

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 416

[CMS-3887-P]

RIN 0938-AL80

Medicare and Medicaid Programs; Ambulatory Surgical Centers, Conditions for Coverage

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Proposed rule.

SUMMARY: This proposed rule would revise some of the existing conditions for coverage (CfCs) that ambulatory surgical centers must meet to participate in the Medicare and Medicaid programs. The proposed modifications are intended to update the existing CfCs to reflect current practice and set forth new requirements to promote and protect patient health and safety.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on October 30, 2007.

ADDRESSES: In commenting, please refer to file code CMS-3887-P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (no duplicates, please):

1. *Electronically.* You may submit electronic comments on specific issues in this regulation to <http://www.cms.hhs.gov/eRulemaking>. Click on the link "Submit electronic comments on CMS regulations with an open comment period." (Attachments should be in Microsoft Word, WordPerfect, or Excel; however, we prefer Microsoft Word.)

2. *By regular mail.* You may mail written comments (one original and two copies) to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, *Attention:* CMS-3887-P, P.O. Box 8017, Baltimore, MD 21244-8017.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments (one original and two copies) to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, *Attention:* CMS-3887-P, Mail Stop C4-26-05, 7500 Security Boulevard, Baltimore, MD 21244-1850.

4. *By hand or courier.* If you prefer, you may deliver (by hand or courier) your written comments (one original and two copies) before the close of the comment period to one of the following addresses. If you intend to deliver your comments to the Baltimore address, please call telephone number (410) 786-7195 in advance to schedule your arrival with one of our staff members. Room 445-G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201; or 7500 Security Boulevard, Baltimore, MD 21244-1850.

(Because access to the interior of the HHH Building is not readily available to persons without Federal Government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

Submission of comments on paperwork requirements. You may submit comments on this document's paperwork requirements by mailing your comments to the addresses provided at the end of the "Collection of Information Requirements" section in this document.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT:

Jacqueline Morgan, (410) 786-4282.
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SUPPLEMENTARY INFORMATION:

Submitting Comments: We welcome comments from the public on all issues set forth in this rule to assist us in fully considering issues and developing policies. You can assist us by referencing the file code CMS-3887-P and the specific "issue identifier" that precedes the section on which you choose to comment.

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: <http://www.cms.hhs.gov/eRulemaking>. Click on the link

"Electronic Comments on CMS Regulations" on that Web site to view public comments.

Comments received timely will also be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1-800-743-3951.

I. Background

[If you choose to comment on issues in this section, please include the caption "BACKGROUND" at the beginning of your comments.]

As the single largest payer for health care services in the United States, the Federal Government assumes a critical responsibility for the quality of care furnished under its programs.

Historically, the Medicare program's quality assurance approach was focused on identifying health care entities that furnish poor quality care or that fail to meet minimum Federal standards.

Overall, we have found that this problem-focused approach has had inherent limitations and does not necessarily translate into better care for patients. Ensuring quality through the enforcement of prescriptive health and safety standards alone has resulted in expending many of our resources on working with marginal providers, rather than stimulating broad-based improvements in quality of care.

Section 1832(a)(2)(F)(i) of the Social Security Act (the Act) specifies that an ASC must meet health, safety, and other requirements specified by the Secretary of Health and Human Services (HHS) (the Secretary) in regulation if it has an agreement in effect with the Secretary. Under the agreement, the ASC agrees to accept the standard overhead amount determined under section 1833(i)(2)(A) of the Act as full payment for services, and to accept an assignment described in section 1842(b)(3)(B)(ii) of the Act for payment for all services furnished by the ASC to enrolled individuals. The Secretary is responsible for ensuring that the CfCs and their enforcement are adequate to protect the health and safety of individuals treated by ASCs.

To implement the CfCs, we determine compliance through State survey agencies that conduct onsite inspections utilizing these requirements. ASCs may be deemed to meet Medicare standards if they are certified by one of the national accrediting organizations whose standards meet or exceed the

CfCs. Currently, there are four Medicare approved national accreditation organizations: The Joint Commission; American Association for Accreditation of Ambulatory Surgical Facilities (AAAASF); Accreditation Association for Ambulatory Health Care (AAAHC); and the American Osteopathic Association (AOA).

The current ASC CfCs were originally published on August 5, 1982 (47 FR 34082), and, for the most part, these regulations have remained unchanged since that time. From 1990 to 2000, the number of ASCs participating in the Medicare program has increased at a rate of about 175 facilities a year. The total number of ASCs more than doubled from 1,197 to 2,966 during this ten year period, making ASCs one of the fastest growing facility types in the Medicare program. The annual volume of procedures performed on both Medicare and non-Medicare patients have also tripled. Currently, over 4,600 ASCs participate in the Medicare program.¹ This growth is due in part to advances in medical technology that have produced additional surgical procedures that can be safely performed outside of a hospital setting and increased focus on patient health and safety and patient convenience. This shift has paved the way for increasing numbers of procedures to be performed in an ASC. We believe that the changes we are proposing will strengthen and modernize the CfCs to be more aligned with today's ASC health care industry standards.

In addition, the recent transparency initiative directed by President Bush requires that more data be made available to all Americans as part of the Administration's commitment to make health care more affordable and accessible. In support of this initiative, we announced in August 2006 the release of Medicare payment information for 61 procedures performed in ASCs. The new information is available on our Web site at <http://www.cms.hhs.gov/HealthCareConInit/> and will help patients undergoing surgical procedures select the most appropriate setting for the delivery of high quality, efficient care. The information will show "Commonly Performed Procedures in ASCs," and will contain charge and Medicare payment data for ASC facility costs for a limited number of services

administered in States and counties. The data is broken down at the county, State and national level. Moreover, the CMS Web site at <http://www.cms.hhs.gov/center/ombudsman.asp> is available to the public and ASC patients to get information about the Medicare and Medicaid programs, prescription drug coverage, and how to coordinate Medicare benefits with other health insurance programs. The Web site also includes information about filing a grievance or complaint.

Section 109 of Division B, Title I of the Tax Relief and Health Care Act of 2006 (Pub. L. 109-432) (TRHCA), Quality reporting for hospital outpatient services and ambulatory surgical center services, requires that the Secretary develop measures that are appropriate to determine the measurement of quality care (including medication errors) furnished by ASCs that reflect the consensus among affected parties. These measures, to the extent feasible and practicable, shall include measures set forth by one or more national consensus building entities. The Secretary is authorized to reduce the annual payment update for failure to report on the chosen quality measures. We expect Medicare beneficiaries to receive high quality surgical services and for that reason, we are proposing to include a Quality Assurance Performance Improvement Requirement (QAPI) as a new condition for coverage (§ 416.43). (See section II.B.2 of the preamble of this proposed rule for a more detailed discussion of the quality assurance improvement requirement.)

We are soliciting public comments on quality measures appropriate to ASCs. We are interested in public comments regarding the extent to which ASCs are currently utilizing quality measures, the data source for those measures (for example, claims data and chart abstraction), and the extent to which those data are maintained electronically. We are also interested in how the measures were developed and why they are appropriate to measure the care provided to Medicare patients in ASCs.

We have developed a patients' right condition that emphasizes an ASC's responsibility to respect and promote the rights of each ASC patient.

II. Provisions of the Proposed Regulation

[If you choose to comment on issues in this section, please include the caption "PROVISIONS" at the beginning of your comments.]

Eliciting quality health care for Federal beneficiaries from CMS-certified providers and suppliers requires taking

advantage of continuing advances in the health care delivery field. As a result, we are revising the Medicare ASC requirements to focus on a patient-centered, outcome-oriented process that promotes patient care foremost, rather than a prescriptive, inflexible approach that penalizes providers of substandard care.

The conditions for coverage (CfCs) for ambulatory surgical centers (ASCs) were originally issued in 1982. Most of the revisions made since then have been payment related. Since 1982, significant innovations in ASC patient care delivery and quality assessment practices have emerged. In an effort to ensure continued quality in the ASC setting, we are proposing to revise three of the existing conditions and create three new conditions. The proposed revised conditions are: Governing body and management; Evaluation of quality (renamed Quality Assessment and Performance Improvement (QAPI); and Laboratory and radiologic services. The proposed new conditions are: Patient rights; Infection control; and Patient admission, assessment and discharge. Our objective is to achieve a balanced regulatory approach by ensuring that an ASC furnishes health care that meets essential health and quality standards, while ensuring that it monitors and improves its own performance.

To achieve this objective, we are working to revise not only the ASC requirements but the requirements for other major health care provider types, such as hospitals, home health agencies and end-stage renal disease facilities, through separate rules. All of the revised and new requirements are directed towards improving patient outcomes of care and satisfaction.

A. Definitions (§ 416.2)

Existing § 416.2 sets forth definitions for terms used in the ASC CfCs. We are proposing to revise the definition of "Ambulatory surgical center (ASC)." Also, we are proposing to add the definition for "overnight stay."

The ASC definition would read as follows:

Ambulatory surgical center or ASC would mean any distinct entity that operates exclusively for the purpose of providing surgical services to patients not requiring an overnight stay following the surgical services, has an agreement with CMS to participate in Medicare as an ASC, and meets the conditions set forth in subparts B and C of this part.

The overnight stay definition would read as follows:

Overnight stay, for purposes of the ASC CfCs, would mean the patient's

¹ Only comprehensive rehabilitation facilities and rural health clinics have experienced a higher rate of growth. Office of Evaluations and Inspections (OEI) analysis of Part B Medicare data. See Office of Inspector General Quality Oversight of Ambulatory Surgical Centers Supplemental Report 1: The Role of Certification and Accreditation.

recovery requires active monitoring by qualified medical personnel, regardless of whether it is provided in the ASC, beyond 11:59 p.m. of the day on which the surgical procedure was performed.

To provide further clarification on the overnight stay definition, we are proposing to use the 11:59 p.m. threshold as the standard for determining a patient's status when receiving services in an ASC facility. In the Medicare cost reporting manual (Provider Reimbursement Manual, Part 1, Section 2205 (Medicare Patient Days, page 22–16)), we have defined a hospital inpatient day as beginning at midnight and ending 24 hours later. Consistent with this longstanding policy, we would codify in regulations that any patient whose recovery requires active monitoring by qualified personnel beyond 11:59 p.m. of the day on which the surgical procedure was performed, is a patient who may require hospitalization or more intensive care. Accordingly, ASCs that are Medicare-certified may not keep patients beyond 11:59 p.m. of the day on which the surgical procedure was performed.

The Medicare Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates proposed and final rules (71 FR 49506 and 71 FR 67960) address the denial of payment of an ASC facility fee for any procedure for which prevailing medical practice dictates that the beneficiary will typically be expected to require active medical monitoring and care at midnight following the procedure. We also note that the patient's location at midnight is a generally accepted standard for determining his or her status as a hospital inpatient or skilled nursing facility patient and as such, it is reasonable to apply the same standard in the ASC setting.

B. Specific Conditions for Coverage

We are proposing to retain many current requirements because they still reflect current practice and are predictive of ensuring desired outcomes and preventing harmful outcomes.

The changes we are proposing to the current CfCs are the result of three main considerations.

First, we considered the suggestions put forth in a February 2002 report by the HHS Office of Inspector General (OIG) entitled, *Quality Oversight of Ambulatory Surgical Centers; A System in Neglect* [Janet Rehnquist, Inspector General, OEI-01-00-00450]. The report provided two recommendations specifically related to ASC patient health and safety. It recommended updating the CfCs to include patient rights and quality improvement. It also

recommended that the CfCs be written in a manner that takes into consideration the scope and severity of the different types of surgical procedures, thereby establishing varied sets of requirements to which ASCs would be accountable.

In response to the suggestions in the OIG report, we are proposing to replace the current Evaluation of Quality requirement with a new QAPI requirement and are proposing to add a new Patient Rights requirement. However, from both a policy perspective and an operational perspective, we are unable to propose different sets of ASC CfCs that are based on the scope of severity of the procedures offered by an ASC. Since ASCs are free to host a wide range of surgical procedures, enforcement of a variety of sets of requirements based on the type of procedures provided would be difficult to implement, since this would demand changes in the type and frequency of State agency oversight. In addition, ASCs wishing to upgrade their certification (if the regulations were approached as a tiered system) would require recertification and add additional oversight burden to the State agencies. This would continue to impact available resources. However, we would expect each ASC's QAPI program to reflect the scope and severity of the surgical services they perform.

Second, we received feedback from the various ASC stakeholders that attended a 1996 Town Hall meeting sponsored by CMS. Recommendations were overwhelmingly directed toward payment issues, updating CPT codes, coverage of specific procedures, and reclassification of the procedure codes. However, a number of the commenters did favor incorporating a QAPI program in place of the existing requirement at § 416.43 (Evaluation of quality) since most ASCs had already implemented a quality assurance performance improvement program as the standard of practice.

Third, this proposed rule is part of a larger CMS effort to bring about improvements in the quality of care furnished to Medicare and Medicaid beneficiaries through an outcome-oriented approach. The existing ASC CfCs do not, in any practical manner, address patient rights or a way to incorporate a quality assessment program that will assist ASCs in managing patient care more effectively. Accordingly, in light of such concerns, we would revise the CfCs to include a QAPI program and patient rights requirement.

1. Condition for Coverage—Governing Body and Management (§ 416.41)

The current regulation contains a condition for Governing Body and Management. We are proposing new language in the condition statement which would require the governing body to assume direct oversight and accountability for the QAPI program. The governing body would be responsible for ensuring that QAPI efforts, at a minimum, focus on identifying areas needing improvement and that QAPI is implemented in accordance with § 416.43 of this part. Specific governing body QAPI responsibilities are detailed in the proposed QAPI requirement at § 416.43. By focusing on QAPI, ASC management would be expected to be better able to improve care being furnished to patients. We are also proposing that the governing body be responsible for creating and maintaining a disaster preparedness plan. In addition, we are proposing to retain the current requirement which provides that the ASC can contract for services with an outside resource. However, we propose to incorporate this language into a separate standard, located at § 416.41(a). The ASC's governing body would still be responsible for the services that are furnished.

The standard on hospitalization will remain the same but has been separated into two subparts for purposes of State agency survey findings. This would enable State surveyors to cite an ASC's compliance with these requirements more precisely. All ASCs will still be required to transfer patients requiring emergency medical care beyond the capabilities of the ASC to the nearest local, Medicare-participating hospital or a local, non-participating hospital that meets the requirements for payment for emergency services under § 482.2 of this chapter. Moreover, the definition of local hospital would require the ASC to consider the most appropriate facility to which the ASC would transport its patients in the event of an emergency. If the closest hospital could not accommodate the patient population or the predominant medical emergencies associated with the types of surgeries performed by the ASC, a more distant hospital might also meet the local definition. Regardless of any business issues that arise between ASCs and their local hospital, the ASC would be required to transfer patients to the nearest, most appropriate local hospital, since this would affect patient health. Any transfers that do not meet the requirements of proposed § 416.41(b)(1) and (2) would be determined to be out

of compliance with Medicare regulations.

Lastly, we are also proposing the addition of a disaster preparedness standard at § 416.41(c). In response to the problems affecting health care facilities across much of the Gulf Coast region in September 2005 as a result of Hurricane Katrina, we are proposing this requirement to ensure the health and safety of patients and staff members alike. The ASC's governing Body, as part of the ASC leadership component, would be responsible for maintaining a written disaster preparedness plan that would provide for the emergency care of patients in the event of fire, natural disaster, functional failure of equipment, or other unexpected events or circumstances that threaten the health and/or safety of its patients and staff members. We recommend ASCs coordinate the plan with their State and local agencies, as appropriate. In an effort to achieve successful outcomes in a real-life disaster emergency, we are proposing at § 416.41(c)(3), that ASCs conduct annual drills for effectiveness. The ASC would then also be required to complete a written evaluation of every disaster drill and immediately implement any corrections to the plan.

2. Condition for Coverage—Quality Assessment and Performance Improvement (§ 416.43)

The existing "Evaluation of quality" requirement found at § 416.43, relies on a problem-oriented, reactive approach and primarily focuses on ASC self-assessment and evaluation of the procedures already performed and appropriateness of care issues. However, during the last decade, the health care industry has moved beyond the problem-oriented approach of monitoring quality assurance to an approach that addresses quality improvement prospectively through focused projects designed to reduce errors and address omissions of care *before* patients are adversely affected. We have already introduced the QAPI philosophy to the hospital, hospice and end stage renal disease facility programs either through a final regulation or a proposed rule. To raise the performance expectations for ASCs seeking entrance into the Medicare program, as well as the expectations of those ASCs already participating in Medicare, we are proposing that each ASC also develop, implement, and maintain an effective QAPI program. Our aim is to support the development of patient-centered, outcome-oriented efforts that focus on patient health and safety. An ASC QAPI program would be designed to stimulate the ASC to constantly monitor and

improve its own performance, and to be responsive to the needs, desires, and satisfaction levels of the patients it serves. With an effective QAPI program in place, the ASC would be better able to identify and reinforce the activities it is doing well, identify activities that are leading to poor patient outcomes, and take actions to improve performance. The ASC would be expected to take whatever actions are necessary to implement improvements in its performance as identified through its QAPI program. We are also proposing to change the CfC title from "Evaluation of quality" to "Quality assessment and performance improvement."

In proposed § 416.43(a), Program scope, we are proposing that the ASC's QAPI program must include, but not be limited to, an ongoing program that demonstrates measurable improvement in patient health outcomes, and improves patient safety by using quality indicators or performance measures associated with improved health outcomes and with the identification of medical errors. Although ASCs may certainly develop their own QAPI program, we encourage them to be open to considering QAPI programs in use by other health care entities since QAPI programs in general contain the same basic elements.

Monitoring care in an ASC can be challenging since the typical patient may be seen for only one visit. Therefore, it is critically important that an ASC's QAPI program identify high-risk areas and areas of problematic care and conduct follow-up analysis in a timely manner to identify specific areas in need of improvement. The ASC would be expected to measure, analyze and track quality indicators, including adverse patient events, infection control and other aspects of performance that include processes of care and services furnished in the ASC. Once a problem is identified, we would expect the ASC to establish and implement a plan to correct all deficiencies. We would expect the ASC to track its improvement and compliance over time to determine, in part, if its corrective actions were effective. Because staff members are in a unique position to provide the ASC with structured feedback on its performance and suggestions on how performance can be improved, we would expect the ASC to utilize staff in conducting its QAPI program. An ASC that decided to utilize an outside resource to conduct its QAPI program would still need to have its staff involved in the process.

In proposed § 416.43(b), Program data, we would require the ASC to utilize quality indicator data to monitor the

effectiveness and safety of services, and identify opportunities for improving the ASC's services. Where an ASC professional organization has made QAPI-related programs available to ASCs, we believe an ASC should consider exploring the feasibility of using such applicable programs to meet its needs. We would encourage ASCs to use a wide variety of information and data, in addition to their own findings, to guide improvement efforts. This information could include material available from national accrediting and other ASC organizations such as the AAAASF, the AAAHC, The Joint Commission, and the AOA. Many organizations offer a variety of quality improvement-related services such as benchmarking, quality indicators and quality assurance instructions. For example, the AAAHC offers information on the AAAHC Institute for Quality Improvement at its Web site, <http://www.aaahc.org>. Information made available by these organizations and others could provide an opportunity for an ASC to learn about and be more involved in clinical quality performance measurement.

We are not proposing that an ASC utilize specific quality indicators or collect specific data. An ASC could utilize existing resources or incorporate information from an existing QAPI program developed by other organizations, to potentially elicit a greater degree of insight into how to improve the quality of its services and patient satisfaction rather than developing a totally new program. An ASC would be free to develop programs that meet its individual needs and, in some cases, might benefit from an internally developed process. Regardless of what type of quality improvement program is chosen, we would require that the governing body approve the program. Since ASCs are currently required to "conduct an ongoing, comprehensive self-assessment of the quality of care provided * * *" under the current evaluation of quality measurement requirement at § 416.43, we do not believe ASCs will experience a protracted or difficult transition period.

At proposed § 416.43(c)(1), Program activities, we propose to require that the ASC set priorities for its performance improvement activities that: (1) Focus on high risk, high volume and problem-prone areas; (2) consider the incidence, prevalence and severity of identified problems; and (3) give priority to improvement activities that affect health outcomes, patient safety and quality of care. We expect an ASC would take immediate action to resolve any

identified problems that directly or potentially threaten the care and safety of patients. For example, patients with minimal support at home, surgery on patients with concurrent health issues, and those whose diagnosis and care may be unique to the ASC, could be the subject of more intense QAPI activity. Prioritizing areas of improvement would be essential for the ASC to gain a strategic view of its operating environment and to ensure a consistent quality of care provided over time.

At § 416.43(c)(2), we are proposing that the ASC track adverse patient events, examine their causes, implement improvements aimed at preventing a reoccurrence of the adverse events and ensure that those improvements are sustained over time. We have not proposed specific methods that ASCs would be required to use in implementing these actions. ASCs would be free to choose methods that are compatible with their operations. ASCs would be expected to view their staff as partners in the quality improvement process. As a follow-up requirement to tracking adverse patient events, we are proposing at § 416.43(c)(3) that ASCs would implement preventive strategies throughout the facility targeting any adverse patient events and ensuring all staff members are familiar with these strategies for improvement.

At § 416.43(d), Performance improvement projects, we are proposing the number and scope of improvement projects conducted annually must reflect the scope and complexity of the ASC's services and operations. For example, we would expect that where endoscopy services constitute the majority of an ASC's services, performance projects related to endoscopic procedures, issues, and follow-up care would be implemented. The ASC would be expected to fully document the projects that are being conducted, and documentation, at the very least, would be expected to include the reason(s) for implementing the project, and a description of the results of the project. Through meaningful data collection and analysis of adverse patient events and outcomes, an ASC would be able to determine how best to select projects that coincide with its existing nature and operations.

We are proposing at § 416.43(e), Governing body responsibilities, that the ASC's governing body would be responsible and accountable for ensuring that:

- The ongoing QAPI program is defined, implemented and maintained;

- The program addresses priorities and that all improvements are evaluated for effectiveness;

- The QAPI data collection methods, frequency and details are appropriate;
- Safety expectations are established; and

- Adequate resources are allocated for implementing the facility's QAPI program.

Any long-term program would require acceptance and direction from an organization's leadership in order to be successfully implemented, thus the ASC governing body's role would be critical to QAPI success. Once an improvement plan is developed and implemented, the ASC must track its progress to determine its effectiveness. The ASC governing body is responsible for assuring that the plan is carried out and that documentation can support the effort. If documentation is not available, selected requirements would be marked deficient at the time of a State survey. We would expect the governing body to be involved in the QAPI process. With an effective QAPI program in place and operating properly, the ASC could better identify and reinforce the activities it is doing well, identify activities that lead to poor patient outcomes, and take actions to improve performance.

3. Condition for Coverage—Laboratory and Radiologic Services (§ 416.49)

The current CfC Laboratory and radiologic services, located at § 416.49, would require laboratory and radiological services to be provided by certified facilities, regardless of whether the ASC performs the services or if the services are referred out to another facility.

In § 416.49, we would divide the current condition into two separate standards: Laboratory and radiologic services; in addition, we are proposing the expansion of the radiologic services requirement. The laboratory standard requirements would not change.

The proposed changes to the radiologic services standard would parallel the current laboratory standard by including requirements that the ASC would be required to meet, if applicable, when providing services directly or under arrangement.

The requirement at § 416.49(b)(1) is part of the current laboratory and radiologic services condition and the language would remain unchanged. The proposed language at § 416.49(b)(2) would require the ASC to meet the requirements of the CfCs for portable x-ray suppliers found at § 486.100 through § 486.110 of this chapter if it is furnishing these services directly. We have also proposed that radiologic

services furnished under arrangement would be performed by an entity that was certified by Medicare as a supplier of portable x-ray services by meeting the Medicare CfCs for portable x-ray services. This change would better ensure that high quality radiologic services are available to ASC patients.

4. Condition for Coverage—Patient Rights (§ 416.50)

This proposed new requirement would require ASCs to notify patients of their rights, provide for the exercise of rights, establish the right of privacy and safety, and maintain the confidentiality of clinical records. Although the number of surgical procedures performed in ASCs continues to grow (for example, from 1990 to 2000,² the annual volume of procedures performed by ASCs increased from 1.3 to 4.3 million), the current ASC regulation does not address patient rights.

In February 2002, the HHS Office of the Inspector General (OIG) issued a report, "Quality Oversight of Ambulatory Surgical Centers; A System in Neglect" [Janet Rehnquist, Inspector General, OEI-01-00-00450] which was based on a 2001 assessment of CMS's quality oversight of ASCs. The OIG recommended that CMS include a patient rights provision in the CfC for ASCs. The report specified that a "patients' rights CfC" is necessary to address issues such as how ASCs will respect patient dignity and resolve patient grievances. In developing the patient rights requirement we examined the current requirements for end stage renal disease facilities and hospitals.

The addition of a patient rights provision would be consistent with the philosophy of assuring patient participation in his or her care. A similar provision has been included in other recently issued rules (for example, Hospital Conditions of Participation: Requirements for Approval and Re-Approval of Transplant Centers to Perform Organ Transplants (72 FR 15198, March 30, 2007)).

The proposed standard at § 416.50(a), Notice of rights, would require the ASC to provide the patient or representative with verbal and written notice of the patient's rights in a language and manner the patient understands prior to furnishing care to the patient. The ASC would also be responsible for posting written notice of the patient rights in a place or places within the ASC where they are likely to be noticed by patients

²Department of Health and Human Services Office of Inspector General Quality Oversight of Ambulatory Surgical Centers, The Role of Certification and Accreditation, Supplemental Report 1, February 2002, OEI-01-00-00451.

waiting for treatment. In addition, the notice of patient's rights must include the name, address and telephone number for a representative in the State agency to whom patients can report complaints about ASCs, and the CMS Web site for the Medicare Beneficiary Ombudsman (<http://www.cms.hhs.gov/center/ombudsman.asp>). (Section 923 of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (Pub. L. 108–173) (MMA), mandated the creation of the Medicare Beneficiary Ombudsman at section 1808(c) of the Act, to ensure that Medicare beneficiaries receive the information and help they need to understand their Medicare options and to apply their rights and protections. A Medicare Beneficiary Ombudsman Open Door Forum (ODF) has been established to provide an opportunity for beneficiaries, their caregivers and advocates to publicly interact with the Medicare Beneficiary Ombudsman to discuss issues and concerns regarding ways to improve the systems and processes within the Medicare program.

The ASC would also be responsible for meaningfully disclosing, if applicable, physician financial interests or ownership in the ASC facility in accordance with 42 CFR part 420 (Program Integrity). The ASC must disclose the information in writing and furnish it to the patient prior to the first visit.

The disclosure of financial information should be such that patients and their representatives are able to clearly understand if the physician(s) who will be performing a procedure has a financial relationship with the ASC. It is incumbent on the ASC to be able to provide information that is not only technically correct, but which is also easily understood by persons not familiar with financial statements, legal documents or technical language. The ASC should be aware of the age and the cognitive abilities of its patients and recognize that older patients may be confused when presented with a document that they cannot readily understand at first glance.

In § 416.50(a)(2), Advance directives, the ASC would also be responsible for providing the patient or representative with verbal and written information concerning its policies on advance directives, including a description of applicable State law and, if requested, official State advance directive forms. In addition, the ASC would be required to inform the patient or representative of the patient's right to make informed decisions regarding their care, and to document in a prominent part of the patient's current medical record,

whether or not the individual has executed an advance directive.

We believe that ASCs should be given flexibility to meet this requirement within the context of their unique patient populations. Differences exist among ASCs and, therefore, ASCs should be allowed to determine the process they would use to comply with this proposed requirement. As a result, we are not establishing specific guidelines for implementation. We also believe that the ASC should be aware that questions may arise when informing patients of their rights; and therefore, they should provide ample time for answering questions.

If the patient is unable to effectively communicate in English, the ASC could have the family members assist in providing an explanation of rights. If a family member is not available, an ASC could make arrangements to furnish translation services to ensure that patients understand their rights. We would expect that advance patient scheduling would enable the ASC to secure the translation services that might be necessary. If the ASC is not able to furnish translation services and believes that neither the patient nor his or her representative will understand the explanation of rights, the ASC would be required to reschedule the procedure or request assistance from the parties in securing translation services. ASCs would have flexibility in determining how best to inform patients of their rights. We would also require that a written explanation of patient rights would be made available to the patient in a language the patient could understand.

Most Medicare facilities, including hospitals, critical access hospitals, skilled nursing facilities, nursing facilities, home health agencies, and hospices are required to maintain written policies and procedures that meet the requirements for advance directives for all adult individuals receiving medical care. In § 489.100, an advance directive is defined as a written instruction, such as a living will or durable power of attorney for health care, that is recognized under State law, whether statutorily or by the courts of the State, and relates to the provision of health care when the individual is incapacitated.

The current ASC regulation does not contain an advance directive provision. This is because Medicare suppliers of services, of which an ASC is one type, are not currently required to maintain written policies and procedures concerning advance directives. However, because ASCs are performing an increasing number of surgical

procedures on Medicare beneficiaries, many of which are invasive and require general anesthesia, we are proposing that advance directives be made available in an ASC.

We are also proposing a requirement entitled "Submission and investigation of grievances" at § 416.50(a)(3). This requirement would respond directly to the OIG report referenced earlier regarding management of patient grievances and any alleged violations against patients.

Grievance procedures are already in effect for numerous health care providers including ASCs. Similar to other internal procedures (for example, admission and discharge procedures, infection control procedures and others that are common to health care entities) the development and implementation of grievance procedures vary. Therefore, we have determined that it would be better to allow ASC to establish the specifics of a grievance system that may match its current one or needs rather than requiring that every ASC conform to a single grievance system.

We are proposing that the ASC would establish clearly explained procedures for documenting the existence, submission, investigation, and disposition of grievances presented to the ASC (either written or verbal) made by the patient or the patient's representative. ASCs would document all alleged violations related to and including, but not limited to, mistreatment, neglect, verbal, mental, sexual or physical abuse. If other allegations of mistreatment arise, such as theft of personal property, the ASC would document this allegation, as well. The ASC would immediately report these allegations to a person in authority in the ASC, the State, and local bodies having jurisdiction, and the State survey agency if warranted, to the extent that such reports are consistent with the Health Insurance Portability and Accountability Act of 1996 (Pub. L. 104–191) (HIPAA) and privacy provisions.

We are proposing that the grievance process specify time frames for review and response to the grievance. We are also proposing the ASC would be required to investigate, document, and respond to all grievances made by a patient or the patient's representative regarding treatment or care that is (or fails to be) furnished.

We are proposing that certain information be captured when documenting and responding to grievances. Proposed documentation should include such information as how the grievance was addressed, the steps taken during the investigation; written

notice to the patient or representative of the ASC's decision (containing the name of an ASC contact person); the results of the grievance process; and the date the grievance process was completed consistent with HIPAA and privacy requirements. ASCs could use different approaches to effectively meet this CfC. We would set forth the general elements that should be common to grievance processes across all ASCs, but we are not explicitly delineating strategies and policies that ASCs are required to use to comply with the requirement. Also, we would leave the degree of documentation to the discretion of the ASC.

The OIG Report specifies the growing need for a grievance process which would ensure that ASCs provide quality care. It also specifies that the process should provide Medicare consumers with a forum to have their grievances about ASCs documented and investigated by State agencies and accreditors. The process should also identify poor or even dangerous ASCs for intervention and follow-up. Consistent with the recommendations in the OIG's report, we are proposing a new standard, "Exercise of rights and respect for property and person," at § 416.50(b) which would specify that every patient would have the right to: (1) Exercise his or her rights without being subjected to discrimination or reprisal; (2) voice grievances regarding treatment or care that is (or fails to be) furnished; and (3) be fully informed about a treatment or procedure and the expected outcome before it is performed.

In addition, if the patient is determined to be incompetent under State law by a court of proper jurisdiction, the person appointed under State law could act on the patient's behalf. If a State court has not adjudged the patient incompetent, any legal representative designated by the patient in accordance with State law could exercise the patient's rights on his or her behalf to the extent allowed by State law. The ASC would retain flexibility in developing the policies that would support these rights. Although, we are not proposing a specific method stating how the ASC would implement § 416.50(b), we expect that an ASC would educate its staff on the importance of patients' full exercise of their rights and record and maintain complete and full documentation with respect to allegations concerning violation of these rights.

We would propose at § 416.50(c), Privacy and safety, that patients have the right to personal privacy and safety, to receive care in a safe setting, and to

be free from all forms of abuse or harassment. For example, ASCs would be required to provide a private space in which patients could disrobe and wait until the surgical procedure begins because we believe it is inappropriate for patients to be required to sit in a public waiting area while in a hospital gown with other fully clothed or similarly gowned patients or be in a common patient area without the benefit of partitions. This right would also allow patients, for example, to identify and report dangerous or unsafe conditions, harassment or abusive behaviors within the ASC that the patient believes could negatively impact the services received at the ASC. We believe this requirement would act as an additional safeguard to patient health and safety.

The proposed "Confidentiality of clinical records standard" at § 416.50(d) is designed to safeguard patients against unauthorized use of their clinical record. We would assure that the patient's right to confidentiality consistent with HIPAA standards and that access to or release of patient information and clinical records is permitted only with written consent of the patient or representative or as authorized by law. We are proposing to add this requirement because patients have the right to communicate with health care providers in confidence and to have the confidentiality of their health care information protected. In addition, all ASCs would be required to comply with the HIPAA health information privacy rule at 45 CFR parts 160 and 164.

5. Condition for Coverage—Infection Control (§ 416.51)

There is currently a requirement for Infection control. The current requirements on infection control are incorporated within the Physical environment standard of the Environment Condition for coverage (§ 416.44). Current requirements include the establishment of a program for identifying and preventing infections, maintaining a sanitary environment, and reporting the results to appropriate authorities.

We propose to establish a separate condition for infection control since control of infection is critically important to overall patient and staff health and safety.

We believe that surgery in an ASC must not entail a greater risk of infection to the patient than surgery in an inpatient setting. Medicare approved surgical procedures are performed in a variety of settings and we believe that an effective infection control program

should be present in all ASCs. One primary cause of infections is poor surgical technique and follow-up care. The Centers for Disease Control and Prevention (CDC) 1999 Guideline for Prevention of Surgical Site Infection [Infection Control and Hospital Epidemiology, Vol. 20 No. 4], also states that serious surgical infections can be explained by the emergence of antimicrobial-resistant pathogens and the increased numbers of surgical patients who are elderly. Furthermore, the CDC also reports that two million people are affected by infections that annually occur in hospitals and not including those healthcare associated infections that occur in long-term care facilities, ambulatory-care facilities and outpatient settings (CDC. Public health focus: surveillance, prevention and control of nosocomial infections (MMWR 1992; 41: 783–7)). A recent report on maximizing hand hygiene compliance and improved outcomes published in Infection Control Today reported that healthcare associated infections subject patients to increased risk of morbidity and mortality, increased durations of care and increased healthcare treatment costs (E. Fendler and P. Groziak; Maximizing Hand-Hygiene Compliance to Improve Outcomes: A New Tool for Infection Control, Infection Control Today, November 2001). Furthermore the report by Fendler and Groziak, according to CDC estimates, states that implementing effective infection control programs prevents one-third of these infections.

The proposed infection control condition would place accountability on ASCs to prevent, control, and investigate infections and communicable diseases, and take action that result in improvements for those problematic areas identified and monitored as part of the proposed QAPI program. However, the proposed infection control condition allows flexibility for ASCs to determine how to meet these objectives. This includes the flexibility to determine how much training in infection control is necessary for the ASCs personnel.

The first standard, sanitary environment, would require the ASC to provide a sanitary environment by following acceptable infection control standards of practice in the ASC setting to avoid sources and transmission of infections and communicable diseases. We have proposed to expand the current requirement of maintaining a sanitary environment to include the utilization of infection control standards of practice as guidelines in the ASC infection control program.

The proposed infection control program standard would require the ASC to designate a qualified professional, such as a registered nurse, as the infection control officer. The infection control program would operate under the direction of that designated individual who would be accountable for the investigation and resolution of infection and communicable disease incidents. In addition, the infection control program would be required to follow an organized plan of action to identify infection control problems and implement corrective measures and preventive mechanisms when necessary. We considered requiring ASCs to meet CDC and Occupational Safety and Health Administration (OSHA) standards for providing an environment to avoid infections and communicable disease. However, such a requirement would raise questions as to which CDC or OSHA standards must be met. Moreover, where dual sets of professionally recognized standards exist, we would not wish to restrict ASC flexibility by mandating compliance with a particular body of standards. Therefore, we are not mandating that ASCs follow any specific set of infection control guidelines.

However, we would strongly encourage the ASCs adhere to infection control guidelines that are published by the CDC, the Association of Practitioners in Infection Control (APIC) and the JCAHO as a reference for the utilization of infection control standards of practice.

As stated in the infection control standard, infection control must be an integral part of the QAPI program. In addition, infection control would also be targeted as a required area to be monitored in the proposed QAPI condition. The designated ASC personnel responsible for the infection control program would be required to coordinate with the QAPI program to maintain and improve outcomes in ASC infection control.

We would expect that the ASC will integrate knowledge gained from past and current experiences to modify policies, procedures or practice that would lead to improvements for those problematic areas identified and monitored as part of the QAPI program.

We also considered including specific requirements concerning preoperative hand/forearm antisepsis between surgical patient contacts. The CDC reports that failure to perform appropriate hand hygiene is considered the leading cause of healthcare associated infections and spread of multi-resistant organisms and has been recognized as a substantial contributor

to outbreaks. (Centers for Disease Control and Prevention, *Guideline For Hand Hygiene in Health-Care Settings*, October 25, 2002; Vol. 51; No. RR-16). However, we believe the ASC's obligation to protect patients and staff from facility acquired infections could be assured if an ASC is required to follow current infection control standards of practice. ASCs would be held accountable for establishing hand hygiene policies. Adequate policy and practice of hand hygiene between all patients that addresses antiseptic agents used, scrubbing technique, duration of the scrub, condition of the hands, and techniques used for drying and gloving would all fall under the responsibilities of the ASC to protect its staff and patients from infection.

In addition, we are not proposing to include a prescriptive requirement that mandates a specific method of cleaning and sterilization of equipment utilized in ASC procedures. We would require each ASC to be responsible for creating and implementing its own policies and procedures for proper instrument cleaning and maintenance of the sterilization equipment to prevent patient exposure to infectious organisms by ensuring all equipment is properly cleaned and sterilized. If an ASC utilizes equipment that has been improperly sterilized, a potential exists to put all of its patients at risk.

With the increasing popularity of ASCs, adherence to the most basic elements of infection control, like simple hand hygiene techniques, are of paramount importance.

6. Condition for Coverage—Patient Admission, Assessment and Discharge (§ 416.52)

This proposed condition continues to reflect a more patient-centered approach and underscores our view of essential steps to improve quality of care and patient outcomes. The proposed new condition would augment the current regulations that require an evaluation of the patient for anesthesia risk before surgery and proper recovery from anesthesia before discharge.

As noted by the former CMS Administrator, Dr. Mark McClellan, during his testimony before the Senate Finance Committee on May 18, 2006, "Medicare payments to ASCs are expected to better reflect the resources required to perform specific surgical procedures and to be similar to payments under other payment systems. In its 2005 Report to Congress, CMS found that many orthopedic surgical specialty hospitals were more similar to ASCs than to acute care hospitals." To address this problem, CMS is

developing revisions to the payment rates and also the list of procedures eligible for payment. The payment revisions are slated to be in effect by January 1, 2008, and it is anticipated there will be many more procedures performed in ASCs than in the past. We believe that with the expansion of procedures being performed in ASCs, there is a need for a requirement that addresses thorough patient assessment and recovery issues.

Older patients generally face greater risks when using anesthetics during surgical procedures than do younger patients. The normal aging process can extend healing time, increase the recovery time from medications, and complications may be more severe (Merck Manual of Geriatrics, Section 3, Chapter 27, Anesthesia Considerations). It is our intent to ensure that accurate and thorough assessments would be conducted to assure appropriate and safe surgery, and that patients would be able to tolerate a scheduled surgical procedure.

We are proposing this new condition as a method to capture specific patient care requirements in the pre-admission, pre-surgical, post-surgical and discharge phases of the ASC surgery process. The core objectives of this condition would be to ensure: (1) The patient can tolerate a surgical experience; (2) the patient's anesthesia risk and recovery are properly evaluated; (3) the patient's post-operative recovery is adequately evaluated; (4) the patient receives effective discharge planning; and (5) the patient is successfully discharged from the ASC.

Under the first proposed standard, "Admission and pre-surgical assessment", we would propose that each patient must have a comprehensive medical history and physical assessment completed not more than 30 days before the date of scheduled surgery by a physician (as defined in section 1861(r) of the Act), or other qualified practitioner in accordance with State law and ASC policy. We are proposing the 30-day time limit to remain consistent with our hospital conditions of participation that also requires a medical history and physical assessment be completed no more than 30 days before an elective procedure or admission. In addition, to ensure the ASC healthcare team would have all patient information available if needed, the ASC would be required to place the medical history and physical assessment in the patient's medical record before the surgical procedure is started.

The information to be included in the assessment would be determined by the

ASC based on accepted standards of practice and the characteristics, health risks and needs of the patient. ASCs would continue to have the flexibility to define the content and extent of the pre-surgical assessment; however, we would propose several items that must be included. The pre-surgical assessment entry in the medical record would be required to include an updated entry documenting an examination for any changes in the patient's condition since the most recently documented medical history and physical assessment. In addition, we believe that ASCs must provide specific documentation addressing the patient's capacity, both physically and mentally, to undergo the planned surgery and documentation of any allergies. As stated in the current pre-surgical assessment requirement at § 416.42(a), a physician is required to examine the patient immediately before surgery to evaluate the risk of anesthesia and of the procedure to be performed. The proposed additional pre-assessment items are to be completed by a physician or other qualified practitioner in accordance with State law and in conjunction with the current pre-surgical requirements. We believe that this proposed standard would set a clear expectation for a direct, effective relationship between the patient medical history and assessment and the procedures performed; a relationship that is essential for achieving desired healthcare outcomes.

The proposed standard § 416.52(b), "Post-surgical assessment" would require the ASC to ensure that a thorough assessment of the patient's post-surgical condition is completed, documented in the medical record and that any post-surgical needs are addressed and included in the discharge notes. We propose to retain the current standard at § 416.42(a) that requires a physician to evaluate each patient for anesthesia recovery before discharge. The post-surgical assessment must be performed by a physician or other qualified practitioner in accordance with State law. The post-surgical assessment would assess all body systems and identify any unforeseen or unanticipated post-surgical medical issues. The goal would be to decrease the amount of post-surgical complications experienced after discharge in the home recovery setting.

The last proposed standard, Discharge, would require the ASC to provide each patient with written discharge instructions and ensure that all patients have the best possible transition to home and that all post-surgical needs would be met. In addition, we are proposing that each

patient have a discharge order signed by the physician or the qualified practitioner who performed the surgery or procedure unless otherwise specified by State law. The discharge order must indicate that the patient has been evaluated for proper anesthesia and medical recovery. The requirement of a signed discharge order would ensure our beneficiaries are stable and safe to be discharged. We believe it is imperative, especially in preparation for the upcoming changes to the approved procedures in an ASC setting, that a physician or the qualified practitioner who performed the surgery or procedure be available to provide assistance in the ASC if needed, until all patients have been given a signed discharge order by the aforementioned practitioner. We believe this would eliminate any confusion with respect to the level of care and the ability of the ASC to respond to a patient emergency before the patient is discharged. We have not included language specifically requiring a physician to be on the premises while there are patients in the ASC. However, when the discharge order is signed, the patient would be expected to be discharged, that is, physically leave the ASC facility within a reasonable amount of time. Fifteen to thirty minutes would be a reasonable timeframe for the patient to complete the discharge process and leave the facility. Although most patients know how to contact their physician during nonroutine office hours, professional standards of practice dictate the ASC should include physician coverage information in the written discharge instructions regarding emergency care in the event of any postoperative adverse effects. We believe adding the three additional discharge elements would be essential for our beneficiaries because advanced age could pose slower healing times, unforeseen complications, and depending on the individual, difficulty with home self-care. The proposed discharge standard would not be intended to require lengthy and burdensome documentation. However, the intent is to ensure our beneficiaries receive the appropriate care once the surgical procedure is completed.

Lastly, early in the ASC regulation drafting process, we considered creating a revised list of required emergency equipment. However, we decided not to create a new list since the emergency equipment that is currently stated in § 416.44(c) is what we consider to be the minimum requirement. Advances and improvements in medical technology generate improvements in emergency equipment used by medical

professionals. As a result, a variety of applicable equipment is available from which to choose. Technology and professional judgment should dictate the kind of emergency equipment a facility should be using. If another list of "current" emergency equipment were to be created it would soon be outdated. Conversely, not specifying any emergency equipment would lead to ambiguity and there is a need to ensure that a minimum amount of emergency equipment will be available on-site at the ASC.

We believe that substitutions for a specific piece of emergency equipment, listed in § 489.44(c), could be appropriate if it performs the same emergency function for which the equipment listed in the current regulation was intended. For example, in the event a patient experiences cardiac fibrillation, it is critical that ASCs provide their medical professionals with the appropriate equipment to respond to this kind of emergency. The use of automatic external defibrillators (AED) has recently increased in various settings and in healthcare facilities. The intent of the current and proposed regulation is to make certain that an ASC uses emergency equipment which is deemed appropriate. We believe that ASCs should be required to have available all forms of emergency equipment listed in § 416.44(c), or other equipment which can meet the intended purpose.

III. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We are soliciting public comment on each of these issues for the following sections of this document that contain information collection requirements:

Conditions for Coverage—Governing Body and Management (§ 416.41)

In summary, this section outlines the conditions of coverage related to the governing bodies and management of ASCs. Ambulatory surgical centers must have a governing body that assumes full legal responsibility for determining, implementing, and monitoring policies governing the ASC's total operation. Section 416.41(b)(3) states that as a condition of coverage, an ASC must have a written transfer agreement with the hospital as referenced in § 416.41(b)(1) and § 416.41(b)(2).

The burden associated with this requirement is the time and effort involved in the ASC having a written transfer agreement with the hospital receiving the transfer. While this requirement is subject to the Paperwork Reduction Act of 1995 (PRA), this requirement is currently approved in OMB No. 0938–0266, with a current expiration date of February 29, 2008.

Section 416.41(c)(1) requires that an ASC maintain a written disaster preparedness plan that provides for the emergency care of patients in the event of fire, natural disaster, functional failure of equipment, or other unexplained circumstances that threaten the health and safety of its patients. Section 416.41(c)(3) requires that an ASC complete a written evaluation of drills conducted to test the effectiveness of the disaster preparedness plan.

The burden associated with the requirements in § 416.41(c)(1) and § 416.41(c)(3) is the time and effort necessary to draft and maintain the written disaster preparedness plan. In addition, there is burden associated with drafting and maintaining the reports on the effectiveness of the plan. While these requirements are subject to the PRA, we believe the burden is exempt as stated in 5 CFR 1320.3(b)(2), because the time, effort, and financial resources necessary to comply with the requirement would be incurred by persons in the normal course of their activities.

Conditions for Coverage—Quality Assessment and Performance Improvement (§ 416.43)

In summary, this section details the conditions of coverage for quality assessment and performance improvement. Ambulatory surgical centers, through the governing body and with the active participation of the medical staff, must develop, implement and maintain an ongoing, data-driven quality assessment and performance improvement (QAPI) program. This

section outlines the standards for the scope of the QAPI programs, the use of quality indicator data, the prioritization of performance improvement program activities, the complexity of performance improvement projects, and the responsibilities of ASC governing bodies. Specifically, § 416.43(d)(2) states that an ASC must fully document the performance improvement projects that are being conducted. The documentation at the very least must include the reason(s) for implementing the project, and a description of the results of the project.

The burden associated with this requirement is the time and effort involved in documenting the performance improvement projects. While this requirement is subject to the PRA, this requirement is currently approved in OMB No. 0938–0266, with a current expiration date of February 29, 2008.

Conditions for Coverage—Patient Rights (§ 416.50)

This section outlines the requirements an ASC must meet when informing a patient of his or her rights, in addition to the protection and promotion of these rights. Section 416.50(a)(1) requires that an ASC provide the patient or the patient's representative with verbal and written notice of the patient's rights prior to furnishing care to the patient and in a language and manner that the patient or patient's representative understands. Section 416.50(a)(1)(i) requires ASCs to post the written notice of patient rights in a place or places within the facility that is likely to be noticed by patients or their representatives.

The burden associated with these requirements is the time and effort required to inform the patient or the patient's representative of the patient's rights, and the time and effort associated with posting the written notice of patient rights. While these requirements impose burden, we believe it is exempt from the PRA as defined in 5 CFR 1320.3(b)(2).

Section 416.50(a)(2)(i) requires ASCs to provide the patient or representative with verbal and written information concerning its policies on advance directives, including a description of applicable State law. Section 416.50(a)(2)(iii) requires documentation in a prominent part of the patient's medical record that indicates whether or not the patient has executed an advance directive. The burden associated with these requirements is the time and effort necessary for disseminating the information to the patient, both orally and in writing, and maintaining the

necessary documentation in the medical record. While these requirements are subject to the PRA, we believe the associated burden is exempt from the PRA as defined in 5 CFR 1320.3(b)(2).

Section 416.50(a)(3) imposes both recordkeeping and reporting requirements. Specifically, § 416.50(a)(3)(iii) states that an ASC must fully document all alleged violations relating, but not limited to, mistreatment, neglect, verbal, mental, sexual or physical abuse. In addition, an ASC must immediately report the allegations to a person in authority in the ASC, the State and local bodies having jurisdiction, and the State survey agency. In addition, § 416.50(a)(3)(iv) requires an ASC to document how the grievance was addressed. The ASC must also provide the patient with a written notice of its decision.

The burden associated with these requirements is the time and effort involved in documenting the alleged violations and reporting the alleged violations to the aforementioned entities. While this requirement is subject to the PRA, the burden is exempt as it meets the requirements set forth in 5 CFR 1320.3(b)(2).

Conditions for Coverage—Patient Admission, Assessment, and Discharge (§ 416.52)

Section 416.52(a) requires each patient to have a comprehensive medical history and physical assessment prior to the scheduled surgery date. The pre-surgical assessment must occur upon admission. Section 416.52(b) requires that an ASC conduct an evaluation of the patient's post-surgical condition. Section 416.52(c) requires ASCs to establish a discharge planning process that is applied to all patients. As part of the process, each patient must have a physician signed discharge order.

The burden associated with the aforementioned requirements in § 416.52 is the time and effort necessary to perform the assessments and to document the information in the medical record.

While this requirement is subject to the PRA, the burden is exempt as it meets the requirements set forth in 5 CFR 1320.3(b)(2).

If you comment on these information collection and recordkeeping requirements, please mail copies directly to the following:

Centers for Medicare & Medicaid Services, Office of Strategic Operations and Regulatory Affairs, Regulations Development Group, *Attn.*: William N. Parham, III, [CMS–3887–P], Room C4–

26-05, 7500 Security Boulevard, Baltimore, MD 21244-1850; and Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503, Attn: Carolyn Lovett, CMS Desk Officer, [CMS-3887-P] Carolyn_Lovett@omb.eop.gov. Fax (202) 395-6974.

IV. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the "DATES" section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

V. Regulatory Impact Analysis

If you choose to comment on issues in this section, please include the caption "IMPACT" at the beginning of your comments.

A. Overall Impact

We have examined the impact of this proposed rule as required by Executive Order 12866 (September 1993, Regulatory Planning and Review), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96-354), section 1102(b) of the Social Security Act, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4) and Executive Order 13132.

Executive Order 12866 (as amended by Executive Order 13258, which merely reassigns responsibility of duties) directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A Regulatory Impact Analysis (RIA) must be prepared for major rules with economically significant effects (\$100 million or more in any 1 year). This is not a major rule, since the overall economic impact for all proposed new Conditions for coverage is estimated to be \$21 million annually.

The RFA requires agencies to analyze options for regulatory relief of small businesses. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues

of \$6.5 million to \$31.5 million in any 1 year. Individuals and States are not included in the definition of a small entity. We estimate there are approximately 4,600 Medicare participating ASCs (that includes both deemed and non-deemed facilities) with average admissions of approximately 1000 patients per ASC (based on the number of patients in ASCs in 2005 divided by the number of ASCs in 2005). Most ASCs are considered to be small entities, either by non-profit status or by having revenues of \$9 million to \$31.5 million in any one year (for details, see the Small Business Administration's regulation that sets forth size standards for health care industries at 65 FR 69432, November 17, 2000)). We certify that this rule would not have a significant impact on a substantial number of small entities because the cost of this rule is less than 1 percent of the total ASC Medicare revenue. According to the CMS 2005 national expenditure data, Medicare paid approximately \$2.2 billion to ASCs in 2005.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 100 beds. This regulation will not have a significant impact on the operations of a substantial number of small rural hospitals since ASCs are designed to only provide procedures on an out-patient basis and thus are not competing with rural hospitals for in-patient procedures. In addition, most ASCs are located in nonrural areas.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of \$100 million in 1995 dollars, updated annually for inflation. That threshold level is currently approximately \$120 million. The proposed rule will not have an effect on the expenditures of State, local or tribal governments, and the impact on the private sector is estimated to be less than \$120 million.

Executive Order 13132 establishes certain requirements that an agency must meet when it issues a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has

Federalism implications. This rule has no Federalism implications and will not affect State and local governments.

Throughout this document, we have noted that a portion of ASCs are already implementing the changes that would be required if these proposed rules were made final. For purposes of burden estimates however, we are unable to accurately determine the number of ASCs that are already compliant with these proposed requirements. Therefore, we have decided to err on the high cost side and apply the derived cost estimates to the total number of ASCs participating in Medicare. Additionally, we believe the increased quality initiatives outlined in the regulation should have little or no effect on the benefit cost of ASC services.

B. Anticipated Effects on Ambulatory Surgical Centers

As described in the preamble, the proposed regulation presents new provisions, as well as provisions that are carried over from the existing ASC regulations. For purposes of this section, we have assessed only the impact of the new provisions. Other provisions have not been revised; and therefore, do not present a new burden to ASCs.

Table 1 contains data that is frequently used in this impact statement. The salary-related cost data is referenced from the *Salarywizard.com* Web site at <http://hrs.salarycenter.salary.com>. Some of the requirements contained in the new provisions are already standard medical or business practices. Therefore, these requirements do not present an additional burden to ASC providers.

We recognize that in describing what the effect of this rule would be on ASCs, suggested burden estimates may not accurately reflect the experience of all ASCs. Facilities vary in the complexity of operations and processes, and therefore, associated costs may differ.

TABLE 1.—DATA USED THROUGHOUT THE IMPACT ANALYSIS *

Number of Medicare certified ASCs nationwide	4,600
Average number of patients per ASC	1000
Hourly rate of administrator	\$46.00
Hourly rate of registered nurse	\$39.00

*Hourly salary rates include base salary, bonuses, Social Security, 401k/403b, disability, healthcare, pension, and time off.

We are proposing revisions to the current conditions: Governing body and management; Evaluation of quality; and Laboratory and radiologic services conditions. The following new conditions are being proposed: Patient

rights, Infection control and Patient admission, assessment and discharge.

1. Anticipated Effects of the Governing Body and Management Provision (§ 416.41)

The proposed rule would expand the responsibility of the governing body to include the QAPI program and the creation and maintenance of a disaster preparedness plan. The governing body's specific responsibilities for QAPI are detailed in the new QAPI condition located at § 416.43(e). The assignment of burden for this requirement can be found under the description of the QAPI requirement.

The existing regulations require that ASCs meet certain safety requirements under § 416.44, Condition for coverage—Environment. We are working to establish emergency preparedness requirements for all providers/suppliers in a proposed rule that is currently under development. Issues relative to ASC cost and resources required to formulate and maintain an effective disaster preparedness plan will be discussed in the global regulation on emergency preparedness. In an effort to ensure ASCs are equipped to handle emergencies and disasters, we are proposing that ASCs develop a plan specific to disaster preparedness that would provide for the emergency care of patients in the event of unexpected events or circumstances that threaten their health. The plan would require an ASC to coordinate with appropriate State and local agencies and, as available, seek their advice on plan development. The plan would also require an annual review to test its effectiveness. It would be added as standard (c) under the Governing body and management condition.

In addition to annual review, the proposed rule also requires that the ASC staff be able to demonstrate, through annual drills and written evaluations, the ASCs ability to manage emergencies that are likely to occur within their geographic area. It would be added as standard (c) under the Governing body and management condition.

We estimate that an administrator, earning \$46.00 per hour, would be largely responsible for developing the plan and for managing the yearly drills and evaluations. We are estimating that the yearly cost for one ASC to develop and implement a disaster preparedness

plan will be approximately 4 hours at \$46.00 per hour, with a net cost of \$184.00 per ASC. Total cost for all ASCs would be \$846,400.

2. Anticipated Effects of the Quality Assessment and Performance Improvement (QAPI) Provision (§ 416.43)

In section § 416.43, we are revising the section heading, Evaluation of quality, to read as Quality assessment and performance improvement. As part of the agency's efforts to establish regulatory consistency where possible among providers and suppliers, we have proposed adding a QAPI program that requires ASCs to continuously monitor quality improvement through focused projects, take efforts to measure improvements in patient health outcomes, identify barriers to improvements, and work to reduce medical errors. ASCs would also be expected to measure, analyze and track quality indicators, including adverse patient events, infection control, and other aspects of performance, including processes of care and services furnished in the ASC.

Once an area of concern is identified, the ASC would develop a plan for improvement designed to address these concerns. The ASC would determine the specifics of the plan, assess its effectiveness, and would continue to monitor the results learned.

This condition includes five standards: program scope, program data, program activities, performance improvement projects, and governing body responsibilities.

Many providers are already using some version of a comprehensive quality assessment and performance improvement program which they have either developed or obtained from other sources. We estimate that it would take 12 hours for ASCs to develop their own quality assessment performance improvement program. We also estimate that ASCs would spend 18 hours a year collecting and analyzing the findings. In addition, we estimate that ASCs would spend 4 hours a year training their staff and 18 hours a year implementing performance improvement activities. Both the program development and implementation functions would most likely be managed by the ASC's administrator. Based on an hourly rate of \$46.00, the total cost of the quality assessment and performance

improvement condition for coverage would be \$2,392 per ASC.

The hourly burden is based on estimates that are found in the Hospital Conditions of Participation: Quality Assessment and Performance Improvement final rule (68 FR 3435, January 24, 2003). We estimated that a hospital would spend 80 hours collecting and analyzing information on 12 identified measures. According to our 2002 statistics, 5,985 hospitals discharged 11.8 million patients in 2000. This means that the statistically average hospital discharged approximately 2,000 patients that year. Collecting and analyzing data for 2,000 patients, we estimate that the implementation burden would take 80 hours. Based on the estimate, that the average ASC treats and discharges 1000 patients per year, we reduced the burden for ASCs to 40 hours. ASCs would be required to collect information in four areas: adverse patient events; infection control; processes of care; and services furnished in the ASC.

A new standard, Program scope, would require that the existing evaluation activities demonstrate measurable improvement in patient health outcomes. The proposed rule would also require the use of quality indicator data in the quality assessment and performance improvement program, but would not require any specific data collection or utilization, nor would it require ASCs to report the collected data. This would give the ASCs flexibility and minimize burden.

A proposed new standard, Program activities, would identify priority areas that an ASC must consider in its program. ASCs would be expected to carry out assessment activities according to the scope and complexity of their programs.

The proposed rule would require the governing body to become involved in all aspects of the quality assessment performance improvement program. We have estimated the burden based on management by an administrator. There should be direct and open communication between the program manager and the governing body. The analysis of a variety of reports, program prioritization, and allocation of resources are all standard business practices and therefore, we have not assigned additional burden to these functions.

TABLE 2.—SUMMARY OF QUALITY ASSESSMENT AND PERFORMANCE IMPROVEMENT BURDEN

Standard	Time per ASC (hours)	Total time (hours)	Cost per ASC	Total cost
QAPI development	12	55,200	\$552	\$2,539,200
QAPI implementation	40	184,000	1,840	8,464,000
Total annually	52	239,200	2,392	11,003,200

The various ASC accreditation and professional health organizations (that is, The Joint Commission; American Association for the Accreditation of Ambulatory Surgical Facilities; Accreditation Association for Ambulatory Health Care; and the American Osteopathic Association) support advances in patient care in a number of ways and actively encourage health care entities to expand and improve their existing programs. These organizations are familiar with quality improvement programs and are likely to have actual or referral information available to assist ASCs in setting up their QAPI programs.

In developing a QAPI program, ASCs are urged to take advantage of the variety of information that exists from the industry. ASCs may also find that QAPI programs for other entities such as hospitals, can be adapted to fit certain needs.

3. Anticipated Effects of the Laboratory and Radiologic Services Provision (§ 416.49)

The proposed rule would add a specification that an ASC must meet the requirements of the Conditions for coverage for portable x-ray services under § 416.100 through § 416.110 if it is furnishing these services directly. In addition, there is a new requirement that radiologic services furnished under arrangement must be performed by an entity that is certified by Medicare as a supplier of portable x-ray services by meeting the Conditions for coverage for portable x-ray services. These additions reflect standard practice in the industry and present no additional burden.

4. Anticipated Effects of the Patient Rights Provision (§ 416.50)

The existing regulation does not contain a condition-level patient rights requirement. The proposed rule recognizes that ASC patients are entitled to certain rights that must be protected and preserved, and that all patients must be free to exercise these rights. The proposed rule details basic information that ASCs would be required to provide to patients: Notice of rights, exercise of patient rights and respect for property and person, privacy and safety, and

confidentiality of clinical records. This condition also includes a requirement for Advance Directives, as specified at subpart I of part 489, and a requirement for the submission and investigation of grievances.

We have identified potential burden in the following areas.

a. Effects of the Notice of Rights—Verbal and Written Notice Provision

An ASC would be required to provide patients or their representatives with verbal and written notice of the rights and responsibilities of the patient prior to furnishing care to the patient. Generally, the most effective and efficient manner to furnish a written notice of rights is to initially develop a general notice which can be subsequently distributed as needed. We expect that an ASC will use this simple and inexpensive approach in order to meet this requirement. More than likely, this message would be written by a registered nurse or similar professional. A typical message might be in three parts: An introduction; the information section; and a section for follow up questions and issues. We expect the effort to develop this one-time message would not exceed 1 hour at a cost of \$39.00 for each ASC. This would be a one-time cost for ASCs and would total \$179,400 for all ASCs.

In many cases, notifying patients verbally of their rights is already being done and some ASCs may already be employing interpreters to make certain that patients who do not understand English fully understand their rights and responsibilities. However, for purposes of this analysis we will assume that all ASCs need to budget for this activity. The cost for language services can range from moderate hourly amounts to daily, full-time interpreters at \$800 per day. Telephonic services are more reasonable and more accessible and can be purchased for \$2.00 per minute. We are not able to determine the percentage of non-English speaking patients an ASC would care for in a year as that depends on a number of variables including the ASC's geographic location. In addition, the availability of in-person language services would also vary from location

to location and while it may not be preferred, in some cases the use of family members may be necessary.

Given this discussion, we estimate that 3 percent of an average annual ASC caseload of 1000 cases might require interpreter services and 15 minutes of time would be needed for an interpreter to provide a general description of the rights to which the patient is entitled. We base this estimate on the fact that both Spanish and French are commonly spoken in some parts of the country. (Other than English, Spanish is the language most commonly spoken in 42 States.) We expect that friends and relatives of patients speaking these languages would be available to assist in understanding issues related to his or her scheduled procedure. Therefore, the need for an ASC to hire an interpreter in these cases would be infrequent. The ASC may have to take steps to arrange for interpreter services for some patients when other options are not available.

- Telephone interpreter services at \$2.00/minute x 15 minutes = \$30.00 per patient. The cost for telephone interpreter services is, for example, dependent upon the language, the consumed time, or frequency. Costs range from \$75.00 an hour to \$160.00 or more an hour. The figure of \$2.00 per minute is an estimated average cost.

- 3 percent x 1000 patient caseload = 30 patients per year per ASC requiring interpreter services.

- \$30.00 x 30 = \$900 per ASC
- \$900 x 4600 ASCs = \$4,140,000 estimated cost total for all ASCs

b. Effects of the Advance Directives Provision

Each ASC would be required to establish an advance directive policy, and provide the patient or representative with verbal and written information concerning its policies on advance directives, including a description of applicable State laws and, if requested, official State advance directive forms. Each ASC would also be required to explain these policies to their patients, document whether an individual has executed an advance directive, and educate staff on the importance of advance directives. We expect that many ASCs already

communicate information about advance directives to their patients and thus, have already formulated some type of advance directives policy. We estimate that the development of an advance directives document utilizing generic advance directives forms obtained from existing Web sites or from State agency Web sites, by a registered nurse or equivalent will take 1 hour at \$39.00 per ASC. The estimated cost for all ASCs is \$179,400. We randomly queried a small sample of State Web sites and found generic advance directives forms in English and Spanish that were posted and available for downloading. The proposed rule would also require the ASC to document advance directive information in the patient's medical record, and to educate staff and patients about advance directives. We believe that these functions reflect standard industry practice, and therefore, would add no burden. While this requirement is subject to the PRA, we believe the burden associated with this requirement is exempt from the requirements of the Paperwork Reduction Act of 1995 as defined in 5 CFR 1320.3(b)(2) because the time, effort, and financial resources necessary to comply with the requirement would be incurred by ASCs in the normal course of their activities.

c. Effects of the Submission and Investigation of Patient Complaints Provision

We estimate that an ASC may have to investigate complaints from approximately 1 percent (10 patients) of its caseload due to allegations of mistreatment, and neglect, for example. We are not aware of an existing repository of records that accurately identifies the number and exact nature of ASC complaints. Therefore, 1 percent is an estimate.

An investigation could average 1 hour and would be managed by an administrator. Ten hours could be spent by each ASC in this activity.

- 10 hours $\times$ \$46.00 (administrator's hourly salary) = \$460 estimated cost for each ASC

- \$460 $\times$ 4600 ASCs = \$2,116,000 estimated cost for all ASCs

In its resolution of the grievance, an ASC must investigate all allegations, document how the violation or grievance was addressed, and provide the patient with written notice of its decision containing the name of an ASC contact person, the steps taken to investigate the grievance, the results of the grievance process, and the date the grievance process was completed.

The burden associated with this requirement is the time and effort

necessary to fully document the alleged violation or complaint and to disclose the written notice to each patient who filed a grievance. We estimate that, on average, it will take each ASC 15 minutes at a cost of \$39.00 an hour to develop and disseminate 10 notices on an annual basis (2.5 hours per ASC), for a total ASC burden of 11,500 hours at a cost \$448,500.00.

While this requirement is subject to the PRA, we believe the burden associated with this requirement is exempt from the requirements of the Paperwork Reduction Act of 1995 as defined in 5 CFR 1320.3(b)(2) because the time, effort, and financial resources necessary to comply with the requirement would be incurred by ASCs in the normal course of their activities.

d. Anticipated Effects of the Exercise of Rights and Respect for Property and Person Provision

Since ASCs began operating under Medicare in 1982, and during that time they have had to provide information to patients about the procedures to be performed and the expected outcomes. The proposed rule would require that ASCs continue this practice. Therefore, we do not anticipate that ASCs will incur significant costs associated with this proposed requirement.

e. Anticipated Effects of the Privacy and Safety Provision

The current regulatory language requires that an ASC provide a safe and sanitary environment to protect the health and safety of patients. The proposed regulation would add the requirement that the patient has the right to personal privacy. We are defining personal privacy in this case as providing the patient access to an area of the ASC which is shielded from view from others to prepare for the procedure to be performed. This would mean a place to disrobe, speak with ASC personnel about issues and concerns and then get dressed following the procedure. We believe that if ASCs do not now have facilities similar to this, they are in the minority and would be experiencing criticism and significant reduction in patients. At the very least, patients expect and will demand privacy when disrobing. Consequently, we do not believe that this proposed requirement would be a significant burden to ASCs now operating.

f. Anticipated Effects of the Confidentiality of Clinical Records Provision

The current regulation at § 416.47 (a) requires that an ASC develop a system for the proper use of patient records.

The proposed change merely provides a formal clarification of the current requirement's approach to how records are to be used. Specifically, an ASC is to respect the individual's right to maintain some control over his or her private medical information. The intent of the current regulation remains the same. In addition, most health care facilities recognize the need for privacy regarding patient medical records and have already instituted a policy, based on the HIPAA regulation that provides for a patient to sign a release before sensitive information is sent to others. Under the HIPAA regulation, patients have rights that protect their health information. Forty-eight States have medical privacy laws and Federal regulations at 45 CFR parts 160 and 164 are applicable to patients' health information. Some State laws are specific in prohibiting unlawful disclosure of patient information while, in other States, prohibitions are linked to laws governing specific medical entities. At the very least, most health care facilities are concerned about possible legal repercussions resulting from unauthorized use of patient clinical record information and have already instituted procedures to address this issue. Therefore, we do not believe this proposed rule will impose any significant additional financial or resource burdens on ASCs.

5. Anticipated Effects of the Infection Control Provision (§ 416.51)

We are proposing to elevate the current infection control requirements, located at § 416.44(a)(3), to the condition level. The ASC would be required to ensure that the infection control program minimizes infections and communicable diseases that could affect both patients and ASC staff. We are also requiring that a designated professional in the ASC be responsible for the program. We estimate the burden increase to be minimal, except for the proposed expense to make certain that the designated professional is familiar with infection control information.

ASCs are currently required to have a program that identifies and prevents infections, maintains a sanitary environment and reports results to the appropriate authorities. The proposed condition requires the ASC to designate a trained professional to be responsible for the ASC infection control program. The ASC can continue to designate the individual that currently oversees the infection control program; however, the ASC must also assure that the person who is designated has training or knowledge in infection control. Registered nurses with experience in

infection control could assume this duty. However, to ensure current knowledge of infection control methodologies and techniques, the designated person would need to engage in continuing education in infection control on a frequent or at least an annual basis. We estimate that an ASC would spend approximately \$500 per calendar year on infection control training for the designated individual. This cost was based on the quantity of technical information that we believe is appropriate to be included in an infection control program. The cost also includes the time spent by the ASC infection control officer (the trainee), the cost for a qualified trainer and the training materials. We estimate that the course would run 4 hours. The total estimated cost for all ASCs would be \$2,300,000.

The proposed infection control condition also includes the requirement that the infection control program be part of the ASC's QAPI program. We have not prescribed specific areas to be monitored or a process that must be followed to meet the requirement. We have not assigned any burden to this requirement because the ASC should already be evaluating quality activities and executing an infection control program. This requirement has been included as a formal way of ensuring it is an integral part of the ASCs QAPI process.

6. Anticipated Effects of the Patient Admission, Assessment and Discharge Provision (§ 416.52)

The proposed condition reflects a more patient-centered approach, improved quality of care, and more emphasis on patient outcomes. Specifically, we are proposing this new condition as a way of capturing specific patient care requirements in the pre-admission, pre-surgical, post-surgical and discharge phases of the ASC surgery process.

a. Effects of the Admission and Pre-Surgical Assessment Provision

We are proposing the completion of a comprehensive medical history and physical assessment no more than 30 days before the day of the scheduled surgery. The comprehensive medical history most likely will not be completed at the ASC. Therefore, there is no ASC burden associated with this requirement.

We are proposing a pre-surgical assessment be completed upon admission to the ASC. The assessment, which would be placed in the patient's medical record, would include a determination of the patient's physical

and mental ability to undergo the surgical procedure. Current regulations at § 416.42(a) require a physician to examine the patient immediately before surgery to evaluate the risk of anesthesia and of the procedure to be performed. Physicians must determine that patients, including those at high risk, are able to undergo the surgery itself and be able to manage recovery. Pre-surgical assessments represent a current standard of practice and do not pose additional burden.

To ensure the ASC healthcare team has all patient information available when needed, the medical history and physical assessment must be placed in the patient's medical record before the surgical procedure is started. There is no burden associated with this requirement.

b. Effects of the Post-Surgical Assessment Provision

The post-surgical assessment would require the ASC to ensure that a thorough assessment of the patient's post-surgical condition is completely documented in the medical record and that any post-surgical needs are addressed and included in the discharge notes. We are also proposing to retain the current standard at § 416.42(a) that requires a physician to evaluate each patient for anesthesia recovery before discharge. Post-surgical assessments reflect current ASC standard of practice, and therefore, do not pose additional burden.

c. Effects of the Discharge Provision

The discharge Standard requires the ASC to have a discharge planning process that assures all patients will have the best possible transition to home and that all post-surgical needs are met for all patients. The ASC would be required to provide each patient with a discharge order, signed by a doctor of medicine or osteopathy or the qualified practitioner who performed the surgery or procedure, indicating the patient has been evaluated for proper anesthesia and medical recovery and that the patient is approved for discharge from the ASC. Requiring the patient to have a signed discharge order by a doctor of medicine or osteopathy or the qualified practitioner who performed the surgery or procedure is standard practice. Therefore, we do not believe this is new burden for ASCs.

C. Alternatives Considered

One alternative was to maintain the existing CfCs without revisions; however, we concluded this was not a reasonable option because our existing CfCs are problem-focused. Under a

problem-focused approach, the goal has been to ensure quality through the enforcement of prescriptive health and safety standards. This after-the-fact approach does not generally contribute to ASC improvement or stimulate broad-based quality of care initiatives.

Revising the existing CfCs would take advantage of continuing advances in the health care delivery field. We believe it is necessary to keep pace with growing demands for services. In addition, listed below are other alternatives.

1. Alternatives to the Governing Body and Management Provision (§ 416.41)

We considered not including the requirement for the disaster preparedness plan. However, as witnessed by the problems affecting health care facilities across the Gulf region in September 2005 as a result of Hurricane Katrina, we have proposed this requirement to ensure the safety of patients and staff members alike.

2. Alternatives to the Quality Assessment and Performance Improvement (QAPI) Provision (§ 416.43)

We discussed eliminating any reference to the use of quality indicator data, including patient care data. However, in light of the existing and proposed hospital, home health and rural health clinic quality assessment and performance improvement requirements, we believe ASCs also must begin to build a foundation where quality indicator data can be used to identify activities that lead to poor patient outcomes.

3. Alternatives to the Patient Rights Provision (§ 416.50)

We considered not requiring that an ASC provide both written and verbal notice of rights in a language that the patient understands as this might pose an insurmountable problem for ASCs. However, options for furnishing these rights are available (as noted earlier).

4. Alternatives to the Discharge Provision (§ 416.52)

We considered requiring the ASC to have a physician on the premises of the ASC whenever a patient is in the facility. However, we decided this might impose undue burden when there are circumstances when patients are present in the ASC facility before and after procedures that do not warrant the need for physician coverage. Therefore, we believe the proposed requirement of a signed discharge order, by a physician, that evaluates the patient for proper anesthesia and medical recovery will provide more flexibility and continue to

ensure proper physician coverage until the patient has completely recovered and physically left the ASC facility.

D. Conclusion

We are not preparing analyses for either the RFA or section 1102(b) of the Act because we have determined, and we certify, that this proposed rule would not have a significant economic impact on a substantial number of small entities or a significant impact on the operations of a substantial number of small rural hospitals. This is not a major rule, because the overall impact for all proposed new conditions is estimated to be \$21 million annually. Moreover, a detailed assessment of the associated costs and benefits, as outlined by section 202 of the Unfunded Mandates Reform Act, will not be performed since the impact of this proposed regulation does not reach the \$120 million threshold. Additionally, the potential costs associated with implementing the requirements of this regulation could be less than anticipated since a portion of ASCs have already implemented the changes that would be required if these proposed rules were made final.

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

List of Subjects in 42 CFR Part 416

Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services proposes to amend 42 CFR part 416 as follows:

PART 416—AMBULATORY SURGICAL SERVICES

1. The authority citation for part 416 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

Subpart A—General Provisions and Definitions

2. Section § 416.2 is amended by—
A. Revising the definition of “Ambulatory surgical center or ASC.”
B. Adding the definition of “Overnight stay” in alphabetical order.
The revision and addition reads as follows:

§ 416.2 Definitions.

As used in this part:

Ambulatory surgical center or ASC means any distinct entity that operates exclusively for the purpose of providing surgical services to patients not

requiring an overnight stay following the surgical services, has an agreement with CMS to participate in Medicare as an ASC, and meets the conditions set forth in subparts B and C of this part.

* * * * *

Overnight stay means the patient's recovery requires active monitoring by qualified medical personnel, regardless of whether it is provided in the ASC, beyond 11:59 p.m. of the day on which the surgical procedure was performed.

Subpart C—Specific Conditions for Coverage

3. Section 416.41 is revised to read as follows.

§ 416.41 Condition for coverage—Governing body and management.

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

(a) *Standard: Contract services.* When services are provided through a contract with an outside resource, the ASC must assure that these services are provided in a safe and effective manner.

(b) *Standard: Hospitalization.*

(1) The ASC must have an effective procedure for the immediate transfer, to a hospital, of patients requiring emergency medical care beyond the capabilities of the ASC.

(2) This hospital must be a local, Medicare-participating hospital or a local, nonparticipating hospital that meets the requirements for payment for emergency services under § 482.2 of this chapter.

(3) The ASC must—

(i) Have a written transfer agreement with a hospital that meets the requirements of paragraph (b)(2) of this section; or

(ii) Ensure that all physicians performing surgery in the ASC have admitting privileges at a hospital that meets the requirements of paragraph (b)(2) of this section.

(c) *Standard: Disaster preparedness plan.*

(1) The ASC must maintain a written disaster preparedness plan that provides for the emergency care of patients in the event of fire, natural disaster, functional failure of equipment, or other unexpected events or circumstances that are likely to threaten the health and safety of its patients.

(2) The ASC coordinates the plan with State and local agencies, as appropriate.

(3) The ASC conducts drills, at least annually, to test the plan's effectiveness. The ASC must complete a written evaluation of each drill and immediately implement any corrections to the plan.

4. Section 416.43 is revised to read as follows:

§ 416.43 Conditions for coverage—Quality assessment and performance improvement.

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

(a) *Standard: Program scope.*

(1) The program must include, but not be limited to, an ongoing program that demonstrates measurable improvement in patient health outcomes, and improves patient safety by using quality indicators or performance measures associated with improved health outcomes and with the identification and reduction of medical errors.

(2) The ASC must measure, analyze, and track quality indicators, including adverse patient events, infection control and other aspects of performance that includes processes of care and services furnished in the ASC.

(b) *Standard: Program data.*

(1) The program must incorporate quality indicator data including patient care and other relevant data regarding services furnished in the ASC into its QAPI program.

(2) The ASC must use the data collected to—

(i) Monitor the effectiveness and safety of its services, and quality of its care.

(ii) Identify opportunities that could lead to improvements and changes in its patient care.

(c) *Standard: Program activities.*

(1) The ASC must set priorities for its performance improvement activities that—

(i) Focus on high risk, high volume and problem-prone areas.

(ii) Consider incidence, prevalence and severity of problems in those areas.

(iii) Affect health outcomes, patient safety and quality of care.

(2) Performance improvement activities must track adverse patient events, examine their causes, implement improvements and ensure that improvements are sustained over time.

(3) The ASC must implement preventive strategies throughout the facility targeting adverse patient events and ensure that all staff are familiar with these strategies.

(d) *Standard: Performance improvement projects.*

(1) The number and scope of distinct improvement projects conducted annually must reflect the scope and complexity of the ASC's services and operations.

(2) The ASC must document the projects that are being conducted. The documentation at a minimum must include the reason(s) for implementing the project, and a description of the project's results.

(e) *Standard: Governing body responsibilities.* The governing body must ensure that the QAPI—

(1) Program is defined, implemented and maintained by the ASC.

(2) Program addresses the ASC's priorities and that all improvements are evaluated for effectiveness.

(3) Data collection methods, frequency and details are appropriate.

(4) Program expectations for safety are clearly established.

(5) Resources are adequately allocated for implementing the facility's program.

5. Section 416.49 is revised to read as follows:

§ 416.49 Condition for coverage—Laboratory and radiologic services.

(a) *Standard: Laboratory.* If the ASC performs laboratory services, it must meet the requirements of part 493 of this chapter. If the ASC does not provide its own laboratory services, it must have procedures for obtaining routine and emergency laboratory services from a certified laboratory in accordance with part 493 of this chapter. The referral laboratory must be certified in the appropriate specialties and subspecialties of service to perform the referred tests in accordance with the requirements of part 493 of this chapter.

(b) *Standard: Radiologic services.*

(1) The ASC must have procedures for obtaining radiological services from a Medicare approved facility to meet the needs of patients.

(2) When radiologic services are medically necessary and integral to the performance of surgical procedures the ASC must meet the requirements of the Conditions for Coverage for Portable X-ray Services under § 486.100 through § 486.110 of this chapter if it is furnishing these services directly. Radiologic services furnished under arrangement must be performed by an entity that is certified by Medicare as a supplier of portable x-ray services by meeting the Conditions for Coverage for Portable X-ray Services.

6. Add new § 416.50 to read as follows:

§ 416.50 Condition for coverage—Patients' rights.

The ASC must inform the patient or the patient's representative of the

patient's rights, and must protect and promote the exercise of such rights.

(a) *Standard: Notice of rights.*

(1) The ASC must provide the patient or the patient's representative with verbal and written notice of the patient's rights prior to furnishing care to the patient and in a language and manner that the patient or patient representative understands. In addition, the ASC must—

(i) Post the written notice of patient rights in a place or places within the ASC likely to be noticed by patients (or their representative, if applicable) waiting for treatment. Notice of rights must include the name, address, and telephone number for a representative in the State agency to whom patients can report complaints about ASCs, as well as the Web site for the Medicare Beneficiary Ombudsman.

(ii) Disclose, if applicable, physician financial interests or ownership in the ASC facility in accordance with part 420 of this subchapter. Disclosure information must be in writing and furnished to the patient prior to the first visit to the ASC.

(2) *Advance directives.* The ASC must comply with the following requirements:

(i) Provide the patient or representative with verbal and written information concerning its policies on advance directives, including a description of applicable State law and, if requested, official State advance directive forms.

(ii) Inform the patient or representative of the patient's right to make informed decisions regarding their care.

(iii) Document in a prominent part of the patient's current medical record, whether or not the individual has executed an advance directive.

(3) *Submission and investigation of grievances.*

(i) The ASC must establish clearly explained procedures for documenting the existence, submission, investigation and disposition of a patient's written or verbal grievance to the ASC.

(ii) All alleged violations/grievances relating, but not limited to, mistreatment, neglect, verbal, mental, sexual or physical abuse, must be fully documented.

(iii) All allegations must be immediately reported to a person in authority in the ASC, the State and local bodies having jurisdiction, and the State survey agency if warranted.

(iv) The grievance process must specify time frames for review of the grievance and the provision of a response.

(v) The ASC, in responding to the grievance, must investigate all grievances made by a patient or the patient's representative regarding treatment or care that is (or fails to be) furnished.

(vi) The ASC must document how the grievance was addressed, as well as provide the patient with written notice of its decision. The decision must contain the name of an ASC contact person, the steps taken to investigate the grievance, the results of the grievance process, and the date the grievance process was completed.

(b) *Standard: Exercise of rights and respect for property and person.*

(1) The patient has the right to—

(i) Exercise his or her rights without being subjected to discrimination or reprisal.

(ii) Voice grievances regarding treatment or care that is (or fails to be) furnished.

(iii) Be fully informed about a treatment or procedure and the expected outcome before it is performed.

(2) If a patient is adjudged incompetent under State law by a court of proper jurisdiction, the rights of the patient are exercised by the person appointed under State law to act on the patient's behalf.

(3) If a State court has not adjudged a patient incompetent, any legal representative designated by the patient in accordance with State law may exercise the patient's rights to the extent allowed by State law.

(c) *Standard: Privacy and safety.* The patient has the right to—

(1) Personal privacy.

(2) Receive care in a safe setting.

(3) Be free from all forms of abuse or harassment.

(d) *Standard: Confidentiality of clinical records.* The patient has the right to confidentiality of his or her clinical records maintained by the ASC. Access to or release of patient information and clinical records is permitted only with written consent of the patient or the patient's representative or as authorized by law.

7. Add new § 416.51 to read as follows:

§ 416.51 Conditions for coverage—Infection Control.

The Ambulatory Surgical Center (ASC) must maintain an infection control program for patients and ASC staff that seeks to minimize infections and communicable diseases.

(a) *Standard: Sanitary environment.* The ASC must provide a functional and sanitary environment for the provision of surgical services by adhering to professionally acceptable standards of practice.

(b) *Standard: Infection control program.* The ASC must maintain an ongoing program designed to prevent, control, and investigate infections and communicable diseases. The program is—

(1) Under the direction of a designated and qualified professional who has training in infection control.

(2) An integral part of the ASC's quality assessment and performance improvement program; and

(3) Responsible for providing a plan of action for preventing, identifying and managing infections and communicable diseases and for immediately implementing corrective and preventive measures that result in improvement.

8. Add new § 416.52 to read as follows:

§ 416.52 Conditions for coverage—Patient admission, assessment and discharge.

The ASC must develop specific assessments for each patient's medical needs with respect to their visit to the ASC.

(a) *Standard: Admission and pre-surgical assessment.*

(1) Not more than 30 days before the date of the scheduled surgery, each patient must have a comprehensive medical history and physical assessment completed by a physician

(as defined in section 1861(r) of the Act) or other qualified practitioner in accordance with State law and ASC policy.

(2) Upon admission, each patient must have a pre-surgical assessment that includes, at a minimum, an updated medical record entry documenting an examination for any changes in the patient's condition since the most recently documented medical history and physical assessment. The assessment must include documentation to determine the patient's physical and mental ability to undergo the surgical procedure, and any allergies to drugs and biologicals.

(3) The patient's medical history and physical assessment must be placed in the patient's medical record before the surgical procedure is started.

(b) *Standard: Post-surgical assessment.*

(1) A thorough assessment of the patient's post-surgical condition must be completed and documented in the medical record.

(2) Post-surgical needs must be addressed and included in the discharge notes.

(c) *Standard: Discharge.* The ASC must—

(1) Provide each patient with written discharge instructions.

(2) Ensure the patient has a safe transition to home and that the post-surgical needs are met.

(3) Ensure each patient has a discharge order, signed by a physician or the qualified practitioner who performed the surgery or procedure unless otherwise specified by State law. The discharge order must indicate that the patient has been evaluated for proper anesthesia and medical recovery.

Authority: (Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program).

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: January 30, 2007.

Leslie V. Norwalk,

Acting Administrator, Centers for Medicare & Medicaid Services.

Approved: May 22, 2007.

Michael O. Leavitt,
Secretary.

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