

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**Quality Oversight of
Ambulatory Surgical Centers**

A System in Neglect



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Inspector General**

**FEBRUARY 2002
OEI-01-00-00450**

OFFICE OF INSPECTOR GENERAL

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EXECUTIVE SUMMARY

Purpose and Background

This inquiry assesses how State agencies and accreditors oversee ambulatory surgical centers (ASCs) and how the Centers for Medicare & Medicaid Services (CMS) holds them accountable. In addition to this report, this inquiry includes two supplemental reports: Supplemental Report 1: *The Role of Certification and Accreditation* and Supplemental Report 2: *Holding the State Agencies and Accreditors Accountable*.

Medicare annually pays over \$1.6 billion for procedures performed by over 3,000 ASCs. Quality oversight of ASCs revolves around the Conditions of Coverage, Medicare's set of minimum health and safety requirements. ASCs must become Medicare certified by a State survey and certification agency or privately accredited to show that they meet the Conditions. The overwhelming majority of ASCs choose to become certified by State agencies.

While ambulatory surgery has been shown to have good outcomes, routine procedures can result in serious complications and death. For example, a patient undergoing a routine Medicare-covered gynecologic procedure died in an ASC from complications; 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.

Findings

Oversight of ASCs is more important than ever

Medicare ASCs are experiencing explosive growth—more than doubling in number from 1990 to 2000. Over the same period, the annual volume of major procedures they performed increased by 730 percent, from 12,000 to over 101,000 procedures.

But Medicare's system of quality oversight is not up to the task

Nearly a third of ASCs certified by State agencies have not been recertified in 5 or more years. Accredited ASCs are surveyed at least every 3 years, but the survey process devotes less attention to verifying compliance.

And it lacks accountability

CMS does little to hold State certification agencies and accreditors accountable to the Medicare program and the public.

Recommendations

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

CMS should update the Medicare Conditions of Coverage for ASCs

Add sections to address 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.

CMS should hold State agencies and accreditors fully accountable to the Medicare program for their performance overseeing ASCs

Use electronic data reporting, Federal oversight surveys, and formal, periodic evaluations to monitor and provide feedback to State agencies and accreditors.

CMS should do more to hold State agencies and accreditors accountable to the public for their performance overseeing ASCs

Take steps to increase public information about State agency certified and accredited ASCs and the accessibility of State agencies' and accreditors' complaint processes. Publish performance information about State agencies and the accreditors.

Comments on the Draft Reports

Within the Department, we received comments from CMS. We also solicited and received comments from the Accreditation Association for Ambulatory Health Care, the Joint Commission on Accreditation of Healthcare Organizations, and the American Association for Accreditation of Ambulatory Surgical Facilities. The full text is included in appendix A. In response, we made several clarifying and technical changes.

The commenters expressed much general support for our recommendations. CMS elaborated on options it is considering that are in accord with many of our recommendations. However, citing resource constraints and other concerns, it did not fully commit itself to a number of our recommendations, particularly those calling for a minimum survey cycle and a more accessible complaint process. We urge CMS to devote a sense of urgency to the early warning signal we provide and to develop an action plan detailing the specific actions it will take to improve ASC oversight.

Some commenters took issue with our concerns about the depth of accreditation surveys. We still conclude that accreditation surveys tend to pay more attention to education and improvement than to verifying compliance, but in the final reports did give more prominence to the need for balance between compliance and improvement.

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INTRODUCTION

Purpose

To assess how State agencies and accreditors oversee ambulatory surgical centers (ASCs) and how the Centers for Medicare & Medicaid Services (CMS) holds them accountable.

Background

ASCs in the Medicare Program

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.¹ Currently, over 3,000 ASCs participate in Medicare.

While ambulatory surgery has been shown to have good surgical outcomes, even routine procedures can result in serious complications and death.² 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.³

Quality Oversight of ASCs

Quality oversight of ASCs revolves around the Conditions of Coverage, Medicare's set of minimum health and safety requirements. CMS requires that ASCs become Medicare-certified by a State survey and certification agency or privately accredited to show that they meet the Conditions. While ASCs are free to choose which route they take, over 90 percent elect to become certified by State agencies rather than through accreditation. Some ASCs that are certified by State agencies, however, are also accredited for reasons other than Medicare certification.

The focus of certification by State agencies and accreditation is routine inspections of ASCs, called surveys. Generally, surveys are conducted to add new ASCs to Medicare, 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, are based on accreditors' own standards. Thus, only accreditors whose standards meet or exceed the Conditions may survey ASCs for Medicare.⁴ CMS has approved three accreditors: 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.⁵

Holding State Agencies and Accreditors Accountable

CMS' tools for monitoring and holding State agencies and accreditors accountable to Medicare include: 1) electronic data reporting that, for each survey, identifies the provider, survey date, standards not met by the provider, and follow-up activity; 2) Federal oversight surveys during which CMS staff observe surveys unfold or evaluate recently surveyed facilities; and, 3) periodic evaluations whereby CMS conducts formal reviews of State agencies' and accreditors' performance.

Tools for holding State agencies and accreditors accountable to the public include:

1) public release of data on the performance of ASCs; 2) complaint processes that investigate complaints about poor care received in ASCs; and 3) public release of data on the performance of State agencies and 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. In addition to this report, this inquiry includes two supplemental reports: Supplemental Report 1: *The Role of Certification and Accreditation* and Supplemental Report 2: *Holding the State Agencies and Accreditors Accountable*.

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

FINDINGS

Oversight of ASCs is more important than ever

Medicare ASCs are experiencing explosive growth

From 1990 to 2000, the number of ASCs has increased by close to 200 facilities a year while during the same period the number of hospitals decreased slightly. In fact, over the past 5 years, the growth rate of ASCs 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. From 1990 to 2000, the annual volume of procedures performed by ASCs grew by over 220 percent, from 1.3 to 4.3 million procedures. This growth outpaces that of Medicare's two other main surgical settings, hospital outpatient departments and inpatient hospitals, which grew by 78 percent and 38 percent respectively.

Scope and complexity of procedures are on the rise

From 1990 to 2000, CMS approved over 800 new procedures for ASCs—bringing the total number of approved procedures to nearly 2,300.⁶ Many of these new procedures are major procedures that involve high levels of anesthesia and invasiveness. In fact, CMS now allows ASCs to conduct over 600 major procedures that together represent over a quarter of all approved procedures. Recently CMS proposed expanding its list of approved procedures to over 2,500 procedures, 743 of which are major procedures.⁷

These changes in the list of approved procedures have resulted in a dramatic increase in the volume of major procedures performed in ASCs. Between 1990 and 2000, the annual volume of major procedures taking place in ASCs increased by 730 percent, from 12,000 to over 101,000 procedures, while those in outpatient departments and hospitals grew by 392 percent and 57 percent respectively.

But Medicare's system of quality oversight is not up to the task

State agencies' ability to adequately oversee ASCs is crumbling

Nearly a third of ASCs certified by State agencies (872) have gone 5 or more years and 136 facilities have gone 10 or more years without a recertification survey.⁸ 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. Elapsed time between surveys grew so dramatically during this period because the level of State agency surveys changed little while the number of ASCs certified by State agencies more than doubled.⁹ These numbers are significant because the overwhelming majority of ASCs—over 90 percent—are certified by State agencies.

State agencies' oversight of ASCs is also weak in following through with complaints. In the past 5 years, State agencies responded to 141 complaints with a complaint survey.

Yet, as of 2001, 47 percent of these complaints remain unresolved—in some cases for as many as 5 years. In fact, nearly a fifth of these complaints are against facilities that have deficiencies serious enough to warrant termination from Medicare.¹⁰

In addition, the standards that drive State agency surveys, the Medicare Conditions of Coverage, have not been updated since the inception of the ASC program in 1982. Thus, State agency certification has failed to keep pace with important advances in quality oversight. For example, the Conditions do not address patient rights, such as handling patient complaints and safeguarding patient privacy. They also fail to address continuous quality improvement.¹¹ CMS has begun to address these issues in the Conditions for other provider types including nursing homes, home health agencies, and hospitals.¹² We note that CMS attempted to update the Conditions in 1996, but its effort never reached conclusion.

Finally, State agency surveys perform a focused review around the Conditions, but fail to encompass quality improvement. These surveys are characterized by a challenging, direct approach in which surveyors aim to enforce minimums, rather than educate toward quality improvement. This approach is reinforced by CMS' survey policy, which states that surveyors are not to educate, advise, or consult with the facility on ways to improve its quality of care.

Accreditors offer routine surveys based on up-to-date standards, but pay less attention to verifying compliance

Unlike State agencies, accreditors survey ASCs every 3 years. This gives them and their standards high visibility and allows them to keep abreast of changes in facilities. In addition, the accreditors update their standards far more often than CMS, in some cases annually. This allows them to keep pace with advances in technology and changes in the ASC industry. For example, each has developed standards concerning malignant hyperthermia, a recently recognized complication triggered by common general anesthetics. Finally, accreditors tailor their standards to reflect the varying risk and complexity of services offered by different ASCs.

By their nature, accreditors focus on continuous quality improvement through peer-to-peer interaction during surveys.¹³ Yet, while on-site, accreditation surveyors must assess compliance with hundreds of standards, usually within surveys that last less than 2 days. This packed agenda and the accreditor's instructive approach result in less attention to verifying compliance with their standards. For example, we observed surveyors asking a series of questions about key standards, but not verifying the existence of supporting evidence. At times this approach can result in superficial review.

Medicare's system of quality oversight lacks accountability

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

CMS does little to monitor the performance of State agencies and accreditors. It limits its use of electronic survey data to reviewing quarterly summaries of deficiencies, and does

not use it to monitor elapsed times between surveys, disciplinary actions, or other metrics of performance. It cannot obtain 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.¹⁴ It rarely performs Federal oversight surveys to monitor State agencies' and accreditors' performance surveying ASCs. While State agencies and accreditors conducted over 3,400 surveys of ASCs from 1995 to 2001, CMS conducted just 15 Federal oversight surveys—11 of which were in California. Finally, CMS' periodic, formal evaluations shed little light on performance. Evaluations of State agencies only address their performance surveying nursing homes and those for accreditors are largely removed from their performance surveying ASCs.

With so little monitoring of their performance, CMS is hard-pressed to provide meaningful feedback to State agencies and accreditors. It provides virtually no feedback to the State agencies on their performance overseeing ASCs. Its feedback to the accreditors, which is comprised of a letter following formal evaluation, is limited since it focuses on their policies and procedures rather than the quality of surveys they conduct.

Finally, CMS' routine, operational feedback to State agencies and accreditors is problematic. Officials from State agencies and accreditors cited lingering confusion over the permissibility of keeping Medicare patients for overnight stays, the required frequency of Life Safety Code surveys, and which accreditors were approved to survey ASCs.

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

State agency certification provides little public information on the performance of ASCs; accreditation provides slightly more. While CMS uses the Medicare web site, a telephone hotline, and postings within facilities to disseminate State agency survey reports for other provider types, it does not do so for ASCs.¹⁵ The Medicare handbook, which it sends to all Medicare beneficiaries, makes no mention of survey reports. Such reports are available through CMS offices or State agencies. However, these reports lack comparative information, leaving the public with no information on an ASC's performance relative to its past or its peers.

The availability of accreditation survey reports is also limited; only the Joint Commission makes them available to the public. The Joint Commission makes survey results, called performance reports, available over the phone and on-line. These reports include accreditation decisions, dates of surveys, and comparative information to other ASCs. They also identify those areas requiring improvement and whether they were resolved.

CMS does little to make State agencies' complaint process accessible to Medicare consumers. 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.^{16, 17} In the Medicare handbook it instructs beneficiaries to bring complaints to peer review organizations, but recent OIG inquiries have found that they have flawed complaint processes.¹⁸ The complaint processes of the accreditors are slightly more accessible. Though not required by CMS, they include toll-

free numbers on certificates of accreditation, which ASCs generally post in their lobbies, and/or solicit complaints or feedback through their web sites.

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

RECOMMENDATIONS

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

In determining a minimum survey cycle for ASCs, CMS should consider the nature and risks of care ASCs deliver.¹⁹ CMS should also 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 a legislative change. Such steps might enable CMS to better manage and plan for growth in the number of certification surveys required to adequately oversee certified providers.

CMS should update the Medicare Conditions of Coverage for ASCs

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

CMS should add a section to the Conditions that addresses issues such as how ASCs will respect patients' dignity and resolve patient complaints. Such a step would reflect CMS' renewed focus on beneficiaries within its strategic plan and goals aimed at strengthening beneficiary satisfaction and protections.

CMS should ensure that the Conditions require ASCs to conduct continuous quality improvement efforts. Over the longer term, we urge CMS to explore developing a set of standardized performance measures for ASCs. CMS could also use such measures to monitor ASCs' performance and adjust the frequency and focus of surveys. CMS already has a similar initiative underway for 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.²⁰

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 surveyors to tailor them to individual ASCs.²¹ Such an approach might take into account anesthesia, invasiveness, and other factors that drive the risk and complexity 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 around the level of services offered by each ASC.

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 both approaches have value, but not so much that one should dominate at the expense of the other.²² 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.

CMS should hold State agencies and accreditors fully accountable to the Medicare program for their performance overseeing ASCs

Use electronic data reporting to monitor basic metrics of performance

CMS should use metrics such as elapsed time between surveys, follow-through with deficiencies and complaints, and trends in deficiency citations to continuously monitor State agencies' and accreditors' progress overseeing ASCs. This type of monitoring would allow CMS to detect problems within State agency certification and accreditation and take actions to correct them. In addition, it 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 some specifics for it to consider. First, CMS should ensure that its approach captures both State agency and accreditation data and allows them to be aggregated. The data should support monitoring the performance of accreditors and State agencies. Second, CMS should ensure that its system captures data on termination tracks, plans of correction, and reduced accreditation periods. 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.²³

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

In conducting these surveys, CMS should use an approach that allows for consistency among Federal reviewers. CMS should also ensure that oversight surveys result in both routine and formal feedback to State agencies and accreditors. Without the benefit of Federal oversight surveys, it is nearly impossible for CMS to judge the quality of review conducted by State agencies and accreditors on Medicare's behalf.

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

CMS' newest approach to evaluation of State agencies uses national thresholds that 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, in addition to assessing their organizational capacity and operating policies.

Provide feedback to State agencies and accreditors on their performance

CMS should use electronic survey data, Federal oversight surveys, and formal evaluations to inform routine and formal feedback to State agencies and accreditors. However, we note that for CMS to effectively monitor and provide feedback to State agencies and accreditors, it should first work with them to establish a common set of performance expectations for the oversight of ASCs.

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. Such a clearinghouse would 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.

CMS should hold State agencies and accreditors accountable to the public for their performance overseeing ASCs

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.²⁴ The CMS Administrator has recently reaffirmed CMS' commitment to enhancing the information available to the public on the Medicare program.²⁵ However, at this time, the information available to Medicare beneficiaries about the performance of ASCs, their ability to complain about poor quality of care, and the performance of the quality oversight system itself is woefully inadequate.

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

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.

CMS should improve the usefulness of survey results 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’ complaint process

CMS should make full use of tools it has available to solicit complaints from Medicare consumers. 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. These steps are in line with CMS’ commitment to collecting and investigating complaints that it outlines in its strategic plan.

Negotiate with the accreditors to increase public information about accredited ASCs and the accessibility of their complaint processes

CMS should work with the accreditors to define a minimum amount of information that they will make available about the Medicare ASCs 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, CMS should require accredited ASCs to post survey results and complaint instructions.

Publish information on the performance of State agencies and accreditors

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. Such disclosure holds State agencies and accreditors accountable for how well they oversee ASCs and can be useful for Medicare beneficiaries who have a choice between State agency certified and accredited facilities.

COMMENTS ON THE DRAFT REPORT

We received comments from CMS, the Accreditation Association for Ambulatory Health Care, the Joint Commission on Accreditation of Healthcare Organizations, and the American Association for Accreditation of Ambulatory Surgical Facilities. Below, we summarize their comments and offer our response to them in italics. Appendix A contains the full text of all the comments.

CMS

CMS expressed general concurrence with many of our recommendations and cited many options it is considering that are in accord with them. However, noting resource constraints and other concerns, it did not fully commit itself to our key recommendations calling for a minimum survey cycle, a more accessible complaint process, and the publication of survey results.

We understand the constraints CMS faces and the complexity of the issues associated with ASC oversight. Yet, we urge CMS to view our report as an early warning signal and to devote a sense of urgency to our recommendations. As we note in the report, Medicare ASCs are experiencing explosive growth and increasingly are performing major procedures that involve high levels of anesthesia and invasiveness. We urge CMS to develop an action plan and timetable that set forth specific actions it will take to improve its oversight of ASCs.

Accreditation Association for Ambulatory Health Care

The Accreditation Association for Ambulatory Health Care generally agreed with our findings and recommendations. It asked that our reports include comparative data on safety across surgical settings and took issue with our concern about the depth of accreditation surveys. It noted that it has added a form to its website to solicit feedback, such as complaints, about its accredited centers. It also supported our call for a balance between compliance and continuous quality improvement efforts and noted its new policy for random, unannounced surveys, which will be effective in 2002.

While our reports do reference literature on the safety of ambulatory surgery, presenting comparative data on safety across all settings was outside the scope of our inquiry, which focused on the oversight of ambulatory surgery centers. Future inquiries are planned that will examine the oversight of ambulatory surgery performed in hospital outpatient departments and physician offices. We still conclude that accreditation surveys pay more attention to education and improvement than to verifying compliance, and spell out the details for that conclusion in the supplemental report, “The Role of Certification and Accreditation.” Furthermore, we give more prominence to the importance of balance

between compliance and improvement in the final reports. Finally, we made changes to the reports to clarify certain points and acknowledge the Association's feedback mechanism on its web site.

Joint Commission on Accreditation of Healthcare Organizations

The Joint Commission generally agreed with the findings in our reports. It pointed out that many accredited ASCs have not elected to use their accreditation for deemed status. The Joint Commission took issue with our concern about the depth of accreditation reviews and the helpfulness of the survey information it discloses.

In the final reports, we clarified that some ASCs surveyed by State agencies for Medicare certification may also, in fact, be accredited without electing to use their accreditation for deemed status. We urge CMS to consider this information, along with volume of Medicare claims and complaints, in determining how to best use its limited resources and prioritize ASCs for State agency surveys. We still conclude that accreditation surveys pay more attention to education and improvement than to verifying compliance. We give more prominence to the importance of balance between compliance and improvement in the final reports. Finally, although we still contend that a scoring system that results in the great majority of ASCs falling into one broad category of accreditation (Accreditation with Type I Recommendations) does little to help consumers differentiate between an ASC with few or many recommendations for improvement, we did clarify the performance information available from the Joint Commission.

American Association for Accreditation of Ambulatory Surgery Facilities

The American Association generally agreed with our conclusions. It noted that its certificates of accreditation include a toll-free number for complaints and that these certificates are generally displayed prominently by its accredited ASCs.

In the final reports, we clarified that the certificates of accreditation include a toll-free number and address for filing complaints.

Full Text of Comments on the Draft Report

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Administrator
Washington, DC 20201

DATE: DEC 17 2001

TO: Janet Rehnquist
Inspector General
Office of Inspector General

FROM: Thomas A. Scully *Tom Scully*
Administrator
Centers for Medicare & Medicaid Services

SUBJECT: Office of Inspector General (OIG) Draft Reports: *Quality Oversight of Ambulatory Surgical Centers, A System in Neglect* (OEI-01-00-00450); *The Role of Certification and Accreditation, Supplemental Report 1* (OEI-01-00-00451); and *Holding State Agencies and Accreditors Accountable, Supplemental Report 2* (OEI-01-00-00452)

Thank you for the opportunity to review and comment on the above-referenced draft reports. Overall, we generally concur with the findings and many of the recommendations detailed in the reports. We share your concerns that data on quality issues in ambulatory surgical centers (ASCs) are limited and that analysis of these issues is largely based on anecdotal information. Through our own analysis of survey and certification issues with regard to ASCs, we have recognized many of the same concerns identified in your reports. We have, in fact, already begun implementing many of the proposals included in the recommendations. Our detailed comments to the specific recommendations are outlined below.

OIG Recommendation

The Centers for Medicare and Medicaid Services (CMS) should determine an appropriate minimum cycle for surveying certified ASCs.

CMS Response

The CMS generally agrees that given the nature of surgical procedures being performed in ASCs, there are inherent risks involved. However, there are risks involved in receiving any type of health care in any setting. Absent any verifiable data to support such a risk analysis, we do not believe it is possible at this time to move to a process in which facilities are prioritized for surveys based primarily on the risks inherent to the types of procedures performed.

The CMS does take a strategic approach to performing surveys of health care facilities in which we attempt to balance current legislative and budgetary priorities with available

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resources, and we will continue to do so. The overarching goal in this approach is the protection of the Medicare beneficiaries. Additionally, we will explore the use of a basic analysis of claims data for ASCs in order to manage survey resources within our minimum cycle to survey high-volume facilities and those with aberrant billing patterns first. One particular strategy that we are exploring is to review claims data to identify certified facilities that never or seldom bill for Medicare services, and use this information in managing survey workload priorities.

Within this recommendation, it is suggested that CMS may wish to consider whether the financial demands presented by the rising number of Medicare-certified providers warrant establishing user fees. This Agency action would require a legislative change. User fees may be more appropriate for ASCs than for other provider types given the fact that a large number of ASCs that become Medicare certified do so to meet the requirements of other third-party payers, and do not treat Medicare beneficiaries.

OIG Recommendation

CMS should update the Medicare Conditions for Coverage for ASCs.

- At a minimum, add sections that deal with patient rights and continuous quality improvement.

CMS Response

We recognize that the current ASC Conditions for Coverage do not adequately address the many changes that have taken place in the ASC community in recent years. The CMS is very interested in ensuring that our proposed revisions to the ASC regulations strengthen patients' rights and continuous quality improvement. This aspect of the OIG recommendation will be considered in the revision of the ASC Conditions for Coverage.

- Make the Conditions adjustable to match the levels of surgery performed by different ASCs.

CMS Response

This OIG recommendation will be considered in the revision of the ASC Conditions for Coverage.

OIG Recommendation

CMS should hold State agencies and accreditors fully accountable to the Medicare program for their performance overseeing ASCs.

- Use electronic data reporting to monitor basic metrics of performance.

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CMS Response

We concur with this recommendation. The CMS is already involved in designing the new Quality Improvement Evaluation System for survey data. As mentioned in the report, the new system is currently being used to capture survey data for nursing homes and home health agencies. We hope to expand its use to include survey data for other facility types in the near future. We have long recognized the value in developing standardized performance indicators for all providers. At this point in time, there are no organizations that have developed reliable quality indicators for surgical procedures. We will continue to discuss this approach with the accrediting organizations and other representatives of the health care community in hopes of developing such systems in the future.

- Conduct periodic Federal oversight surveys to monitor the nature and extent of review done during certification and accreditation surveys.

CMS Response

We acknowledge that Federal surveyors conduct very few look-behind surveys of certified facilities for the purpose of overseeing and evaluating the state agency surveyors. The CMS Central Office and Regional Office (RO) staff will work together to devise strategies to increase Federal presence and to improve our oversight of state agency certification of ASCs. However, CMS ROs face many of the same resource constraints that the state agencies do, and any improvements in this area will likely be hampered by limited resources and current legislative and budget priorities. As we have done with some other provider categories, we will explore the possibility of obtaining funding, and by contracting with organizations to function as our agents and perform validation surveys of facilities approved by the state survey agencies.

- Conduct formal, periodic evaluations of state agencies' and accreditors' performance overseeing ASCs.

CMS Response

We concur with this recommendation. The CMS has begun to incorporate elements of the program beyond nursing homes in the oversight evaluation of state agency performance, and we plan to continually enhance our evaluation of the state agencies.

There are procedures detailed in regulations that address oversight and evaluation of accrediting organizations, and we have conducted rigorous evaluations of each application with deeming authority for ASCs. We also note that two of three organizations currently approved will be evaluated for renewal of their deeming authority this year. However, the number of accredited ASCs deemed to meet Medicare's Conditions of Coverage is currently very small. For us to develop a validation process with statistical significance is close to impossible at this point in time, given the small number of accredited ASCs. The CMS will expand its accreditation and validation program to other provider types including ASCs during this fiscal year. As previously

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mentioned, obtaining a statistically valid sample this year will not be possible given the small number of accredited ASCs and current resource constraints, but we will use this validation process as a starting point to build upon in the future.

- Provide feedback to State agencies and accreditors on their performance.

CMS Response

As we improve our evaluation of the state agencies and accreditors and develop additional performance measures, we will provide the states and accreditors with additional feedback regarding their performance.

OIG Recommendation

CMS should hold State agencies and accreditors accountable to the public for their performance overseeing ASCs.

- Take steps to increase the availability of performance information about certified ASCs, including publishing it on the Medicare website.

CMS Response

In the future we plan to do this; however, given the current delay in survey cycles for many ASCs, we are reluctant to publish data that are out of date, or are not an accurate reflection of the ASCs' quality of care. To the extent that we can move ahead with more frequent surveys, electronic data reporting, and increasing their usefulness, it is our intent to make performance information more readily available to the public.

- Increase the accessibility of certification's complaint process.

CMS Response

We recognize that the complaint process is an important component of quality oversight and therefore concur with this recommendation. The CMS is currently working to improve the complaint process for all provider types. We hope to standardize and improve the complaint process across all provider types- creating a system that is more responsive and consistent.

- Negotiate with the accreditors to increase public information about accredited ASCs and the accessibility of their complaint processes.

CMS Response

We will continue to have an open dialogue with the accrediting organizations on this issue.

Page 5- Janet Rehnquist

- Publish information on the performance of State agencies and accreditors.

CMS Response

To the extent that we develop viable performance measures and data, we will explore the possibility of making the information readily available to the public.

The Role of Certification and Accreditation, Supplemental Report 1

OIG Recommendation

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

CMS Response

We agree with your findings that striking a balance between compliance and quality oversight is essential to protect the public from poorly performing ASCs while encouraging the rest to improve beyond minimal health and safety standards. We also believe that adding continuous quality improvement to the Conditions for Coverage would be very useful in bringing balance between compliance and continuous quality improvement. As we revise our Conditions for Coverage affecting the various provider groups, we are utilizing Quality Assessment Performance Initiatives that encourage self-assessment by providers of service. Thus, this aspect of the OIG recommendation will be considered in our revisions of the ASC Conditions for Coverage.

It is difficult to isolate quality when examining the issues surrounding ASCs. We believe it would be beneficial for a future study to examine the ASC benefit in its entirety, specifically to evaluate the statutory description of an ASC, as well as payment policy and provider enrollment issues.

Attachment

Page 6- Janet Rehnquist

Technical Comments

OEI-01-00-00450

Page 15, endnote 14, last sentence- Recommend replacing the word "we" with *were*.

OEI-01-00-00451

Page 22, second paragraph, second sentence- Recommend replacing the word "sample" with *samples*.

Page 29, endnote 24- The number "24" should be number 23.

OEI-01-00-00452

Page 5, second paragraph- Recommend changing sentence to read: *The Conditions are established in the regulations by CMS.*

Page 17, second paragraph, second sentence- Recommend replacing the word "sample" with *samples*.

Page 18, third paragraph, third sentence- Remove the word "the."

Page 19, endnote 9, second sentence- Insert the word *to* between the words "approved" and "accredit."

Page 21, first sentence- Replace "Health Plans and Providers (CHPP)" with *Medicare Management (CMM)*.

Page 21, endnote 22, first sentence- Recommend placing the word *website* before (www.medicare.gov).

Page 21, endnote 22, last sentence- Replace the word "we" with *were*.



Accreditation Association
for Ambulatory Health Care, Inc.

John E. Burke, Ph.D.
Executive Director & CEO

December 6, 2001

Janet Rehnquist, Inspector General
HHS/Office of Inspector General
Room 5246, Cohen Building
330 Independence Avenue, S.W.
Washington, DC 20201

Dear Inspector General Rehnquist:

On behalf of the Accreditation Association for Ambulatory Health Care, I am pleased to submit the attached comments on the draft report, *Quality Oversight of Ambulatory Surgical Centers*, and its two supplemental reports.

We agree that this study is timely and important for the reasons stated in your letter of November 6. We appreciated the opportunity to participate in the study and enjoyed working with the OIG staff in its development. Please let us know if we can be of any further assistance.

Sincerely,


John E. Burke, PhD
Executive Director & CEO

Enc.

JEB/jjb

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Accreditation Association
for Ambulatory Health Care, Inc.

December 6, 2011

Janet Rehnquist, Inspector General
HHS/Office of Inspector General
Room 5246, Cohen Building
330 Independence Avenue, S.W.
Washington, DC 20201

Re: Draft Report: Quality Oversight of Ambulatory Surgical Centers
Supplemental Report 1: The Role of Certification and Accreditation
Supplemental Report 2: Holding State Agencies and Accreditors Accountable

Dear Inspector General Rehnquist:

Thank you for the opportunity to provide comments on the draft report, Quality Oversight of Ambulatory Surgical Centers, and two supplemental reports, The Role of Certification and Accreditation (Supplemental Report 1), and Holding State Agencies and Accreditors Accountable (Supplemental Report 2). We appreciate the opportunity to be involved in this process.

The AAAHC mission is to develop standards to advance and promote patient safety, quality, value and measurement of performance for ambulatory health care through peer based accreditation processes, education, and research. AAAHC is committed to working with the Centers for Medicare & Medicaid Services (CMS) to ensure that ambulatory surgery centers (ASCs) provide the highest quality of care. With this as background, AAAHC would like to take this opportunity to comment on several specific areas of the above referenced reports.

We agree with the Draft Report's findings that 1) accreditors survey ambulatory care organizations more frequently than state agencies; 2) accreditors update their standards annually, or more frequently if necessary, with input of national experts, surveyors, and the public; 3) accreditors apply their standards to reflect the varying risk and complexity of services offered by ASCs.

AAAHC's Standards and Survey Process Committee meets regularly to review current standards and procedures and recommend to the Board of Directors changes to improve the accreditation process.

AAAHC also agrees with the recommendation that CMS should determine an appropriate minimum cycle for surveying Medicare-certified ASCs. (Draft Report, p. 10) We recognize both the value of the ongoing monitoring of ASCs and the need for a specified minimum time between surveys. On the other hand, the report should point out that some ASCs that have not been surveyed recently by CMS may be accredited and may have been subject to a more recent accreditation survey.

Another recommendation is that CMS should update the Medicare Conditions of Coverage by adding sections on patient rights and continuous quality improvement. (Draft Report, p. 10) Again, we applaud this recommendation. AAAHC has always emphasized the importance of patient rights and quality improvement, described in the Chapter 1 and 5 of the *AAAHC Accreditation Handbook*.

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We do not agree with the statement on p. 7 that accreditation's instructive approach may result in superficial review. AAAHC vigorously verifies compliance with its standards. We require extensive and ongoing training of AAAHC surveyors in order to assure they maintain a working knowledge of all standards resulting in an effective verification of compliance. This is accomplished through assessment of appropriate documentation, responses from personnel to detailed questions concerning implementation and other on-site observations and information gathering methodologies. Surveyors are trained health care professionals who are able to verify compliance through knowledgeable observation.

As recommended on page 20 of Supplemental Report 1, CMS should ensure that there is an appropriate balance between certification and accreditation, and compliance and continuous quality improvement. AAAHC accreditation recognizes the need for this important balance and attempts to achieve it in the following ways:

- As stated above, quality improvement is the cornerstone of the AAAHC accreditation program. Assessments of the elements of an active quality improvement program are interwoven throughout the standards in the *AAAHC Handbook*.
- While compliance with each AAAHC standard may not be necessarily discussed at the summation conference after a survey, surveyors evaluate compliance with all applicable standards in reporting their survey findings to AAAHC.
- Contrary to the assertion on p. 18 of Supplemental Report 1, ASC staff do not have the authority to select the medical records to be reviewed by surveyors. To assure both randomness and the ability to identify potential problem areas through clinical record review, surveyors are specifically instructed to review a sample of medical records that illustrate the types of health care services provided; a spectrum of providers that have privileges at the organization; and all records involving deaths, transfers, litigation, and unplanned outcomes/incidents.
- Effective in 2002, AAAHC has adopted a policy to conduct random, unannounced surveys as an additional tool for verifying compliance between regular on-site surveys.

Supplemental Report 2 contains a finding that patient complaint mechanisms have limited accessibility. (Draft Supp. Report 2, page 11) We take seriously AAAHC's responsibility to the Medicare Program and ensuring, through accreditation, quality care for Medicare beneficiaries. We recognize and agree that ASCs must provide patients a mechanism by which to file complaints. One of the requirements in the AAAHC chapter covering Rights of Patients is that organizations must inform patients about procedures for expressing suggestions to the organization and policies regarding grievance procedures and external appeals. Several other standards also refer to the organization's responsibility to adopt policies and procedures to resolve grievances and appeals.

AAAHC policy offers interested individuals the opportunity to present relevant information about an ASC being surveyed, with a prominent posting of notice of survey required 30 days prior to the survey. We also added a patient complaint form on the AAAHC web site to solicit this type of information.

AAAHC is concerned about a lack of context with certain statements in the draft report. We urge the deletion of examples cited of patient deaths allegedly occurring in ASCs. Adverse outcomes occur in all health care settings due to various reasons, including those unrelated to the care provided. The report lacks sufficient detail regarding those deaths for the information to be useful to policymakers. Moreover, without more context such as comparative data on safety across surgical settings, these examples do not serve a useful purpose and will likely serve to mislead the public and policymakers. References on

studies on complications and deaths should be deleted, as the studies involved are not of ASCs. Any references used with regard to negative outcomes should be balanced with readily available data showing ASCs' positive record in providing safe, high quality surgical services. In fact, we believe that the report should explicitly recognize the low rates of complications for procedures performed in ASCs and previous OIG findings in this regard.

One of the findings is that CMS has approved new procedures for ASCs that involve "high levels of anesthesia or invasiveness." (p. 6) As a point of clarification, current regulations prohibit CMS from adding to the ASC list any procedures that generally result in extensive blood loss, require major invasion of body cavities, directly involve major blood loss or are generally life threatening. This is important information for users of the report.

The report discusses Medicare certification and accreditation as if they are mutually exclusive items. To clear up any confusion, the final report should make it clear that compliance with the Medicare Conditions of Coverage may be achieved either through a state survey or accreditation. ASCs are relieved of the obligation of undergoing a state survey by choosing an accreditation deemed status survey.

Also on page 6, the report cites statistics on the number of ASCs that have not been subject to a recertification survey by a state agency in 5-year and 10-year periods. We suggest that the final report include information, if available, on whether this situation is limited to a few states or Medicare contractors, or is a chronic nationwide problem.

Finally, we believe that this study of Medicare ASCs should be released at the same time as the other two studies on outpatient surgery, covering hospital outpatient departments and physician office based surgery. Releasing similar data on all three settings would provide patients and policymakers with comprehensive and meaningful comparative information.

AAHC supports a collaborative, working relationship with CMS to monitor ASCs. We would be open to exploring various ways to enhance this process, including expanded use of electronic data reporting, Federal oversight of surveys, formal periodic evaluations, and the establishment of a feedback mechanism for monitoring performance. Of course, we would ask that CMS include accreditation organizations and other interested parties in the development of such processes.

We support a reasonable and effective public-private sector partnership on behalf of the Medicare and Medicaid patient population in the United States. Such a partnership is best served through a collaborative evaluation process to promote optimum quality of care for every citizen. We thank you for the opportunity to comment on the above referenced reports and look forward to continuing our work on behalf of CMS in the process of the oversight of ASCs.

Sincerely,

C. William Hanko MD

C. William Hanko, MD
President



Joint Commission
on Accreditation of Healthcare Organizations
Setting the Standard for Quality in Health Care

December 6, 2001

Janet Rehnquist
 Inspector General
 Office of the Inspector General
 5250 Wilber J. Cohen Building
 330 Independence Avenue, SW
 Washington, DC 20201

Re: Draft Report: "Quality Oversight of Ambulatory Surgical Centers
 A system in Neglect"

Dear Ms. Rehnquist:

We appreciate the opportunity to provide comments on the above referenced report and the two supplemental reports, "The Role of Certification and Accreditation" and "Holding State Agencies and Accreditors Accountable."

While we generally agree with the proposed findings of the report, it does make allegations about the effectiveness of the accreditation process to determine compliance that are incorrect and not supported in the report. We will discuss these in relations to the specific findings in the reports:

Oversight of ASCs is more important than ever.

We believe the OIG has accurately assessed the growth in ASCs that has occurred and the fact that approximately 90% of the facilities participate in Medicare as the result of federal medicare certification performed by state agencies. It should be noted that many of these organizations are also accredited, but have not elected to use their accreditation for "deemed status." These ASCs chose to receive the benefits of Joint Commission accreditation, irrespective of Medicare. For example, while we accredit over 300 ASCs, only about 50 elect to use their accreditation for Medicare. We are only one of the three organizations approved for "deemed status" under Medicare and we cannot comment on the experience of the other accreditors in this area.

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Member Organizations
 American College of Physicians
 American College of Surgeons
 American Dental Association
 American Hospital Association
 American Medical Association



Janet Rehnquist
Inspector General
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But Medicare's system of quality oversight is not up to the task.

As noted in the report, resurvey by the state agency is infrequent at best. The Joint Commission accreditation process requires that a provider be resurveyed at least every three years. The report correctly notes that the Joint Commission standards are revised on a regular basis to reflect changes in the industry and to address the varying risk and complexity of the services being offered. The report also correctly notes that adherence to these standards does result in improvements in the quality of care furnished by the ASC. We must, however, take exception to the allegation on Page 7 that accreditors pay less attention to verifying ASC compliance. The statement that the survey approach can result in a superficial review is, in the case of the Joint Commission survey, incorrect. The OIG does not differentiate the three accreditors on this issue. There is no evidence cited in the report that findings were in fact missed. It appears that the OIG does not recognize or acknowledge that the use of well trained, experienced, credentialed surveyors applying appropriate, current standards can do a thorough assessment and evaluation of a provider in the time and manner allotted. We recognize that State survey agencies frequently use more surveyors for a greater period of time than does the Joint Commission when assessing a provider. This does not necessarily result in a more thorough review. The comment by the OIG that they observed accreditation surveyors asking questions about key standards, but not verifying the supporting evidence does not acknowledge or recognize the skill and training of the surveyors in determining compliance. The Joint Commission requires that all surveyors be employees of the Joint Commission, have at least a masters degree and five years experience with the type of organization or services they survey. In addition all surveyors are provided extensive training in the standards, the accreditation process and quality improvement. The Joint Commission's emphasis on the credentials, experience and training of its surveyors have contributed to a comprehensive, credible and consistent survey of ASC.

And Lacks Accountability

CMS reviews the standards used by accreditors for deemed status purposes and must approve any changes to ensure consistency and also survey results. While more feed back on their review of the accreditors process is desirable we recognize that for this provider category the numbers of organizations that are "deemed" in relation to the states workload may result in a different priority than in other areas where deeming occurs. We would concur with the finding of the OIG that CMS should work with accreditors and the states when establishing performance expectations for the oversight of ASCs.

All Joint Commission accredited ASCs, whether deemed for Medicare or not, receive a survey at least every three years and the correction of all deficiencies are monitored and required to be corrected within a prescribed time period. In addition, as acknowledged in the draft report, the Joint Commission is firmly committed to being publicly accountable for the results of its accreditation activities, including the development of its standards

Janet Rehnquist
Inspector General
Page 3 of 4

and by making the results of its survey activity available to the public. We would disagree with the contention that the information publicly disclosed by the Joint Commission is not helpful. While we all strive to improve the presentation of information to consumers, we do include on an organization specific basis the findings of the survey as well as the final accreditation decision, (see Quality Check on the Joint Commission website at www.jcaho.org).

Receipt and processing of consumer complaints is another area of public accountability that the Joint Commission has emphasized. Not only do we have a toll free number available to public to file complaints, we give instructions on filing complaints on our website. We also include the 800 number on the Certificate of Accreditation awarded to each accredited organization. Since the award of accreditation is a significant achievement for the organization, they prominently display the Certificate in public areas.

Report Recommendations:

We would concur that CMS should establish a minimum survey cycle for ASCs. We believe the three-year cycle used by the Joint Commission represents a reasonable balance between cost and oversight and would recommend that CMS adopt this schedule.

The Medicare Conditions of Coverage should also be updated. While accreditors can and do update their standards on a regular basis, we are constrained by the deeming requirement to demonstrate conformance with the 1982 Medicare requirements, even if they now adversely effect attempts to improve the systems of care.

We also agree that accreditors are responsible to the public and when their accreditation is used to meet Medicare requirements to CMS. As noted in the draft report, the Joint Commission does respond to this responsibility in a number of ways, including an active complaint process, the publication of survey results, and the inclusion of multiple stakeholders on its many advisory committees for standards development. It is appropriate for CMS to recognize what the accreditors are doing in these areas when designing its oversight process.

Regarding the supplemental Reports:

We note that much of the information from the supplemental reports is included in the primary report and is included in our comments on that report. Following are additional comments relating to the supplemental reports.

Additional comments:

Supplemental Report 1:

Janet Rehnquist
Inspector General
Page 4 of 4

We take exception to the statement on Page 2 that the educational nature of surveys, number of standards and limited time on-site results in less attention to compliance. As noted in the draft report, the use of well trained, experienced, credentialed surveyors applying appropriate, current standards can and does result in a thorough assessment and evaluation of ASC providers. We recognize that State survey agencies frequently use more surveyors for a greater period of time than does the Joint Commission when assessing a provider. This, however, does not necessarily result in a more complete evaluation of compliance.

We would also request a correction/clarification of Appendix C, endnote no. 32. The report correctly acknowledges that the Joint Commission makes instructions readily available for consumers to file a complaint. The endnote also states, "None of the accreditors require...posting of instructions for lodging complaints..." As noted, not only do we have a toll free number available to public to file complaints, give instructions on filing complaints on our website, we also include the toll free number on the Certification of Accreditation awarded to each accredited organization. While it is not a requirement that the certificate be posted, since the award of accreditation is a significant achievement for the organization, they prominently display the certificate in public areas where patients can see it and therefore the number for contacting the Joint Commission is posted on onsite.

Supplemental Report 2:

We are pleased that the report recognizes the Joint Commission's efforts to provide information to consumers regarding accredited organizations and the extent of information available at no cost to the consumer. The information is available on the Web and can be linked to the Medicare web site to further assist beneficiaries seeking information about providers that are also accredited.

We thank you for the opportunity to comment on these reports. If there are any questions or more information is needed please contact me at 202 783-6655, or E-Mail at atirone@jcaho.org.

Sincerely,



Anthony J. Tirone
Director, Federal Relations



AMERICAN ASSOCIATION FOR ACCREDITATION OF AMBULATORY SURGERY FACILITIES, INC.
ACCREDITATION OFFICE: 1202 ALLANSON ROAD, MUNDELEIN, ILLINOIS 60060-8008 • 1(888)545-5222 or (847)649-9058 • FAX (847)506-4380

December 5, 2001

Ms. Janet Rehnquist
Inspector General
Dept. of Health and Human Services
Washington, D.C. 20201

Dear Ms. Rehnquist:

We wish to take this opportunity to commend you for your review of the roles of certification and accreditation quality oversight of ambulatory surgery centers under Medicare and the three draft reports that you forwarded to us for review. In general, we agree with your conclusions.

However, we would like to make the point that, because accrediting agencies must meet or exceed the conditions of coverage set forth by CMMS, we not only inspect for those conditions of coverage but also for the additional standards set by our accrediting organization as well. In addition, we do look for compliance of all the standards within our program which includes Quality Assurance and Peer Review. We also believe our standards far exceed the conditions of coverage based on the requirement that all surgeons must not only be ABMS certified in their surgical specialty but also hold hospital privileges for those same procedures performed in their surgical facility. We wish to suggest that our standards are developed in a format that makes inspection a simple, systematic, routine review of all the standards required to pass inspection for accreditation by a qualified and trained health care practitioner.

Our program has a comprehensive on-line peer review and quality assurance program. Each facility and each surgeon in that facility is required to report on a semi-annual basis. This unique system can provide us with comprehensive, quantitative, and qualitative data to ensure continuing compliance and outcomes. The program not only confirms 100% compliance to standards but requires Peer Review, Quality Assurance, Outcomes reporting and continuous quality improvement.

We have distributed a certificate type poster to be prominently displayed in the waiting room of each of our facilities with the name of our organization and toll-free telephone number so that complaints can be reported directly to our office. Our organization has an active "Investigative Review Committee" that reviews and investigates all complaints submitted in regards to our accredited facilities. This committee currently reviews an average of six complaints annually and normally adjudicates them within a 12-month period or less.

President
RONALD E. IVERSON, M.D.
Pleasanton, California

JEFFREY APPELDAUM, M.D.
Chicago, Illinois

HARLAN POLLOCK, M.D.
Dallas, Texas

Vice President
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Aventura, Florida

Janet Rehnquist letter
Page 2

In your report you stress the fact that approximately 10% of the facilities are accredited and the remaining 90% are certified. You also make the statement that a substantial number of facilities have not been certified in five years or more. The lack of re-certification on a reasonable periodic basis may be the reason that the overwhelming majority of (Ambulatory Surgery Centers) ASCs continue medicare certification rather than accreditation by an independent agency. Enforcement of periodic inspection through the medicare certification process may alleviate this problem. We concur with your recommendation that the conditions for coverage should be revised and updated to reflect the current state of the art in ambulatory surgery. The levels of accreditation should be reflected in the upgraded conditions of coverage based on the type of procedures performed and anesthesia used.

Hopefully, this information will be of use to you in your final report. If we can be of further assistance to you, please contact our office at 1-888-545-5222.

Sincerely,


Edward J. Stygar, Jr.
Executive Director



AMERICAN ASSOCIATION FOR ACCREDITATION
OF AMBULATORY SURGERY FACILITIES, INC.

is accredited by the American Association for Accreditation of Ambulatory
Surgery Facilities, Inc. (AAAASF). Complaints or concerns regarding
services provided at this facility can be directed as follows:

in writing:	AAAASF
	1202 Allanson Road
	Mundelein, IL 60060-3808
by phone:	1-888-545-5222 (toll-free)
by fax:	847-566-4580

Endnotes

1. 42 C.F.R., sec. 416.2.

2. 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.

3. 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.

4. Social Security Act, sec. 1865, 42 U.S.C. 1395bb.

5. These are the accreditors approved as of August, 2001. 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).

6. 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.

7. 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.

8. 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.
9. 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.
10. 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.
11. CMS does speak to the importance of continuous quality improvement in its interpretive guidelines to ASC surveyors. However, because the Conditions themselves make no demand for ASCs to conduct continuous quality improvement, CMS cannot hold ASCs responsible for not engaging in such activities.
12. 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.
13. 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).
14. CMS stores State agency data in its Online Survey Certification and Reporting System (OSCAR), which resides on its mainframe computer. It stores accreditation data on a personal computer spreadsheet.
15. For example, CMS provides nursing home surveys and comparative data on nursing homes on a special section of its web site called “Medicare Compare”. CMS also requires nursing homes to post recent surveys for consumers to see. In addition, CMS requires State agencies maintain a hotline for beneficiaries to obtain the results of home health surveys.
16. As of July, 2001, the Medicare web site (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 a 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.
17. 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.

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

19. CMS could also consider whether particular ASCs are, in fact, treating Medicare beneficiaries. Our analysis revealed 515 certified ASCs that made no Medicare claims in 2000. Further analysis would be needed to determine whether these 515 are newly certified and therefore unlikely to have claims for the year 2000.

20. 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.

21. Such a change may require legislation.

22. 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.

23. 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.

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

25. *Using Technology to Improve Medicare* Before the Subcomm. on Science, Technology, and Space of the Senate Comm. on Commerce, Science, and Transportation, 107th Cong., 1st Sess. 78 (2001).