the field, it does little toward monitoring their performance. For example, CMS staff do not use the data to monitor elapsed time between surveys, follow through on complaints and deficiencies, or other basic metrics of performance. In fact, CMS staff were surprised when we told them that during two State agency surveys we observed, surveyors did not place the ASCs on accelerated termination tracks, even though both failed to meet 9 of the 10 Conditions. Monitoring survey activity would have allowed CMS staff to detect this problem and intervene to correct it.

Yet, even if CMS wished to enhance its monitoring of survey activity, the survey data that State agencies and accreditors provide have limitations that hinder their usefulness. For example, CMS staff cannot get a unified picture of survey activity in the ASC program because State agency and accreditation data each contain different information and are stored in separate, incompatible systems. Thus, it is difficult for CMS and State agencies to accurately discern which ASCs are accredited. This situation risks accidentally surveying accredited facilities, which is a poor use of State agencies' resources and an added burden on accredited ASCs. Indeed, on one State agency survey we observed, CMS and State agency surveyors conducted a joint survey of an ASC only to learn at the end of the survey that it was accredited a year earlier. Meanwhile, at the time of the survey, 10 ASCs certified by State agencies in that State had not been surveyed in 10 years.

**Federal oversight surveys of ASCs are extremely rare.** Since 1995, CMS conducted just 15 Federal oversight surveys of Medicare ASCs—11 of which were in California. In this time, State agencies and accreditors completed over 3,400 surveys of ASCs. However, with so few Federal oversight surveys, CMS is unlikely to have a firm grasp on what State agencies and accreditors are doing in the field. For example, while observing State agency and accreditation surveys of ASCs, we witnessed questionable performance assessing compliance with the life safety code, privileging standards, and other requirements. Federal oversight surveys allow CMS to uncover problems such as these and address them immediately.

**Periodic, formal evaluations provide little information on performance.** While CMS' process for annual evaluation of State agencies has been evolving for several years, its current approach fails to provide information on how well they oversee ASCs. CMS' previous approach, the State Agency Quality Improvement Program, focused on the State agencies' overall performance completing tasks common to all types of providers, such as documenting deficiencies. However, this approach was criticized by OIG for providing a poor picture of performance and by GAO because it relied on unverified, self-reported data from State agencies.<sup>15,16</sup> CMS' newest approach sets national performance thresholds and uses more reliable data sources; however, right now it focuses only on nursing homes. CMS has yet to set forth criteria for evaluating State agencies' performance overseeing other types of providers.

Performance assessment plays a minor role in CMS' evaluation of accreditors as well. CMS has authority to evaluate the performance of accreditors through oversight surveys. It also has the authority to assess the accreditors' organizational capacity and operating policies, and that is where we found it to focus its reviews.<sup>17</sup> In fact, CMS' focus is so much on policy and paperwork that it is largely removed from accreditors' conduct of surveys. For example, during a recent evaluation of one accreditor, only a fraction of the 3-day agenda focused on evaluating how well the accreditor ensured compliance with the Conditions, made accreditation decisions, and investigated complaints. To assess these functions, CMS relied on reviews of files from 15 surveys as well as information from the accreditor's data system. The evaluation did not include reviews of files from any discretionary surveys, such as those for complaints or adverse events. Also, it did not bring to bear analysis of other data sources that could have lent insight to performance, such as the results of Federal oversight surveys and complaints that CMS received against accredited facilities.

### **It provides little feedback to State agencies and accreditors on their performance**

With little performance monitoring, CMS has little on which to base meaningful feedback to State agencies and accreditors. In fact, CMS provides virtually no feedback to State agencies on their performance. In the past, CMS has sent each accreditor a quarterly report that compares, relative to the Conditions, its top 10 deficiencies to State agencies' top 10 deficiencies.<sup>18</sup> But the report falls short of providing feedback on performance because it lacks commentary from CMS or other data that would shed light on the adequacy of performance, such as comparisons against performance goals or against accepted levels. In addition, CMS staff had proposed holding quarterly conference calls with the accreditors, but as of February 2001, CMS has only held two such calls in the past nine quarters.

Accreditors also receive letters after their formal evaluations that are supposed to provide feedback on their performance. However, we reviewed letters from the only two evaluations that CMS has done and found that both focused primarily on policies and procedures of the accreditors rather than performance. In fact, one provided consultation to the accreditor on how it should run itself, including advice about growing its non-Medicare business.<sup>19</sup>

CMS' routine, operational feedback to State agencies and accreditors is problematic, as well. Policy making for the ASC program is fragmented, emerging from one of several units within CMS with respect to ASCs, depending upon the subject matter at hand.<sup>20</sup> Clear, consistent feedback from CMS is essential if State agencies and accreditors are to properly ensure that ASCs meet Medicare's minimum standards. Yet, officials from State agencies and accreditors cited lingering confusion and inconsistency across surveyors over the permissibility of keeping Medicare patients for overnight stays, how often Life Safety Code surveys should be conducted, and which accreditors were approved to survey ASCs.

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## **CMS does little to hold State agencies and accreditors accountable to the public**

### **Survey results are not readily accessible**

CMS does little to publicize the availability of the results of State agency surveys or to make them accessible to Medicare consumers. CMS does not make survey results available on the Medicare web site, provide them over the Medicare telephone hotline, or require ASCs to post them for consumers to see. Instead, Medicare consumers must request them from a CMS regional office or a State agency, but the instructions for doing so are only available from the Medicare telephone hotline. The Medicare handbook, which CMS sends to all Medicare beneficiaries, makes no mention of the availability of survey results. Yet, CMS does more for other types of providers. For example, it provides nursing home surveys and comparative data on nursing homes on a special section of the Medicare web site called "Medicare Compare." Also, CMS requires nursing homes to post recent survey results and State agencies to maintain a hotline for beneficiaries to obtain the results of home health surveys.

Likewise, two of the three accreditors do little to make survey results readily accessible to the public. In fact, it is the policy of the Accreditation Association for Ambulatory Health Care and the American Association for Accreditation of Ambulatory Surgical Facilities not to release survey results to Medicare consumers. These organizations will only reveal whether an ASC is accredited, providing no indication of the relative quality of an ASC or areas of concern on prior surveys. By contrast, the Joint Commission makes its survey results available on its web page along with additional data for each ASC, including current accreditation status, accreditation and deficiency history, when it was last surveyed, as well as some comparisons to national data. In addition, Medicare consumers can also call the Joint Commission to request a copy of survey results free of charge.

### **State agency certification and accreditation provide few meaningful insights for comparing ASCs**

State agency certification results in either a certified or non-certified status. Yet, it does

not mean a facility is deficiency-free. For example, we observed 2 State agency surveys in which 9 out of 10 conditions were deficient, yet these ASCs remained certified. Surveyors can find ASCs deficient on any number of conditions or their related standards and can place ASCs on a 90- or 28-day termination track, during which the ASC completes a plan of correction. The public, however, remains unaware that an ASC was found deficient, required to submit a plan of correction, or placed on a termination track.

Each of the three accreditors rely on their own systems for determining the accreditation status of ASCs. The American Association for Accreditation of Ambulatory Surgical Facilities, like State agency certification, has just one level of accreditation: fully accredited. If even one of the hundreds of standards is unmet, an ASC cannot be accredited. The Accreditation Association for Ambulatory Health Care and the Joint Commission, however, rely on multiple levels of accreditation based on the extent and nature of concerns identified during the survey. For example, between 1998 and 2000, 30 percent of ASCs surveyed by the Accreditation Association for Ambulatory Health Care were accredited for less than the full 3-year cycle based on survey findings. This information, however, is not disclosed to members of the public when they inquire about the accreditation status of an ASC.

Historically, the Joint Commission has five levels of accreditation. In practice, however, 100 percent of all ASCs it accredited between 1998 and 2000 have fallen into two levels: Accreditation with Commendation and Accreditation with Type I Recommendations. As of January 2000, the Joint Commission no longer uses Accreditation with Commendation. Accreditation with Type I Recommendations is a broad category that encompasses ASCs with few or many recommendations. Thus, with most ASCs falling into this one remaining category, it is difficult for the public to distinguish among ASCs accredited by the Joint Commission. The Joint Commission does, however, make some comparative data, which helps with these distinctions, available through its performance reports.

### **Complaint mechanisms have limited accessibility**

Although CMS' strategic plan highlights the importance of collecting and investigating complaints, it does little to make State agencies' complaint process accessible to Medicare consumers.<sup>21</sup> For example, it does not provide prominent, clear instructions for lodging complaints on the Medicare web site or over the Medicare telephone hotline, nor does it require ASCs to post complaint instructions.<sup>22, 23</sup> While it does instruct beneficiaries to contact their local peer review organization within the Medicare handbook, recent OIG inquiries have found that peer review organizations have flawed complaint processes.<sup>24</sup> CMS goes further to make complaint processes accessible for other provider types. For example, on the Medicare web site, CMS provides dedicated points of contact for complaints about dialysis facilities and nursing homes. Also, CMS requires States to maintain a toll-free hotline to handle complaints about home health agencies.<sup>25</sup>

Each of the three accreditors include a telephone number on their certificates of

accreditation, which ASCs generally post in a place visible to patients, although they are not required to by CMS. The Accreditation Association for Ambulatory Health Care and the Joint Commission solicit complaints and feedback from their web sites. The Joint Commission's web site also provides instructions for submitting complaints by mail, email, and fax. It contains information on the complaint process and instructions for obtaining complaint-related information about accredited facilities. In addition, the Joint Commission also maintains a telephone hotline to answer questions about how to file complaints.

### **CMS makes no information available on the performance of State agencies and accreditors**

CMS makes no information available to the public on how well State agencies and accreditors carry out their charge to the Medicare program. CMS does not publish the results of its formal evaluations, summaries of complaint volumes against State agency certified or accredited ASCs, or other aggregate information that would allow comparison across State agencies and accreditors.

# RECOMMENDATIONS

CMS relies on State agencies and accreditors to ensure that ASCs provide safe care to Medicare beneficiaries. Yet, despite being entrusted with such an important role, State agencies and accreditors operate with virtually no accountability to the Medicare program. In fact, CMS does so little to oversee State agencies and accreditors that the quality oversight system essentially runs itself. However, in our companion report, Supplemental Report 1: *The Role of Certification and Accreditation*, we found serious problems with the quality oversight system for ASCs that warrant expeditious and definitive action from CMS.

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## **CMS should hold State agencies and accreditors fully accountable to the Medicare program**

### **Use electronic data reporting to track basic metrics of performance**

Electronic reporting of survey data offers an efficient and cost-effective way to monitor State agencies' and accreditors' oversight activity. Metrics such as elapsed time between surveys, follow-through with deficiencies and complaints, and trends in deficiency citations would allow CMS to detect problems within State agency certification and accreditation and take actions to correct them. Most notably, they would enable CMS and State agencies to better manage survey resources, thus avoiding problems we found such as unresolved complaints and letting ASCs go 10 or more years without a survey.

Yet, to make better use of survey data, CMS must address limitations in their structure. We note that CMS is in the process of designing a new system for survey data and, in fact, is already using it for nursing homes and home health agencies. Thus, as CMS plans to move ASCs onto its new system, we offer three recommendations. First, CMS should ensure that its approach captures both State agency and accreditation data within a common system and within a common format. This would enable State agencies to identify and avoid surveying accredited ASCs and allow CMS to get a global picture of performance across State agencies and accreditors. Second, CMS should ensure that its system captures data on termination tracks, plans of correction, and reduced accreditation periods. These data are essential to monitoring and managing remedial actions taken by Medicare's system of quality oversight for ASCs. Third, if CMS implements standardized performance indicators for ASCs, its system should house such data and support their use for adjusting the frequency and focus of surveys — as its new system does now for nursing homes and home health agencies.<sup>26</sup>

### **Conduct and use periodic Federal oversight surveys to monitor the nature and extent of review done during State agency and accreditation surveys**

Surveys are the centerpiece of the State agency certification and accreditation processes.

They form the primary interaction between State agencies and accreditors and the facilities they oversee. Observing these surveys can offer valuable insight about the nature and extent of review conducted by State agencies and accreditors. However, in Supplemental Report 1: *The Role of Certification and Accreditation*, we find problems with how State agencies and accreditors survey ASCs. Chiefly, we find that surveys were imbalanced because State agencies focus entirely on ensuring compliance with minimum standards while accreditors instead focus primarily on continuous quality improvement. In that report, we recommend that CMS ensure that oversight of ASCs is appropriately balanced between compliance and continuous quality improvement. Federal oversight surveys would be an important component in an effort to this end because it would help CMS gain insights to that balance. Without such surveys, it is nearly impossible for CMS to judge the adequacy of review conducted by State agencies and accreditors on Medicare's behalf. In conducting these surveys, CMS should use an approach that allows for consistency among reviewers and they contribute toward formal feedback to State agencies and accreditors.

### **Conduct formal, periodic evaluations of State agencies' and accreditors' performance overseeing ASCs**

Formal, periodic evaluations of State agencies and accreditors are an important opportunity for CMS to collect and review performance data on a macro level. CMS' newest approach to evaluation of State agencies uses national thresholds which are based on measurable indicators of performance—but thus far it focuses only on nursing homes. We urge CMS to broaden the scope of its evaluations of State agencies to incorporate other types of providers, including ASCs, and to use them to examine performance specific to each type of provider they survey. In addition, CMS should focus its evaluations of accreditors toward assessing their performance overseeing ASCs, rather than assessing their organizational capacity and operating policies.

### **Provide feedback to State agencies and accreditors on their performance**

Ongoing and periodic feedback are essential to ensuring that State agencies and accreditors are meeting CMS' expectations. Yet, providing feedback requires a meaningful set of performance expectations and mechanisms that collect data on performance. In parallel with its effort to improve its performance monitoring, CMS should work with State agencies and accreditors to establish a common set of performance expectations for the oversight of ASCs. CMS should also pay particular attention to consistency across surveyors. Once this is done, CMS should use electronic survey data, federal oversight surveys, and formal evaluations to inform ongoing and periodic feedback to State agencies and accreditors.

In addition, CMS should consider establishing a policy clearinghouse as a way of disseminating policy to State agencies and accreditors in a simultaneous and consistent manner. Information within the clearinghouse might range from coverage policy that affects quality oversight, such as the permissibility of overnight stays, to performance expectations and guidelines for reporting electronic survey data. Such a clearinghouse



would promote more consistent interpretations and eliminate the confusion around CMS policy that we observed during our review. We note that CMS has already established a similar clearinghouse for nursing homes.

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## **CMS should do more to hold State agencies and accreditors accountable to the public**

As our health care system moves toward increasing public accountability, information about the performance of ASCs, how to complain about poor quality of care, and the performance of the quality oversight system itself remains woefully inadequate.

### **Take steps to increase availability of performance information about ASCs certified by State agencies, including publishing it on the Medicare web site**

Performance information is essential for Medicare beneficiaries who wish to make informed decisions about where they receive their health care. Accordingly, CMS should make full use of mechanisms it has available to disseminate performance information about ASCs. For example, with little effort, CMS could immediately place the results of State agency surveys on the Medicare web site, as it has done for nursing homes and dialysis facilities. In addition, CMS should make them available by request over the Medicare telephone hotline and provide instructions for obtaining them within the Medicare Handbook. Finally, CMS should require ASCs to post survey results on-site for patients to see—as it now does with nursing homes.

However, survey reports alone are limited in that they reveal little beyond the results of a single survey of a single ASC. Thus, CMS should explore ways to improve their usefulness to Medicare consumers by adding comparative information such as the average number and types of deficiencies outstanding at all ASCs. In addition, CMS should seek to supplement them with other data that it already has available, such as the facility's survey and complaint history. Finally, if CMS were to implement performance indicators for ASCs, summaries and comparisons of these data should be made available to consumers as well.

### **Increase the accessibility of State agencies' certification complaint mechanism**

Complaints serve as an important tool for beneficiary protection and as a valuable source of information on potentially poor providers. As part of its commitment to collecting and investigating complaints, CMS should make full use of tools it has available to solicit them. Specifically, CMS should make clear, easy-to-find instructions for how to complain about ASCs available on the Medicare web site and over the Medicare telephone hotline. CMS should also require ASCs to post complaint instructions on-site for patients to see.

## **Negotiate with the accreditors to increase information available to Medicare consumers and to increase the accessibility of their complaint mechanisms**

As the number of Medicare ASCs overseen by the three accreditors continues to grow, it is important that CMS ensures that each is responsive to Medicare consumers. Accordingly, we recommend that CMS work with them to define a minimum amount of information that they will make available about each Medicare ASC they accredit. Similarly, CMS should work with the accreditors to ensure that their complaint mechanisms are accessible to Medicare consumers. In both cases, each of the accreditors already has in place a web site and telephone number where they could make information available. Finally, should CMS require ASCs certified by State agencies to post performance results and complaint instructions, it should extend this requirement to accredited ASCs as well.

## **Publish performance reviews of State agencies and accreditors**

Public disclosure of performance information holds State agencies and accreditors accountable for how well they ensure that ASCs meet Medicare's minimum safety requirements. Such information can also be useful for Medicare beneficiaries who have a choice between State agency certified and accredited facilities. Thus, CMS should use the Medicare web site, the Medicare telephone hotline, and other resources to disclose performance reviews of State agencies and accreditors. Information it discloses could include comparative summaries of survey data reporting, results of Federal oversight surveys, and formal evaluations. Should CMS implement performance indicators for ASCs, information could also include comparative summaries of the performance of State agency certified and accredited ASCs.

## 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
- CMS data compendium from 1995 to 1999
- Internal policy memos from the central and regional offices
- Documentation of CMS evaluation of the accreditors
- 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 State agency certification of ASCs. We obtained a variety of documents from State agency 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.

## 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. Only comprehensive rehabilitation facilities and rural health clinics have experienced a higher rate of growth. OEI analysis of Part B Medicare data. See *Supplemental Report 1: The Role of Certification and Accreditation* for further details.
4. SMG Solutions, 2000 *Report & Directory Freestanding Outpatient Surgery Centers (FOSCs): Industry Characteristics, Trends, Market projections, and Comparative Analysis*, 2000, 24.
5. 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.
6. 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.
7. Based on data provided to OIG by the three accreditors.
8. Social Security Act, sec. 1865, 42 U.S.C. 1395bb.
9. 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).

10. State agencies send survey data to CMS' Online Survey and Certification and Reporting System (OSCAR) as they complete surveys. The system has a number of preprogrammed reports and is accessible to all CMS staff and State agencies. Accreditors began reporting survey data on a quarterly basis in 2000.
11. Department of Health and Human Services, Office of Inspector General, *The External Review of Hospital Quality: Holding the Reviewers Accountable*, OEI-01-97-00053, July 1999.
12. CMS Strategic Plan, Publication HCFA-02135, September, 1998.
13. *Using Technology to Improve Medicare* Before the Subcomm. on Science, Technology, and Space of the Senate Comm. on Commerce, Science, and Transportation, 107<sup>th</sup> Cong., 1<sup>st</sup> Sess. 78 (2001).
14. CMS Strategic Plan, Publication HCFA-02135, September, 1998, p. 29.
15. Department of Health and Human Services, Office of Inspector General, *The External Review of Hospital Quality: Holding the Reviewers Accountable*, OEI-01-97-00053, July 1999.
16. U.S. General Accounting Office, *Nursing Home Care: Enhanced CMS Oversight of State Programs Would Better Ensure Quality*, GAO/HEHS-00-06, November 1999.
17. In 42 CFR part 488, CMS lays out its authority for Federal review of accreditation organizations. According to this regulation, continuing Federal oversight of accreditation organizations will consist of comparability reviews, which ensure that the accreditor's and CMS' requirements are equivalent, and validation reviews, which summarize the results of validation surveys of accredited facilities. If validation surveys generate a 20 percent disparity rate or a widespread problem with the accreditor's process, CMS may take corrective action steps against the accreditor. One step it can take is a deeming authority review, a basic review in which CMS reviews the accreditor's policies and capacities as if it were a new accreditor applying for deemed status. It is this review that CMS conducts of accreditors, even though it has no performance-based information from validation surveys as a reason for doing so.
18. For this report, CMS staff use a crosswalk to convert each accreditor's deficiencies to the comparable Medicare Condition(s) so that the accreditor's deficiencies can be roughly compared to those of State agencies.
19. In correspondence to an accreditor, CMS made recommendations related to corporate ventures unrelated to the Medicare program.
20. Groups from within three units of CMS issue policy regarding ASCs: the Office of Clinical Standards and Quality (OCSQ), the Center for Medicaid and State Operations (CMSO), and the Center for Medicare Management (CMM). OCSQ writes the Conditions of Coverage for ASCs and does clinical evaluation of perspective ASC procedures. One group within CMSO writes the interpretive guidelines for carrying out the Conditions in the field and monitors their implementation

within surveys. Three other groups in CMSO have responsibility for one or more of the following: overseeing accreditation organizations, formulating the annual budget for certification surveys, and evaluation of State agencies. CMM writes the insurance coverage for procedures that have been approved for ASCs.

21. CMS Strategic Plan, Publication HCFA-02135, September, 1998.

22. As of July, 2001, the Medicare website ([www.medicare.gov](http://www.medicare.gov)) listed points of contact for quality of care and complaints together in a section called 'Helpful Contacts', placed two levels beneath the front (home) page. The list contained points of contact for dozen entities including those for complaints about nursing homes and end stage renal disease dialysis facilities. Peer Review Organizations appeared at the end of the list as a point of contact for complaints about quality of care. There were no instructions about how the complaint process works, its time lines, or beneficiaries' rights within the complaint process.

23. We called the Medicare telephone hotline (1-800-MEDICARE) twice in February, 2001 to find instructions for complaining about poor care. One time the operator referred us to the Peer Review Organization and the other to the State agency.

24. See Office of Inspector General, *The Beneficiary Complaint Process of the Medicare Peer Review Organization*, OEI-01-93-00250, November 1995 and *The Medicare Beneficiary Complaint Process: A Rusty Safety Valve*, OEI-01-00-00060, August 2001.

25. Social Security Act, sec. 1864 (42 U.S.C. 1395aa).

26. CMS' new system, called the Quality Improvement and Evaluation System (QIES), uses the Minimum Data Set merged with OSCAR data to allow State agencies to monitor the performance of nursing homes. CMS also uses these data to monitor the performance of State agencies. CMS is now integrating the Home Health Care Outcome and Assessment Information Set into QIES to allow for similar capability for overseeing home health agencies.