State Operations Manual
Appendix L - Guidance for Surveyors: Ambulatory Surgical Centers

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Ambulatory Surgical Center Survey Protocol

Introduction

(Rev. 95, Issued: 12-12-13, Effective: 06-07-13, Implementation: 06-07-13)

Ambulatory Surgical Centers (ASCs) are required to be in compliance with the Federal requirements set forth in the Medicare Conditions for Coverage (CfC) in order to receive Medicare/Medicaid payment. The goal of an ambulatory surgical center (ASC) survey is to determine if the ASC is in compliance with the definition of an ASC, ASC general conditions and requirements, and the conditions for coverage (CfCs) at 42 CFR 416 Subparts A through C.

Certification of ASC compliance with the regulatory requirements is accomplished through observations, interviews, and document/record reviews. The survey process focuses on an ASC's delivery of patient care, including its organizational functions and processes for the provision of care. The ASC survey is the means used to assess compliance with Federal health, safety, and quality standards that will assure that patients receive safe, quality care, and services.

Regulatory and Policy References

- The Medicare definition of an ASC is found at 42 CFR 416.2 Subpart A.
- General conditions and requirements for Medicare-participating ASCs are found at 42 CFR 416 Subpart B
- The CfCs for ASCs are located at 42 CFR 416 Subpart C.
- Survey authority and compliance regulations can be found at 42 CFR 416 Subpart B and at 42 CFR Part 488 Subpart A.
- Should an individual or entity (ASC) refuse to allow immediate access upon reasonable request to either a State Agency (SA) or CMS surveyor, the Department of Health and Human Services Office of Inspector General (OIG) may exclude the ASC from participation in all Federal healthcare programs in accordance with 42 CFR 1001.1301. If a surveyor intends to make a request for immediate access with the threat of possible exclusion for non-compliance, the SA must first contact the CMS Regional Office, which must then contact the OIG Administrative and Civil Remedies Branch at 202-619-1306.
- The CMS State Operations Manual (SOM) provides CMS policy regarding survey and certification activities.

All ASC surveys are unannounced. Do not provide the ASC with advance notice of the survey.

Tasks in the Survey Protocol

The tasks included in a survey protocol for an ASC are:

Task 1 Off-Site Survey Preparation;
Task 2 Entrance Activities;
Task 3 Information Gathering/Investigation;
Task 4 Preliminary Decision-Making and Analysis of Findings;
Task 5 Exit Conference; and
Task 6 Post-Survey Activities.

Task 1 – Off-Site Preparation

General Objectives

The objectives of this task are to determine the size and composition of the survey team and to analyze information about the provider/supplier in order to identify areas of potential focus during the survey. Review of information about the ASC allows the SA (or RO for Federal teams) to develop a preliminary survey plan.

A full or standard survey will be conducted if the purpose of the survey is for initial certification, recertification, or validation of an accreditation organization survey. Surveys in response to a complaint or multiple complaints, or as a revisit to see if a previously cited problem has been corrected, will be focused on the CfCs related to the complaint or on the CfC for which deficiencies were previously identified. This does not preclude the scope of a complaint or revisit survey being expanded, if surveyors observe deficient practices related to other CfCs while on site. (See State Operations Manual, §§5100.1 and 5200.1.)

Types of Surveys

Standard or Full surveys: Initial certification, recertification, and representative sample validation surveys require assessment of the ASC's compliance with all Conditions for Coverage, including the Life Safety Code standards.

- Initial surveys are conducted when an ASC first seeks to participate in the Medicare program.

- Recertification surveys are required to reconfirm at periodic intervals the ASC's ongoing compliance.

- Representative sample validation surveys are conducted to support CMS' oversight of national accreditation organizations (AO) whose ASC programs have been recognized by CMS as suitable for deeming an accredited ASC as meeting the Medicare CfCs. CMS selects the ASCs for this type of validation survey, and

the SA must complete its survey no later than 60 days after the AO's survey. Although the primary purpose of the survey is to validate the AO's oversight, if substantial noncompliance is found by the SA and the RO concurs, the RO initiates appropriate enforcement action. SAs may only survey a deemed ASC when authorized to do so by the CMS Regional Office.

Complaint, Substantial Allegation Validation, or On-site Revisit Surveys: Generally, these types of survey are more narrowly focused than a full standard survey.

- A complaint is an allegation of noncompliance with Medicare health and safety standards. The purpose of a complaint survey is to determine the validity of the allegation and assess the current compliance of the ASC with those CfCs that are relevant to the substance of the allegation that triggered the survey.

- The purpose of the on-site revisit survey is to determine the ASC's current compliance with CfC requirements that the ASC was previously cited for noncompliance.

- The second type of validation survey is the substantial allegation validation. A complaint that alleges substantial noncompliance on the part of a deemed ASC with the Medicare health and safety standards may result in RO direction to the SA to conduct a substantial allegation validation survey. The SA uses the same methodology as for a complaint survey of a non-deemed ASC. The CMS Regional Office must authorize the State Survey Agency to conduct a substantial allegation validation survey and will specify the CfCs to be assessed.

Generally, complaints received by the SA or CMS concern specific cases or incidents that occurred in the past. However, CMS evaluates ASCs only for their current compliance or noncompliance at the time of the survey. Nevertheless, if an investigation of a complaint substantiates a violation in the past of one or more of the CfC requirements, <u>and</u> there is no evidence that the ASC subsequently implemented effective corrective action, then the findings substantiating the violation are documented on the Form CMS- 2567, Statement of Deficiencies and Plan of Correction as evidence of current noncompliance. On the other hand, if an allegation of a violation is substantiated, but the ASC subsequently implemented effective corrective action and the survey reveals no current noncompliant practices, then the ASC is in current compliance and is not cited for a deficiency based on the past noncompliance.

A revisit survey will focus on assessing the ASC's current compliance with the CfCs where deficiencies were cited on the previous survey. The SA must receive an acceptable plan of correction from the ASC before it conducts a revisit survey.

Survey Team Size and Composition

The SA (or the CMS RO for Federal teams) decides the composition and size of the team. In general, a survey team for a standard, i.e., full, survey should include two health standards surveyors and one Life Safety Code (LSC) surveyor, who are on-site for 2

days, but individual circumstances may call for a smaller or larger team, or a shorter or longer period of time on-site. The following factors are considered when determining survey team size and the scheduled length of the survey:

- Size of the ASC, based on its number of operating or procedure rooms (ORs), hours of operation, and/or available information about its average monthly volume of cases;

- Complexity of services offered, e.g., a single type of surgical service, such as eye surgery, or multiple types, such as eye surgery, orthopedic surgery, endoscopies and gynecological procedures;

- Whether the ASC has an historical pattern of serious deficiencies or complaints; and

- Whether new surveyors are to accompany the team as part of their training.

For a complaint or on-site revisit survey, only one surveyor will usually be needed and should be chosen based on their knowledge of the CfC(s) that will be reviewed during the survey.

The ASC surveyors must have the necessary training and experience to conduct a survey. Completion of the Principles of Documentation Training Course is required. Completion of the Basic Ambulatory Surgery Survey Course is required for all health standards surveyors, unless such training has not been offered by CMS in the previous 2 years. All Life Safety Code (LSC) surveys must be conducted by surveyors who have completed the Basic LSC Surveyor Course. All ASC survey teams must include at least one RN with hospital or ASC survey experience who has the expertise needed to determine if the facility is in compliance with the Conditions for Coverage. New surveyors may accompany the team prior to completing the required training.

Team Coordinator

The SA (or the RO) usually designates a Team Coordinator when the survey team consists of more than one surveyor. The Team Coordinator will be responsible for assuring that all survey preparation and survey activities are completed within the specified time frames and in a manner consistent with this protocol. Responsibilities of the Team Coordinator include:

- Acting as spokesperson to the ASC for the team;

- Conducting the entrance and exit conferences,

- Providing other on-going feedback, as appropriate, to ASC leadership on the status of the survey.

- Assigning team members specific survey tasks;
- Facilitating time management;
- Encouraging ongoing communication among team members;
- Evaluating team progress in completing the survey and coordinating team meetings; and
- Coordinating the preparation of the Form CMS-2567, Statement of Deficiencies and Plan of Correction, as well as all other reports/documentation required by CMS.

Assembling Background Information

Surveyors must prepare for the survey offsite, in order to make efficient use of the time onsite at the ASC. If the survey involves more than one surveyor, the Team Coordinator will arrange an offsite preparation meeting. If necessary, this meeting may be by conference call rather than in person. The type of background material to be gathered from the SA's files and/or CMS data bases includes:

- Basic characteristics of the ASC, including the facility's ownership, hours of operation, size, and types of surgical services offered. The most recent Form CMS-377 "Ambulatory Surgical Center Request for Initial Certification or Update of Certification Information in the Medicare Program", shows what the ASC indicates are the services it offers, but this form may be out of date. Other sources of information may include the SA's licensure file;
- Any additional information publicly available about the ASC, e.g., from its Web site, media reports, etc.;
- Any available information on the physical layout of the ASC;
- Whether any Life Safety Code waivers have been issued and are still in effect;
- Survey history and results of previous Federal and State surveys. In the case of a complaint survey, information on whether there were similar complaints investigated in the past; and
- Directions to the ASC.

During the meeting, the team discusses:

- Any significant information identified from the background information assembled;

- Whether there are CfCs requiring particular attention:
  - In the case of a complaint survey, the SA or the RO (in the case of a deemed ASC) identifies in advance of the onsite investigation which CfCs will be surveyed for compliance;
  - In the case of an on-site revisit survey, surveyors will focus on the ASC's current compliance with those CfCs where deficiencies were cited on the most recent Form CMS-2567. Surveyors also review the ASC's plan of correction and will look for evidence while onsite that the plan was implemented. (However, surveyors may not assume that implementation of the plan always means that the ASC is in substantial compliance with the CfC. It is possible that a plan of correction may be implemented, but is not sufficient to bring the ASC into compliance.);
- Preliminary team member assignments;
- Any questions the team has about how they will evaluate the CfCs;
- Date, location, and time team members will meet to enter the facility;
- When daily team meetings will take place if needed; and
- The anticipated date and time of the Exit Conference.

For surveys involving only one surveyor, that surveyor also needs to gather background information and plan the strategy for the survey prior to arriving on-site.

NOTE: Conduct ASC surveys during the ASC's normal business hours. All surveys are unannounced. Do not provide the ASC with advance notice of the survey.

Resources

The following resources are useful to bring on surveys:

- Appendix L – Guidance for Surveyors: Ambulatory Surgical Centers in the SOM;
- Appendix I – Survey Procedures and Interpretive Guidelines for Life Safety Code Surveys in the SOM;
- Appendix Q - Immediate Jeopardy in the SOM;
- Several copies of the regulatory language at 42 CFR 1001.130 regarding the

consequences of failure to permit the survey team access to the facility;

- For deemed accredited facilities, Exhibit 37, Model Letter Announcing Validation Survey of Accredited/Deemed Provider/Supplier, and Exhibit 287, Authorization by Deemed Provider/Supplier Selected for Accreditation Organization Validation Survey.

Task 2 – Entrance Activities

General Objectives

The objectives of this task are to explain the survey process to the ASC staff and obtain the information needed to conduct the survey.

General Procedures

Arrival

The entire survey team should enter the ASC together. Upon arrival, surveyors must present their identification. If the ASC denies entrance to the facility or otherwise tries to limit required survey activities, explain the requirements under 42 CFR 1001.1301 and present a hard copy of the regulatory citation. Explain that failure of the ASC to allow access for an onsite survey could lead to exclusion of the ASC from Medicare.

If surveyors encounter any problems onsite, they should feel free to contact their SA manager or the RO for guidance. For instance, if ASC staff will not let a surveyor into the facility even after they're informed of the possible sanctions that can be imposed for restricting access to their facility, a call to the SA or RO would be appropriate.

Because the survey is unannounced, surveyors should anticipate that in some ASCs, e.g., a small ASC with one physician owner who performs all the ASC's procedures, the ASC's leadership may at the time of entrance by the survey team already be involved in a procedure and unavailable. If there would be a prolonged wait for the ASC's leadership, e.g., a wait exceeding 15 minutes, the team should conduct the entrance conference with available ASC senior staff; a separate brief discussion can be held at a later mutually convenient time with the ASC's leadership.

The Team Coordinator (or the single surveyor for complaint or revisit surveys) will announce to the ASC's Administrator, or whoever is in charge, that a survey is being conducted. If the Administrator (or person in charge) is not onsite or available, the Team Coordinator asks that the Administrator or person in charge be notified that a Federal survey is being conducted. Do not delay the survey because the Administrator is not available.

Entrance Conference

The entrance conference sets the tone for the entire survey. Surveyors must be prepared and courteous, and make requests, not demands. The entrance conference should be informative, concise, and brief.

During the entrance conference, the Team Coordinator or single surveyor:

- Explains the purpose and scope of the survey (initial certification or recertification; complaint investigation; validation; revisit);

- In the case of a validation survey – either representative sample or substantial allegation (complaint) - of a deemed ASC, presents the letter explaining the survey and has the Administrator sign the authorization for the survey
  (Exhibit 287)

- Briefly describes the survey process;

- Introduces the survey team members, including any additional surveyors who may join the team at a later time, and discusses in general what the surveyors will do and the various documents they may request;

- Clarifies that all areas of the ASC, including the OR(s) or procedure rooms may be surveyed, but emphasizes that the survey team will not interfere with the provision of patient care and will take all standard precautions to avoid any infection control breaches; patients will be asked if they object to having their surgery observed;

- Explains that all interviews will be conducted privately with patients, staff, or visitors, unless requested otherwise by the interviewee;

- Discusses how the facility will provide the surveyors in a timely manner photocopies of material, records, and other information as needed;

- Obtains the names, locations, and telephone numbers of key ASC staff and their responsibilities;

- Discusses the appropriate time, location, and possible attendees of any meetings to be held during the survey; and

- Proposes a preliminary date and time for the exit conference.

During the entrance conference, the Team Coordinator arranges with the ASC Administrator or available administrative supervisory staff in his/her absence, to obtain the following:

- A list of all surgeries scheduled for that day (and the next if a 2-day survey); the list should include each patient's name, age, type of surgical procedure scheduled or performed, and the physician performing the procedure. The Team Coordinator indicates that one surveyor will be following the progression of at least one patient from initial registration through to discharge from the ASC (or at least through the initial period in the recovery room), so it is essential that information on these cases be provided as soon as possible, including the expected time between registration and discharge.

- A list of:

    - All surgeries from the past 6 months. In the case of a complaint survey concerning a surgery that took place further in the past, be sure to request a list that includes the month of the complaint case; and

    - All cases in the past year, if any, where the patient was transferred from the ASC to a hospital or where the patient died;

  The list should include each patient's name, age, type of surgical procedure scheduled or performed, and the name of the physician performing the procedure. The Coordinator explains to the ASC that, in order to complete the survey within the allotted time, it is important the survey team is given this information as soon as possible. The ASC should begin compiling this list as soon as the entrance conference concludes. Generally an ASC should be able to provide this information within 1 to 2 hours of the request.

- A location (e.g., conference room, an office not in use) where the survey team may meet privately during the survey, and also conduct record reviews, interviews, etc.;

- A telephone, preferably in the team meeting location;

- A list including the names of the Director of Nursing, active Medical Staff, Allied Health professionals, and all other staff providing patient care;

- A copy of the facility's organizational chart;

- Selected ASC written policies and procedures;

- Selected ASC personnel records;

- Written documentation related to the ASC's infection control program and its program for ongoing self-assessment of quality;

- A list of contracted services; and

- A copy of the facility's floor plan.

For initial or recertification surveys, arrange an interview with the administrative staff member who will be providing information enabling the survey team to complete the Form CMS-377, Ambulatory Surgical Center Request for Initial Certification or Update of Certification in the Medicare Program. Note that for recertification surveys, the ASC's management is not required to sign this form, since certification is ongoing and there is no requirement for the ASC to request recertification.

Task 3 – Information Gathering/Investigation

General Objective

The objective of this task is to determine the ASC's compliance with the CfCs through observations, interviews, and document review.

During the Survey

- Surveyors should always maintain a professional and calm demeanor;

- The SA and surveyors have discretion whether to allow, or to refuse to allow, facility personnel to accompany the surveyors during a survey. However, maintaining open and ongoing dialogue with the facility staff throughout the survey process generally enhances the efficiency and effectiveness of the survey. Surveyors should make a decision whether to allow facility personnel to accompany them based on the circumstances at the time of the survey;

- Surveyors need to respect patient privacy and maintain patient confidentiality at all times during the survey;

- Surveyors are not permitted to conduct clinical examinations or provide clinical services to any of the ASC's patients. Surveyors may direct the attention of the ASC staff to address an immediate and significant concern affecting a patient's care. All significant issues or significant adverse events, particularly those that a surveyor believes may constitute an immediate jeopardy, must also be brought to the Team Coordinator's attention immediately. Immediate jeopardy is defined as a situation in which the ASC's noncompliance with one or more CfCs has caused, or is likely to cause, serious injury, harm, impairment or death to a patient. If the Team Coordinator agrees that there is an immediate jeopardy situation, the team will follow the guidance in Appendix Q of the State Operations Manual.

- Informal conferences with facility staff may be held in order to inform them of preliminary survey findings. This affords facility staff the opportunity to present additional information or to offer explanations concerning identified issues;

- The survey team should meet at least daily in order to assess the status of the survey, progress of completion of assigned tasks, and areas of concern, as well as to identify areas for additional investigation. If areas of concern are identified in the discussion, the team should coordinate efforts to obtain additional information. Additional team meetings can be called at any time during the survey to discuss crucial problems or issues; and

- Surveyors should maintain their role as representatives of a regulatory agency. Although non-consultative information may be provided to the ASC upon request,

the surveyor is not a consultant and may not provide consulting services to the ASC.

Observations

Observations provide direct knowledge of the ASC's practices, which the surveyor must compare to the regulatory requirements in order to determine whether the ASC is in compliance with the requirements. The interpretive guidelines for each of the CfCs provide detailed guidance as to what the regulations require, as well as tips for surveyor activities to determine compliance.

Case Observation

The Team Coordinator should make it a priority at the beginning of the survey to select one or more surgical cases scheduled for observation during the survey. To form a more accurate picture of the ASC's routine practices, it is preferable to observe a case on the first day of the survey. ASC patients remain in the ASC up to a maximum of 24 hours; therefore, following individual cases from start to recovery or discharge is an effective tool for assessing the ASC's compliance with the CfCs. The number of cases selected will depend on the size of the team, the scheduled length of the survey, and the expected duration of the surgical case. Depending on the timing of the case selected, a surveyor may begin a case observation immediately.

The surveyor could follow the patient from pre-operative preparation and assessment to discharge (but at least through post-anesthesia recovery). For larger ASCs, i.e., those with more than 2 ORs or procedure rooms, or for multi-specialty ASCs, surveyors should consider following two cases.

In selecting cases to follow, surveyors should choose more complex cases, based on the type of procedure or patient age or patient co-morbidities. It may also be useful to avoid selecting cases where surveyors anticipate that patient modesty concerns may make it harder to obtain the patient's consent. As a general practice, to make efficient use of onsite time, surveyors should not select cases where the operative time is expected to exceed 90 minutes. Surveyors may opt not to observe the whole surgery from start to finish; however, in such cases they must assure they are in the OR when the patient is brought in, in order to observe the start of the surgery, and they must return to the OR before the case concludes. It may be useful for a surveyor to remain in the OR after the patient leaves, in order to observe how the OR is cleaned and prepped for the next case. In such cases the team should arrange for another surveyor to pick up the observation of the patient's care after the first surveyor leaves the OR.

In following the case(s) surveyors will look for evidence of compliance related to the various CfC requirements, e.g., infection control, physical environment, medication administration, assessment of anesthesia and procedure risk as well as the required pre-operative update assessment of changes from the history and physical, provision of surgical and anesthesia services, post-surgical assessment, recovery from surgery and anesthesia, and discharge orders.

ASC Tour

The tour may be accomplished before case observation, or surveyors who are not following a case may tour the ASC while the ASC staff is assembling the information requested during the entrance conference. The purpose of the tour is to get an overview of the whole ASC and to begin making findings about its compliance with the Cf C governing an ASC's environment, 42 CFR 416.44. The amount of time spent on the tour will depend on the size of the ASC, e.g., the number of ORs/procedure rooms, recovery rooms, etc. For revisit surveys, a tour of the whole facility is generally not necessary.

Observation Methods

When making observations, surveyors attend to the following; specific areas or activities to observe are discussed in the guidance for each CfC requirement.

- Building structure and layout, general appearance of cleanliness, odors;

- Staff-patient interactions, both clinical and non-clinical. For example, what happens to patients from the time they arrive at the ASC until the time they leave? Are their privacy and other rights protected? Is care provided by appropriate, qualified staff? Is patient identity verified by each staff member before care is provided?; and

- Other staff activities. For example, how do staff protect the confidentiality of medical records? Are infection control precautions observed? Are staff aware of regulatory requirements pertinent to their activities?

A surveyor must take detailed notes of all observations, identifying the regulatory standard(s) to which the observations relate to. For example, one set of observations might support findings related to multiple standards, or some surveyors may find it convenient to use interpretive guidance "tag" numbers as a convenient shortcut for identifying the applicable standards. When such tags are used, the surveyor must always recall that tags are just a filing/sorting device, and that the regulatory authority is always based on the specific regulatory language. With the approval of the SA, surveyors should also feel free to use templates or worksheets that will help record their survey findings.

Surveyors must attempt to obtain verification of the factual accuracy of their observations by the patient, family, facility staff, other team member(s), or by another means, as appropriate. For example, when finding an outdated medication on the anesthesia cart, surveyors can ask the ASC staff member who has responsibility for anesthesia to verify the drug's expiration date.

Surveyors must first obtain the permission of the patient or the patient's representative in order to observe the delivery of care to that patient. The privacy and dignity of the patient must always be respected, along with the patient's right to refuse to allow the surveyor to observe his/her care. For observation of a surgical case, the patient's consent to the surveyor's observation must be included/added to the patient's informed consent. It is at the surveyor's discretion whether he or she prefers ASC staff to first approach a

patient about the possible observation of his or her procedure, or whether the surveyor approaches the patient directly to seek permission. In all cases, the surveyor must speak directly with the patient to obtain consent.

The surveyor is not required to obtain the consent of the operating physician prior to observing a surgical procedure. The surveyor may observe any and all cases and activities upon request as needed in order to assess compliance with the Medicare ASC CfCs. An ASC may not condition a surveyor's ability to observe patient care by, for example, requiring a surveyor to sign any written documents or to present proof of vaccinations. The surveyor, however, must ensure that his/her observation protects patient safety and does not interfere with the operating physician or the surgical procedure.

If a facility denies a surveyor access to ASC activities which must be evaluated to determine compliance with the Medicare ASC CfCs, then the facility has failed to provide evidence of compliance and must be cited accordingly. In addition, the ASC may be subject to exclusion from participation in all Federal healthcare programs in accordance with 42 CFR 1001.1301. See "Regulatory and Policy References" section in this Appendix.

For each observation, the surveyor should document:

- The date and time of the observation(s);
- Location within the ASC;
- Patient and staff identifiers. A key containing identifiable information for patients must be kept on a separate identifier list. The ASC/surveyor may not use medical record numbers, Social Security numbers, or billing record numbers to identify patients, or the names or position numbers to identify staff members;
- Individuals present during the observation;
- Activity/area being observed (e.g., observation of sterile technique in the operating room, operative instrument cleaning and sterilization, recovery room care, etc).

Use of Infection Control Tool

CMS has developed, with the assistance of the Centers for Disease Control and Prevention (CDC), a comprehensive survey tool to assist surveyors in evaluating the infection control practices of an ASC. The tool may be found at Exhibit 351 of the State Operations Manual. One surveyor must be assigned to complete this tool during the survey, but all surveyors should be alert to breaches of standard infection control practices and share such observations with the surveyor completing the tool. The tool utilizes a combination of direct observations and interviews in order to document the ASC's infection control practices.

Document Review

ASCs maintain a variety of documents that provide evidence of their compliance/non-compliance with the regulations. Review of documents is a key component of the survey; however, it is important to note that the review must always be supplemented by surveyor observations and interviews. In particular, it is never sufficient to determine compliance by merely verifying that an ASC has an appropriate written policy and procedure in place. Surveyors must use a variety of means, including review of other documents, such as patient medical records, personnel files, maintenance records, etc., to confirm that the ASC actually follows its policies and procedures in its daily operations. Documents reviewed may be both written and electronic and include the following:

- Medical records (see discussion below);
- Personnel files to determine if staff members have the appropriate educational requirements and training, and are licensed and credentialed, if required. The ASC must comply with all CMS requirements and State law as well as follow its own written policies for medical staff privileging and credentialing;
- Maintenance records to determine if equipment is periodically examined and to determine whether the equipment is in good working order and whether environmental and sanitary requirements have been met;
- Policy and procedure manuals. When reviewing policy and procedure manuals, verify with the ASC's leadership that the manuals are current; and
- Contracts and transfer agreements. Review to verify these are current.

Photocopies

Surveyors must photocopy all documents needed to support deficiency findings. The surveyor requires access to a photocopier in the ASC in order to make these photocopies. Generally surveyors must not rely upon ASC staff to make copies for them. However, if the ASC insists that one of its staff must operate the copier, then a surveyor must observe the copying process, in order to assure that changes or omissions do not occur. If requested by the ASC, the surveyor will make an extra copy of the photocopied items for the ASC's benefit. All photocopies must be dated and timed by the surveyor to reflect when they were photocopied. They must be properly identified, as appropriate, e.g., "ASC Recovery Room Policy – 10-25-07 or "Facility Surgical Instrument Sterilization Policy – 10-25-07, or "Patient #3 Preoperative Anesthesia Assessment - 10-25-07."

Medical Record Review

Closed Record Sample Size and Selection

After the ASC provides a log or some other record of closed cases from the past six months, the team/surveyor will select a sample of the medical records for these cases to review.

Sampling for Initial Surveys, Recertification Surveys, or Representative Sample Validation Surveys

For recertification and representative sample validation surveys, the sample selected must represent a cross section of the cases performed at the ASC (i.e., different surgical specialties, types of surgery, surgical cases using different types of anesthesia, different physicians, post-op infection, unplanned post-operative transfer, etc.) The sample must include Medicare beneficiaries as well as other patients. All deaths and transfers to hospitals should be included. At a minimum, the surveyor selects at least 20 records for a facility with a monthly case volume exceeding 50. For lower volume ASCs, the surveyor selects at least 10 records. The sample size may be expanded as needed in order to determine compliance with the ASC CfCs, at the Team Coordinator's discretion.

Initial survey closed record sample sizes should be chosen at the Team Coordinator's discretion, since the volume of closed cases may be small. The Team Coordinator determines if there are enough patients on the current surgical schedule and patient records (i.e., open and closed) for surveyors to determine whether the ASC can demonstrate compliance with all CfCs for each specialty performed in the ASC.

Sampling for Complaint Surveys

CMS always assesses an ASC for its current compliance with the CfCs. Thus, it is not sufficient to look only at the medical record for the complaint case in conducting a complaint investigation. The surveyor must determine whether at the time of the survey the ASC is in compliance with the CfCs selected for evaluation. If evidence of noncompliance is found to have occurred in the past and the systems and processes that led to the noncompliance remain unchanged at the time of the survey, this will be treated as continuing current noncompliance.

The RO (for deemed ASCs) or the SA (for non-deemed ASCs) will determine in advance of the survey which CfCs the surveyors will be evaluating in relation to the complaint. Selection of the CfCs will be determined based on the nature of the allegation(s) explicitly stated or implied by the complaint – i.e., an allegation of transmission of an infectious disease will require review of the infection control CfC, and probably also of the governing body CfC, while an allegation by a hospital that it received an emergency transfer of a patient who had suffered a surgical complication that called into question the safety and competence of the ASC would necessitate reviewing multiple CfCs, including surgical services, medical staff, and governing body, at a minimum.

It will be necessary to review several closed records. The selection of the sample to review will be dependent, in part, on the complaint allegations. Depending on the CfCs to be surveyed for a complaint, it may also be necessary to observe an open case. If the complaint concerns infection control, for example, following a case will provide a good

opportunity to observe infection control practices throughout the ASC. On the other hand, if the complaint concerns a failure to assess patients preoperatively for risk, it would be more appropriate to look at a sample of closed records for the documentation of the assessments, as well as to observe portions of several open cases, as the patients move from registration into the OR or procedure room, to observe the pre-operative assessments.

A revisit survey may or may not require review of open or closed cases, depending on the specific standards and conditions being re-evaluated.

The surveyor must assign a unique identifier to each patient case observed/reviewed during the survey. A key containing identifiable information for patients must be kept on a separate identifier list. Do not use medical record numbers, Social Security numbers, or billing record numbers to identify the patients or names or positions for staff.

Once the medical records are available, surveyors can begin reviewing each record for evidence of compliance/noncompliance. The interpretive guidelines for the specific regulatory standards can be used if that is their primary assignment.

In reviewing the record surveyors should confirm whether it contains items required by various CfCs, including but not limited to:

- A comprehensive medical history and physical assessment completed not more than 30 days before the date of the surgery;
- Pre-surgical assessments – update of the H&P upon admission, and assessment for the risk of the procedure and anesthesia;
- Documentation of properly executed informed patient consent;
- Findings and techniques of the operation, including complications, allergies or adverse drug reactions that occurred;
- Orders signed by the physician for all drugs and biologicals administered to the patient;
- Documentation of adverse drug reactions, if any;
- Documentation of the post-surgical assessment of the patient, including for recovery from anesthesia;
- Documentation of reason for transfer to a hospital, if applicable;
- Discharge notes, including documentation of post-surgical needs; and
- Discharge order, signed by the operating physician.

Interviews

Interviews provide another method to collect information, and to verify and validate information obtained through observations, record review and review of other documents. Informal interviews are conducted throughout the duration of the survey. The information obtained from interviews may be used to determine what additional observations, interviews, and record reviews are necessary. When conducting interviews:

- Prepare detailed notes of each interview conducted. Document the interview date, time, and location, the full name and title of the person interviewed, and key points made and topics discussed. To the extent possible, document quotes from the interviewee.

- Interviews with facility staff should be brief and to the point.

- Interviews should be used to determine whether staff is aware of and understand what they need to do for the ASC to comply with regulatory requirements, as well as the ASC's formal policies and procedures. It is not necessary for staff to be able to cite specific Medicare regulations, but they should be able to describe what they do in a way that allows surveyors to determine compliance with the regulations.

- Be sure to interview staff having responsibilities related to each of the CfCs being surveyed.

- Use open-ended questions whenever possible to elicit staff knowledge rather than questions that lead the staff member to certain responses. For example, to determine if a staff member is aware of building emergency procedures, and his/her role in such events, simply ask, "If you smelled smoke, what would you do?" Do not ask, "Does this ASC have policies and procedures to address emergencies?" Likewise, ask, "Can you describe what typically happens in the OR before surgery begins?" Do not ask, "Does this ASC employ a standard 'time-out' procedure before beginning surgery?"

- Surveyors must always introduce themselves and ask patients or their representatives for permission to interview them. Surveyors must be sensitive when selecting patients for interview; for example, if a patient in recovery appears to still be feeling the effects of the anesthesia, an interview request should not be made. The same holds if a patient appears to be experiencing significant pain or anxiety. The privacy, dignity and well-being of the patient must always be respected, along with the patient's right to refuse to allow the surveyor to conduct an interview.

- Patient interview questions should focus on factual matters about which the patient is likely to have information. For example, ask "Did the doctor discuss your surgery with you today? What information did the doctor discuss with you about the surgery?" "Did you notice whether people washed their hands or used a cleaning gel before providing care to you?"

- Problems or concerns identified during a patient or family interview must be addressed in the staff interviews to validate the patient's perception, or to gather additional information.

- Validate as much of the information collected via interviews as possible by asking the same question of several staff or patients, or by integrating interview responses with related surveyor observations or record review findings.

- If necessary, telephone interviews may be conducted for closed cases; however, in-person interviews are preferred.

Task 4 – Preliminary Decision Making and Analysis of Findings

General Objectives

The general objectives of this task are to integrate findings, review and analyze all information collected from observations, interviews, and record reviews. The team's or surveyor's preliminary decision-making and analysis of findings assist in preparing the exit conference report.

Preparation

Prior to beginning this task, each surveyor must review his/her notes and completed worksheets related to observations and interviews, as well as the documents he/she has photocopied. The surveyor must be confident that he/she has everything needed to support his/her presentation of findings to the team, and to the SA manager when preparing a formal survey report.

Discussion Meeting

At this meeting, the surveyors share their findings, evaluate the evidence, and make team decisions regarding compliance with each requirement. For initial, recertification, and validation surveys, the Team should proceed sequentially through the regulatory requirements for each CfC; for complaint surveys they should proceed to review each CfC selected for investigation. The team must reach a consensus on all findings of noncompliance. Decisions about deficiencies must be team decisions, with each member having input. The team must document the evidence that supports each finding of noncompliance. Any additional documentation or evidence needed to support identified noncompliance must be gathered prior to exiting the facility.

All noted noncompliance must be cited as a deficiency, even when corrected onsite during the survey.

When a noncompliant practice is determined to have taken place prior to the survey, this would be considered evidence of current non-compliance, **unless** there is documentation that the ASC identified the problem prior to the survey and implemented effective corrective action. In evaluating whether the ASC is currently in compliance, the survey team must consider:

- What corrective action the facility implemented;

- Whether the corrective action was sufficient to address the underlying, systemic causes of the deficiency;

- Whether the corrective action was evaluated for its effectiveness to sustain long-term compliance; and

- Whether there are any other findings from the survey indicating current non-compliance.

If the deficient practice is identified and corrected by the ASC prior to the survey and there is no other evidence of current non-compliance, do not cite noncompliance.

In the case of a revisit survey, the surveyor's task is to determine current compliance with the regulatory requirements that were cited during the previous survey and ensure that the implementation of the written plan of correction submitted by the ASC and accepted by the SA was effective in maintaining long term compliance. The surveyor should conduct observations, document reviews and interviews to confirm current compliance with the CfC(s) addressed by the plan of correction.

Integrating Findings

The survey team integrates the findings derived from document review, observations, and interviews that pertain to each CfC surveyed, in order to make a determination of whether there is evidence of compliance/non-compliance.

Determining the Citation Level of Deficiencies

Citing noncompliance at the appropriate level, i.e., standard- or condition-level, is critical to the integrity of the survey process.

The regulations at 42 CFR 488.26 state, "The decision as to whether there is compliance with a particular requirement, condition of participation, or condition for coverage depends upon the manner and degree to which the provider or supplier satisfies the various standards within each condition." When noncompliance with a particular standard within the Conditions for Coverage is noted, the determination of whether the lack of compliance is at the Standard or Condition level depends upon the nature of the noncompliance – i.e., how serious is the deficiency in terms of its potential or actual harm to patients - and extent of noncompliance – i.e., is there noncompliance with the CfC stem statement, or how many different regulatory requirements within a CfC are being cited for noncompliance, or how frequent was a given noncompliant practice, etc. One instance of noncompliance with a standard that poses a serious threat to patient health and safety is sufficient to find condition-level noncompliance. Likewise, when an ASC has multiple standard-level deficiencies in a CfC, this may add up to pervasive non-compliance and could be sufficient to find condition-level noncompliance.

Determinations of citation level for complaint surveys follow the same process that is applied to full surveys; the only difference is that the complaint survey itself is generally limited to the CfCs implicated in the complaint.

Gathering Additional Information

If it is determined that the survey team needs additional information to determine facility compliance or noncompliance, the Team Coordinator determines the best way to gather such information.

Task 5 - Exit Conference

General Objective

The general objective of this task is to inform the ASC management of the team's preliminary findings.

Prior to the Exit Conference

- The Team Coordinator is responsible for organizing the exit conference, including who will have a speaking role.

- The health and Life Safety Code (LSC) surveyors/survey teams must have one joint exit conference if they are exiting at the same time; otherwise they may conduct separate exit conferences.

- If the team feels it may encounter a problem during the exit conference, the Team Coordinator should contact the SA manager in advance to discuss the potential problems and appropriate methods to handle them.

Discontinuation of an Exit Conference

CMS' general policy is to conduct an exit conference at the conclusion of all types of surveys. However, there are some comparatively rare situations that justify refusal to conduct or continue an exit conference. For example:

- If the ASC is represented by an attorney (all participants in the exit conference, both surveyor team members and ASC staff, must identify themselves prior to beginning the exit conference), surveyors may refuse to conduct the conference if the attorney attempts to turn it into an evidentiary hearing; or

- If the ASC staff /administration create an environment that is hostile, intimidating, or inconsistent with the informal and preliminary nature of an exit conference, surveyors may refuse to conduct or continue the conference. Under such circumstances, it is suggested that the Team Coordinator stop the exit conference and call the SA for further direction.

Recording the Exit Conference

If the facility wishes to audio tape the conference, it must provide two tapes and tape

recorders, recording the meeting simultaneously. The Team Coordinator should select one of the tapes at the conclusion of the exit conference to take back to the SA. Videotaping is also permitted, if the survey team agrees to this, and a copy is provided at the conclusion of the conference. The survey team is under no obligation to consent to videotaping and is not required to offer a reason if it refuses to permit videotaping.

General Principles

The following general principles apply when conducting an exit conference:

- The ASC management determines which ASC staff will attend the exit conference;

- The identity of individual patients or staff members must not be revealed by the survey team when discussing the survey results. Identity includes not just the name of an individual patient or staff member, but also includes any reference or characterization by which identity may be deduced; and

- Because of the information gathering activities the survey team has already engaged in, in most instances members of the ASC's staff should generally be aware prior to the exit conference of the areas, if any, where the survey team has concerns. Accordingly, there should be few cases where the ASC has not already had the opportunity prior to the exit conference to present additional information that might be relevant to the survey team's findings. The exit conference is not the correct setting for further information-gathering activities.

Exit Conference Sequence of Events

Introductory Remarks:

- Thank everyone for their cooperation during the survey;

- Reintroduce all surveyors who participated in the survey, even if they are no longer in the facility;

- Briefly reiterate what was the reason for the survey (i.e., initial, recertification, validation, or complaint); and

- Explain how the team will conduct the exit conference and any ground rules:

    - The exit conference is an informal meeting for surveyors to summarize their preliminary findings;

    - Brief comments on the findings may be made by the ASC, but will not be debated; and

    - Whether comments will be permitted in the middle of a surveyor's

presentation or only after the presentation has concluded.

Presentation of Findings

- Do not refer to any specific ASPEN software data tag numbers when describing deficiency findings. In the process of writing up the findings the SA will finalize just which tags/regulatory text to cite for each finding, so it would be premature to make such statements during the exit conference.

- Present the findings of noncompliance, explaining why the findings indicate noncompliance with the regulatory requirement. If the ASC asks for the pertinent regulatory reference, provide the citation for the applicable CfC.

- Do not make any general characterizations about the survey results (e.g., "Overall the facility is very good." or "In general the facility is in compliance with Medicare requirements.") Stick to presenting the specific factual findings.

- Do not make any statements about whether the findings represent condition-level or standard-level deficiencies. Avoid statements such as, "the condition was not met" or "the standard was not met." It is better to state "the requirement related to XXX is not met."

- If an immediate jeopardy situation was identified during the team discussion that the team had not previously discussed with the ASC's management, explain the significance and need for immediate correction. Follow instructions in Appendix Q, Guidelines for Determining Immediate Jeopardy.

- Do not rank findings. Treat requirements as equal as possible.

- Be certain that all deficiency findings are discussed at the exit conference.

Closure

- Indicate the official survey findings are presented in writing to the ASC via the Form CMS-2567, Statement of Deficiencies and Plan of Correction, which will be prepared and mailed to the ASC within 10 working days. It documents either that no deficiencies were found, or the specific deficiencies found, relating each to the applicable regulatory requirement. There will also be a letter communicating whether or not CMS will be taking enforcement action as a result of the survey's findings.

- The ASC's plan of correction (POC) and time frames for implementation of corrective actions are incorporated into the Form CMS-2567 and returned to the SA. Explain that the Form CMS-2567 is the document disclosed to the public about the facility's deficiencies and what is being done to remedy those (Form CMS-2567 with POC). The Form CMS-2567 is made public no later than 90 calendar days following completion of the survey.

- If any deficiencies have been identified, inform the ASC that a written plan of correction must be submitted to the survey agency within 10 calendar days following receipt of the written statement of deficiencies.

- Explain that, if a POC is required, the ASC will have the following three options:

  - Accept the deficiencies stated on Form CMS-2567 and submit a PoC;

  - Record objections to the cited deficiencies on Form CMS-2567 **and** submit a PoC; or

  - Record objections to cited deficiencies on Form CMS-2567, do not submit a PoC, but submit written arguments and documented evidence that the deficiencies are invalid.

    - CMS will consider objections and accompanying documentation that attempt to refute the factual accuracy of the survey findings, but will not entertain objections to CMS's judgment of the level, extent, scope or severity of a deficiency. CMS reviews additional documentation submitted by provider making an objection and, if the added evidence is convincing, will remove the deficiency.

    - If CMS disagrees with the ASC's objections, the ASC must submit an acceptable POC. Failure to submit an acceptable PoC or failure to correct a deficiency may result in termination of the ASC's supplier agreement in accordance with 42 CFR 488.28(a), and 416.35(b).

Explain that an acceptable plan of correction must contain the following:

- Action that will be taken to correct each specific deficiency cited;

- Description of how the actions will improve the processes that led to the deficiency cited;

- The procedure for implementing the corrective actions;

- A completion date for correction of each deficiency cited;

- Monitoring and tracking procedures to ensure the POC is effective in bringing the ASC into compliance, and that the ASC remains in compliance with the regulatory requirements;

- The title of the person responsible for implementing the acceptable plan of correction; and

- The administrator's signature and the date signed on Page 1 of the Form CMS-

2567.

Indicate that the POC will be reviewed by the SA, or in some cases, the RO, to determine whether it is acceptable. If a POC is determined not to be acceptable, it will be returned to the ASC for revision.

State that in some cases, the SA will make an unannounced revisit survey to determine whether the ASC has come into compliance.

If the exit conference was audio- or videotaped, obtain a copy of the tape before exiting the facility.

All team members should leave the facility together immediately following the exit conference. If the facility staff provides further information for review, the team coordinator determines the best way to review the additional information. It is usually prudent for at least two individuals to remain if all of the team members do not leave at the same time.

Task 6 – Post Survey Activities

General Objective

The general objective of this task is to complete the survey and certification requirements, in accordance with the regulations found at 42 CFR Part 488.

General Procedures

Each SA and RO must follow the instructions in the SOM including:

- Timelines for completing each step of the process;
- Responsibilities for completing the Form CMS 2567, "Statement of Deficiencies," following the "Principles of Documentation;"
- Notification to the ASC regarding survey results;
- Additional survey activities based on the survey results (e.g., revisit, forwarding documents to the RO for further action/direction, such as concurrence with findings for deemed ASCs, authorization of a full survey for deemed ASCs with condition-level deficiencies); and
- Compilation of documents for the supplier's file.

Survey Package

The Team Coordinator will assign responsibilities for completion of the various elements of the survey package.

Statement of Deficiencies Report & Plan of Correction

The Statement of Deficiencies Report and Plan of Correction (Form CMS-2567) is the official document that communicates the determination of compliance or noncompliance with Federal requirements. Also, it is the form that the ASC will use to submit a plan to achieve compliance. Form CMS-2567 is an official record and is available to the public on request.

Indicate on Form CMS-2567 whether any deficiency constitutes immediate jeopardy to the individual's health and safety.

Write each deficiency statement in terms specific enough to allow a reasonably knowledgeable person to understand what regulatory requirements were not met. The consequence for incorrectly or unclearly documenting deficiencies can be the inability of CMS to take needed enforcement action.

Refrain from making clinical judgments. Instead, focus on the ASC's policies and procedures, as well as how they were or were not implemented by the ASC's medical and other staff.

After you complete Form CMS-2567 in ASPEN, submit it to your supervisor for review. If, after reviewing the form, your supervisor approves what you have documented, you will begin working on the remainder of the survey package. If your supervisor does not approve the form, then you will make any requested changes.

Other Survey Package Documentation

Complete the following documentation in hard copy. For complaint investigations, attach these materials to the corresponding complaint in the Aspen Complaint Tracking System:

- Description of sample selection;
- Summary listing of sample cases;
- Summary of interviews;
- Complaint investigation narrative;
- Form CMS-378E Ambulatory Surgical Center Crucial Data Extract
- For all surveys with a Life Safety Code component, Form CMS-2786U Fire Safety Survey Report; and
- Form CMS-670, Survey Team Composition and Workload Report

Part II

General Provisions and Definitions;
General Conditions and Requirements

Interpretive Guidelines

Q-0001
(Rev. 56, Issued: 12-30-09, Effective/Implementation: 12-30-09)

§416.25 Basic Requirements

Participation as an ASC is limited to facilities that –

(a) Meet the definition in §416.2; and

(b) Have in effect an agreement obtained in accordance with this Subpart.

Interpretive Guidelines: §416.25

An ASC must satisfy all the elements of the definition of an ASC and have in effect an agreement to participate as an ASC in order to satisfy the basic Medicare ASC requirements.

Q-0002
(Rev. 95, Issued: 12-12-13, Effective: 06-07-13, Implementation: 06-07-13)

§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 hospitalization and in which the expected duration of services would not exceed 24 hours following an admission. The entity must have an agreement with CMS to participate in Medicare as an ASC and must meet the conditions set forth in Subpart B and C of this part.

Interpretive Guidelines: §416.2

According to the definition of an Ambulatory Surgical Center, or ASC, its key characteristics are that it:

- Is a distinct entity;

- Operates exclusively for the provision of surgical services to patients not requiring hospitalization, with the ASC's services expected not to exceed 24 hours in duration following an admission;

- Has an agreement with Medicare to participate as an ASC; and

- Complies with the Conditions for Coverage (CfCs) in Subparts B and C, i.e., 42 CFR 416.25-52.

Distinct Entity

An ASC satisfies the criterion of being a "distinct" entity when it is wholly separate and clearly distinguishable from any other healthcare facility or office-based physician practice. The ASC is not required to be housed in a separate building from other healthcare facilities or physician practices, but, in accordance with National Fire Protection Association (NFPA) Life Safety Code requirements (incorporated by cross-reference at §416.44(b)), it must be separated from other facilities or operations within the same building by walls with at least a one-hour separation. If there are State licensure requirements for more permanent separations, the ASC must comply with the more stringent requirement.

An ASC does not have to be completely separate and distinct physically from another entity, if, and only if, it is temporally distinct. In other words, the same physical premises may be used by the ASC and other entities, so long as they are separated in their usage by time. For example:

- **Adjacent physician office:** Some ASCs may be adjacent to the office(s) of the physicians who practice in the ASC. Where permitted under State law**, CMS permits certain common, non-clinical spaces,** such as a reception area, waiting room, or restrooms to be shared between an ASC and another entity, as long as they are never used by more than one of the entities at any given time, and as long as this practice does not conflict with State licensure or other State law requirements. In other words, if a physician owns an ASC that is located adjacent to the physician's office, the physician's office may, for example, use the same waiting area, as long as the physician's office is closed while the ASC is open and vice-versa. **The common space may not be used during concurrent or overlapping hours of operation of the ASC and the physician office**. Furthermore, care must be taken when such an arrangement is in use to ensure that the ASC's medical and administrative records are physically separate. During the hours that the ASC is closed, its records must be secure and not accessible by non-ASC personnel.

  Permitting use of common, non-clinical space by distinct entities separated temporally does not mean that the ASC is relieved of the obligation to comply with the NFPA Life Safety Code standards for ASCs, in accordance with

§416.44(b), that require, among other things, a one-hour separation around all physical space that is used by the ASC and fire alarms in the ASC.

It is not permissible for an ASC during its hours of operation to "rent out" or otherwise make available an OR or procedure room, or other clinical space, to another provider or supplier, including a physician with an adjacent office.

- **Facilities with Diagnostic Imaging and Surgery Capability:** Some facilities are equipped to perform both ambulatory surgeries and diagnostic imaging. However, Medicare regulations do not recognize a non-hospital institutional healthcare entity that performs both types of services, and actually requires an ASC to operate exclusively for the purpose of providing surgical services. However, the Medicare Independent Diagnostic Testing Facility (IDTF) payment regulations at 42 CFR 410.33(g) prohibit IDTFs that are not hospital-based or mobile from sharing a practice location with another Medicare-enrolled individual or organization. As a result, ASCs may not share space, even when temporally separated, with a Medicare-participating IDTF.

  NOTE: Certain radiology services integral to surgical procedures may be provided when the facility is operating as an ASC.

- **Separately Certified ASCs Sharing Space:** Where permitted under State law, several different ASCs, including ones that participate in Medicare and ones that do not, may use the same physical space, including the same operating rooms, **so long as they are temporally distinct,** i.e., they do not have concurrent or overlapping hours of operation. However, an ASC and a hospital or CAH outpatient surgery department, including a provider-based department that is either on or off the hospital's or CAH's main campus, may not share the same physical space, since the regulations at 42 CFR 413.65(d)(4) require that the provider-based department be held out to the public as a part of the main hospital, and that patients entering the provider-based facility are aware that they are entering the hospital.

  Each of the different ASCs that utilize the same space is separately and individually responsible for compliance with all ASC Conditions for Coverage (CfCs). So, for example, each ASC must have its own policies and procedures and its own medical records. Likewise, although there is no prohibition against each ASC using the same nursing and other staff under an arrangement with the employer of the staff, each is nevertheless required to separately comply with all requirements governing the utilization of staff in the ASC.

  At the same time, each Medicare-certified ASC that shares the same space as another Medicare-certified ASC should be aware, when entering into such an arrangement, that identification of certain deficient practices may result in citation of deficiencies for all ASCs occupying the same premises. For example, building features that violate the Life Safety Code would not vary according to which ASC happened to be operating on the premises at the time of a survey, and all ASCs at that location would be cited for the deficiency.

If there are multiple ASCs utilizing the same space, but at different times, it may be prudent to consider organizing recertification surveys in order to use the time on-site to conduct multiple surveys allowing assessment of each ASC that utilizes the space.

Exclusive Provision of Limited Surgical Services

The ASC must offer only surgical services. Separate ancillary services that are integral to the surgical services, i.e., those furnished immediately before, during or immediately after a surgical procedure, may be provided. The ASC may not, however, offer services unrelated to the surgeries it performs.

What constitutes "surgery"?

For the purposes of determining compliance with the ASC definition, CMS relies, with minor modification, upon the definition of surgery developed by the American College of Surgeons (**www.facs.org/fellows_info/statements/st-11.html**.) Accordingly, the following definition is used to determine whether or not a procedure constitutes surgery:

> Surgery is performed for the purpose of structurally altering the human body by the incision or destruction of tissues and is part of the practice of medicine. Surgery also is the diagnostic or therapeutic treatment of conditions or disease processes by any instruments causing localized alteration or transposition of live human tissue which include lasers, ultrasound, ionizing radiation, scalpels, probes, and needles. The tissue can be cut, burned, vaporized, frozen, sutured, probed, or manipulated by closed reductions for major dislocations or fractures, or otherwise altered by mechanical, thermal, light-based, electromagnetic, or chemical means. Injection of diagnostic or therapeutic substances into body cavities, internal organs, joints, sensory organs, and the central nervous system, is also considered to be surgery. (This does not include the administration by nursing personnel of some injections, subcutaneous, intramuscular, and intravenous, when ordered by a physician.) All of these surgical procedures are invasive, including those that are performed with lasers, and the risks of any surgical procedure are not eliminated by using a light knife or laser in place of a metal knife, or scalpel.

An ASC is further limited to providing surgical services only to patients who do not require hospitalization after the surgery. Further, the ASC's surgical services must be ones that ordinarily would not take more than 24 hours, including not just the time for the surgical procedure but also pre-op preparation and recovery time, following the admission of an ASC patient. These limitations apply to all of the ASC's surgical services, not just to surgeries on Medicare beneficiaries who use the ASC.

- The term "hospitalization" means that a patient needs a supervised recovery period in a facility that provides hospital inpatient care. Whether a patient "requires" hospitalization after a surgical procedure is a function both of the characteristics of the patient and of the nature of the surgery. In other words, an ASC might be an appropriate setting for a particular surgical procedure for

patients under the age of 65 without significant co-morbidities, but might be a very risky, inappropriate setting for that same procedure when performed on a 75-year old patient with significant co-morbidities. ASCs must consider patient-specific characteristics that might make hospitalization more likely to be required when determining their criteria for patient selection.

Any surgery for which a patient must be routinely transferred to a hospital after the surgery is not appropriate for the ASC setting.

Some States permit the operation of "recovery centers" that are neither Medicare-certified healthcare facilities nor licensed hospitals, but which provide post-operative care to non-Medicare ASC patients. If such recovery centers would be considered hospitals if they participated in the Medicare program, then it is doubtful that an ASC that transfers patients to such centers meets the Medicare definition of an ASC. However, surveyors are not expected to make determinations about the nature of such recovery centers. If a SA is concerned that a recovery center is providing hospital inpatient care, it should discuss this matter further with the CMS Regional Office.

- Expected duration of services. ASCs may not provide services that, under ordinary circumstances, would be expected to exceed 24 hours following an admission. Patients admitted to an ASC will be permitted to stay 23 hours and 59 minutes, starting from the time of admission (see 73 FR at 68714 (November 18, 2008)). The time calculation begins with the admission and ends with the discharge of the patient from the ASC after the surgical procedure. While the time of admission normally would be the time of registration or check-in of the patient at the ASC's reception area, for the purposes of compliance with this requirement ASCs may use the time when the patient moves from the waiting/reception area into another part of the ASC. This time must be documented in the patient's medical record. The discharge occurs when the physician has signed the discharge order and the patient has left the recovery room. Other starting or end points, e.g., time of administration of anesthesia, or time the patient leaves the OR, may not be used to calculate compliance with the 24-hour requirement.

This requirement applies to all ASC surgical services. For services to Medicare beneficiaries there are additional payment regulations that further limit the surgical services that Medicare will pay for. For example, payment regulations at §416.166(b) state, among other criteria, that Medicare will generally pay for surgical procedures for which standard medical practice dictates that the beneficiary would not typically require active medical monitoring and care after midnight of the day of the procedure. This more restrictive Medicare payment requirement is enforced through the claims payment and audit processes. The SA surveyors may not cite an ASC for failing to meet the definition of an ASC if instances of Medicare beneficiaries who remain in the ASC are identified, so long as they meet the 24-hour requirement.

Rare instances of patients whose length of stay in the ASC exceeds 24 hours do not

automatically mean that the ASC fails to meet the regulatory definition of an ASC and must be cited as out of compliance with this requirement. The regulatory language refers to surgical services whose "expected duration" does not exceed 24 hours. It is possible for an individual case to take longer than expected, due to unforeseen complications or other unforeseen circumstances. In such rare cases the ASC continues to be responsible for the care of the patient until the patient is stable and able to be discharged in accordance with the regulatory requirements governing discharge, as well as the ASC's policy. However, if an ASC has cases exceeding 24 hours more than occasionally, this might suggest that the facility is not in compliance with the definition of an ASC.

Cases that surveyors identify which exceed 24 hours must be reviewed further to determine whether the expected duration of services for the procedure in question, when performed on a patient with key clinical characteristics similar to those of the patient in the case, would routinely exceed 24 hours. Key clinical characteristics include, but are not limited to, age and co-morbidities. If the procedure is one that Medicare pays for in an ASC setting, then it can be assumed that the expected duration of services related to that procedure would not exceed 24 hours. If the procedure is not one that Medicare pays for in an ASC, then the ASC must provide evidence supporting its expectation that the services to the patient would not exceed 24 hours. Such evidence could include other cases in the ASC where similar patients (in terms of condition prior to surgery) undergoing the same procedure were discharged in 24 hours or less after admission.

In summary, exceeding the 24-hour time frame is expected to be a rare occurrence, and each rare occurrence is expected to be demonstrated to have been something which ordinarily could not have been foreseen. Not meeting this requirement constitutes condition-level noncompliance with §416.25. In addition, review of the cases that exceed the time frame may also reveal noncompliance with CfCs related to surgical services, patient admission and assessment, and quality assurance/performance improvement.

ASCs should be aware that, to the extent that patients remain within the ASC for 24 hours or longer, for purposes of Life Safety Code requirements the ASC would be considered a "healthcare" rather than an "ambulatory" occupancy under the NFPA Life Safety Code.

Has a Medicare Supplier Agreement

An entity cannot be an ASC, as that term is defined in Medicare's regulations, if it does not have an agreement to participate in Medicare as an ASC. Since ASCs are suppliers, the ASC agreement is a supplier agreement. Thus, while Medicare regulations recognize, for example, non-participating hospitals and will pay them for emergency services under certain circumstances, in the case of an ASC, the term "ASC" has a meaning exclusive to the entity's participation in the Medicare program. Applicants to participate as an ASC are not considered "ASCs" until they actually have a Medicare agreement in place.

In the case of a prospective ASC undergoing an initial survey to determine whether it

may be certified for Medicare participation, the SA may not conduct the survey until the Medicare Administrative Contractor/legacy Carrier has reviewed the ASC's Form 855B enrollment application and made a recommendation for approval of the ASC's participation in Medicare.

Compliance with Subparts B and C

Finally, an ASC must comply with each of the requirements found in Subparts B and C, i.e., the provisions found at 42 CFR 416.25 – 35 for Subpart B, and 42 CFR 416.40 – 52 for Subpart C.

Subpart B contains the supplier agreement requirements for an ASC. Enforcement of these provisions generally follows the same process as that outlined in SOM §3030. Although §3030 specifically addresses failures of providers to comply with the statutory provider agreement requirements, noncompliance of an ASC supplier with the provisions of Subpart B may be handled by CMS Regional Offices in the same way.

Subpart C contains the health and safety standards for ASCs, i.e., the Conditions for Coverage. State Survey Agencies survey ASCs for their compliance with the ASC definition and the CfCs. If an ASC has condition-level noncompliance with numerous CfCs, then condition-level noncompliance with §416.25 may also be cited.

Survey Procedures: §416.2

- Determine through interview and observation and consultation with the LSC surveyor whether the ASC facility is physically separated by at least a 1 hour separation from any other healthcare facility or physician office.

- Determine whether it is permissible under State licensure requirements for an ASC to share its physical space with another entity from which it is temporally separated. If sharing physical space that is temporally separate is not permitted under State law, then it is also not permitted under Medicare.

- Where permitted under State law, if the ASC shares common administrative space with an adjoining or contiguous physician's office or clinic, ask the ASC for evidence that use of this common space by the ASC and the other entity(ies) is not concurrent or overlapping in time. Look for signs or schedules that would confirm that the entities do not use the space at the same time.

- If an ASC complies with all other elements of the ASC definition but has permitted concurrent use by an adjacent physician's office or clinic of common administrative space, this would constitute a standard-level violation. However, co-mingling of services may also result in related deficiencies in the areas of medical records, patients' rights, medical staff, nursing staff, etc. that would be cited under the applicable CfCs, and which together might result in a condition-level violation of §416.25 and possibly the other CfCs.

- Where sharing of space by multiple healthcare entities is permitted under State law, determine through interview, observation and review of facility documents whether the ASC shares the same space, including clinical space, such as ORs, procedure rooms, recovery rooms, etc., with another entity.

    - If it does share space with other healthcare entities, ask the ASC for evidence that the two entities never operate concurrently or have overlapping hours. Look for signs or schedules that would confirm that the entities do not use the same space at the same time.

    - If there are multiple ASCs utilizing the same space and there are deficiencies that are common to more than one ASC, citations must be issued to each ASC.

    - If there is evidence that ASC and another entity that provides services other than surgery share the same space, including clinical space, concurrently or have overlapping hours of operation, this would constitute a condition-level violation of §416.25 because the ASC would not be a distinct entity and it would not be operating exclusively to provide surgical services. In addition, co-mingling of services may also result in related deficiencies in the areas of medical records, patients' rights, medical staff, nursing staff, etc. that would be cited under the applicable CfCs, and which together might result in additional condition-level violations.

    - If there is evidence that ASC and another entity that provides surgical services share the same space, including clinical space, concurrently or have overlapping hours of operation, this would constitute a standard-level violation. However, this co-mingling of services may also result in related deficiencies in the areas of medical records, patients' rights, medical staff, nursing staff, etc. that would be cited under the applicable CfCs, and which together might result in condition-level violation of §416.25 and possibly the other CfCs.

- Review all closed medical records in the survey sample to determine whether the time elapsed between the patient's admission or registration and discharge does not exceed 23 hours and 59 minutes. The calculation of the timeframe begins with the time documented in the medical record indicating when the patient moved from the reception or waiting area into another part of the ASC, if the ASC records this separate from the time of admission in the medical record.

- Determine whether the medical records note the patient's admission and discharge time.

- Observe whether the ASC correctly notes the time of admission for patients checking in and being discharged.

- For cases reviewed that exceed the permitted expected time frame, ask the ASC to provide documentation indicating why it was reasonable to have expected that the

time from admission to discharge would not exceed 24 hours. Acceptable evidence could include, but is not limited to, documentation that the procedure is one that Medicare has previously paid the ASC for, or other cases in the ASC involving the same procedure on similar patients that did not exceed the timeframe. ASCs may produce other evidence for surveyors to assess. Surveyors are not expected to know all of the surgical procedures covered by Medicare in an ASC, although they may obtain more information about this if they choose at http://www.cms.hhs.gov/apps/ama/license.asp?file=/ascpayment/downloads/CMS_1404_FC_ASC_AddAA_BB_DD1_DD2_EE.zip (This link requires a consent to use policies and then leads to a series of spreadsheets; the pertinent one is the ASC Addendum AA.) It is the responsibility of the ASC to demonstrate that the procedure is covered by Medicare when performed in an ASC.

Q-0020

(Rev. 56, Issued: 12-30-09, Effective/Implementation: 12-30-09)

§416.40 Condition for Coverage: Compliance With State Licensure Law

The ASC must comply with State licensure requirements.

Interpretive Guidelines: §416.40

State licensure requirements generally exist for both healthcare facilities and healthcare professionals. States vary considerably in their licensure requirements for entities that meet the Medicare definition of an ASC. Some States may not require separate licensure of these facilities, although all States require licensure of healthcare professionals providing services within the ASC. Some States may require separate licensure for some, but not all ASCs within their State; for example, in some States, ASCs that are operated as part of a physician single or group private practice may not require separate licensure as a healthcare facility. This condition requires that an ASC comply with whatever State licensure requirements are applicable to it.

In States where a separate facility license is required for a facility providing ambulatory surgical services, the ASC must have a current license that has not expired or been suspended or revoked. The ASC must also be in compliance with the State licensure requirements.

Failure of the ASC to meet State licensure law may be cited when the State has made a determination of noncompliance and has also taken a final enforcement action as a result. Citation of licensure deficiencies may represent an initial step rather than a final action or determination by the State licensure authority. Additionally, the Federal survey of the ASC focuses on current compliance or non-compliance, not past noncompliance. Thus, for example, evidence that an ASC had been assessed a civil monetary penalty by the State licensure authority in the previous year would not be grounds for citing the ASC for noncompliance with State licensure law, unless the State licensure authority indicates the

ASC remains noncompliant.

If as a result of a State citation of an ASC for deficiencies in its compliance with licensure requirements the ASC has ceased operations and no longer furnishes services, it would be considered to have voluntarily terminated its Medicare supplier agreement as of the last date on which it provided services to Medicare beneficiaries, in accordance with§416.35(a)(3). The SA must advise the RO of the ASC's cessation of business, and the RO will process a voluntary termination.

If at the time of the survey the ASC's State license has been revoked, suspended, or otherwise formally limited (e.g., admissions have been curtailed by the State), then the ASC is not in compliance with this condition and must be cited for a condition-level deficiency. Furthermore, survey of the rest of the CfCs cannot be completed, since the ASC is not providing surgical services to patients. The SA must advise the RO of such formal licensure enforcement actions and the RO will proceed with action to terminate the ASC supplier agreement, in accordance with standard termination procedures.

If the surveyor identifies a situation that suggests the ASC may not be in compliance with State licensure law, the information may be referred to the State licensure authority for follow-up.

While States vary as to the types of healthcare professionals that require licensure, all ASCs have physicians and nursing staff that require State licensure. It is the ASC's responsibility to verify that all ASC personnel who require a State license have a current license that has not expired or been suspended or revoked.

Survey Procedures: §416.40

- Determine prior to the survey whether a facility license is required for the ASC. If there is access to State licensure files, review the ASC's State licensure status. Otherwise, ask to see the ASC's license.

- Review the ASC's documentation of all personnel required to be licensed under State or local laws or regulations. Check that the ASC has evidence that all personnel requiring licensure have current licenses in good standing.

Q-0040

§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. The governing body has oversight and accountability for the quality assessment and performance improvement program, ensures that the facility policies and programs are administered so as to provide quality healthcare in a safe environment, and develops and maintains a disaster preparedness plan.

Interpretive Guidelines: §416.41

The ASC must have a designated governing body that exercises oversight for all ASC activities. The governing body is responsible for establishing the ASC's policies, making sure that the policies are implemented, and monitoring internal compliance with the ASC's policies as well as assessing those policies periodically to determine whether they need revision. The regulation particularly stresses the responsibility of the governing body for:

- direct oversight of the ASC's quality assessment and performance improvement (QAPI) program (see 72 FR 50472, August 31, 2007) and 73 FR 68714, November 18, 2008;
- the quality of the ASC's healthcare services;
- the safety of the ASC's environment; and
- development and maintenance of a disaster preparedness plan.

In the case of an ASC that has one owner, that individual constitutes the governing body.

Although the governing body may delegate day-to-day operational responsibilities to administrative, medical, or other personnel, the ASC's governing body retains the ultimate responsibility for the overall operations of the ASC and quality of its services. The regulation also emphasizes the governing body's responsibilities in the areas of QAPI and disaster preparedness. Delegations of governing body authority should be documented in writing.

The governing body is responsible for creating a safe environment where ASC patients can receive quality healthcare services. This means the governing body is not only responsible for adopting formal policies and procedures that govern all operations within the ASC, but also that it must take actions to ensure that these policies are implemented. Through its direct oversight and accountability for the ASC's QAPI program, it is expected that the ASC is better able to improve care being furnished to its patients. (See 72 FR 51472, August 31, 2007.) When QAPI citations are made related to 42 CFR 416.43, particularly Standard (e), the citation at 42 CFR 416.41should also be considered.

If condition-level deficiencies are cited related to multiple other ASC CfCs, with the result that the ASC does not provide quality healthcare or a safe environment, then it is also likely that the ASC is not complying with the governing body CfC.

Survey Procedures: §416.41

- Ask the ASC for information about its governing body. If there are questions about who constitutes the ASC's governing body, it may help to review the information the ASC reported in Section 6 of its CMS Form 855B application, identifying those individuals with ownership interest or managing control of the ASC.

- Ask the ASC how frequently the governing body meets and what are the typical

items on its meeting agendas.

- Has the governing body delegated operational responsibility to a manager?
- Ask for an organizational chart of the ASC management. Ask who performs the following functions:
  - Human Resources;
  - Medical staff credentialing and granting of privileges;
  - Management of surgical services;
  - Management of nursing services;
  - Management of pharmaceutical services;
  - Management of laboratory (if applicable) and radiologic services;
  - Management of the ASC's physical plant;
  - Medical records maintenance;
  - Infection control;
  - Quality Assurance and Performance Improvement.
- Ask to see meeting minutes or other evidence that the ASC's policies and procedures have been formally adopted by the governing body.
- Ask to see meeting minutes or other evidence of how the governing body assures that its policies are implemented, and of how the governing body monitors internal compliance with and reassesses the ASC's policies. For example, is there any evidence of data collected and submitted to the governing body related to specific ASC policies?
- Ask to see meeting minutes or other evidence of how the governing body exercises ongoing oversight of and accountability for the ASC's QA/PI program. See the discussion of §416.43 for more detail on the regulatory requirements related to QA/PI.

Q-0041

(Rev. 56, Issued: 12-30-09, Effective/Implementation: 12-30-09)

§416.41(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.

Interpretive Guidelines: §416.41(a)

The ASCs may contract with third parties for provision of the ASC's services, including the ASC's environment. However, such a contract does not relieve the ASC's governing body from its responsibility to oversee the delivery of these ASC services. Given that many ASCs operate closely with a physician practice or clinic, or that some ASCs share space with other ASCs or other types of healthcare facilities operating at different times, use of a wide range of contract services may be common in ASCs. The ASC must assure that the contract services are provided safely and effectively. Contractor services must be included in the ASC's QAPI program.

For example:

- If the ASC contracts for cleaning of the ASC, including its ORs/procedures rooms, the ASC's governing body is still responsible for the sanitary condition of the ASC and must exercise oversight over its contractor to assure that standard sanitary practices are employed.

- If the ASC contracts for the provision of nursing services, the ASC remains responsible for assuring that all contract nurses are properly licensed and trained and oriented to perform their duties within the ASC. The ASC is responsible for the direction of nursing staff, regardless of whether they are employees or provided under contract.

- If the ASC contracts for provision of anesthesia services, the ASC remains responsible for reviewing the credentials of all anesthesiologists and anesthetists providing anesthesia services and granting them privileges to do so.

- If the ASC contracts (for example, with an associated adjacent physician practice) for provision of receptionist services, the ASC is responsible for assuring that such services are provided in a manner that complies with the patients' rights CfC requirements.

- If the ASC contracts for medical records services, it must ensure that the contractor meets all requirements of the medical records CfC.

Survey Procedures: §416.41(a)

- Ask the ASC for a complete list of its currently contracted services.

- Review the personnel files of contract personnel to determine, as applicable, their credentials, privileges, evidence of training, evidence of periodic evaluation, etc.

- If the ASC is one that shares space (temporally separated) with other entities, ask

the ASC whether it contracts or has some other formalized arrangement with any of those other entities for services when the ASC is in operation. If employees of an entity other than the ASC perform services while the ASC is in operation, and the ASC has no contract or other formal documentation of an arrangement with the other entity that governs the provision of such services, then the governing body fails to exercise its responsibility for the administration of the ASC's programs.

- Ask the ASC how it assesses the safety and effectiveness of the services provided by each contractor, including how contractor services are incorporated into its QA/PI program. Select several contractors from the list and ask for documentation of the most recent assessment of each by the ASC.

- Ask the ASC management what process it uses to correct deficiencies in contracted services. Ask if there are any cases where it has identified deficiencies and taken corrective action, and if so, ask to see documentation of these cases.

Q-0042

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§416.41(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 *periodically provide the local hospital with written notice of its operations and patient population served.***

Interpretive Guidelines: §416.41(b)(1-3)

Guidance pending and will be updated in future release.

Q-0060

(Rev. 137, Issued: 04-01-15, Effective: 03-27-15, Implementation: 03-27-15)

§416.42 Condition for Coverage: Surgical Services

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

Interpretive Guidelines: §416.42

The standard level tag for §416.42 (Q-0064) provides more detailed guidance on the requirements for performing surgical services in a safe manner, by qualified physicians. It permits standard-level citations for identified deficiencies.

The manner and degree of noncompliance identified in relation to the standard level tags for §416.42 may result in substantial noncompliance with this CoP, requiring citation at the condition level.

Q-0061

(Rev.71, Issued: 05-13-11, Effective: 5-13-11-Implementation: 05-13-11)

§416.42(a) Standard: Anesthetic Risk and Evaluation

(1) A physician must examine the patient immediately before surgery to evaluate the risk of anesthesia and of the procedure to be performed.

Interpretive Guidelines: §416.42(a)(1)

The purpose of the exam immediately before surgery is to evaluate, based on the patient's current condition, whether the risks associated with the anesthesia that will be administered and with the surgical procedure that will be performed fall within an acceptable range for a patient having that procedure in an ASC, given that the ASC does not provide services to patients requiring hospitalization. The assessment must be specific to each patient; it is not acceptable for an ASC to assume, for example, that coverage of a specific procedure by Medicare or an insurance company in an ASC setting is a sufficient basis to conclude that the risks of the anesthesia and surgery are acceptable generically for every ASC patient. The requirement for a physician to examine the patient immediately before surgery is not to be confused with the separate requirement at 42 CFR 416.52(a)(1) for a history and physical assessment performed by a physician, although it is expected that the physician will review the materials from such pre-admission examination as part of the evaluation. Nevertheless, this requirement does constitute one component of the requirement at 42 CFR 416.52(a)(2) for a pre-surgical assessment upon admission. In those cases, however, where the comprehensive history and physical assessment is performed in the ASC on the same day as the surgical procedure, the assessment of the patient's procedure/anesthesia risk must be conducted separately from the history and physical, including any update assessment incorporated into that history and physical. See the interpretive guidelines for§§416.52(a)(1) & (2).

The ASC must have approved policies and procedures to assure that the assessment of anesthesia-related and procedural risks is completed just prior to every surgical procedure. (Ideally, the ASC would conduct such an assessment prior to the patient's admission as well as immediately prior to surgery, but this is not specifically required by the regulations.)

The ASC's policies must address the basis or criteria used within the ASC in conducting these risk assessments, and must assure consistency among assessments.

The regulations do not specify the content or methodology to be employed in such assessments. As an illustrative example, an ASC might choose to incorporate consideration of a patient's ASA Physical Classification into its criteria. Although the American Society of Anesthesiologists did not create its ASA Physical Status Classification System for the purpose of predicting operative risk, this system has nevertheless been found to be useful in predicting morbidity and mortality in surgical patients[1] and has been used by surgical facilities as a standard tool. This system classifies patients' physical status in 6 levels:

ASA PS I – Normal healthy patient;
ASA PS II – Patient with mild systemic disease;
ASA PS III – Patient with severe systemic disease;
ASA PS IV – Patient with severe systemic disease that is a constant threat to life;
ASA PS V – Moribund patient who is not expected to survive without the operation; and
ASA PS VI – Declared brain-dead patient whose organs are being removed for donor purposes.

As the ASA PS level of a patient increases, the range of acceptable risk associated with a specific procedure or type of anesthesia in an ambulatory setting may narrow. An ASC that employed this classification system in its assessment of its patients might then consider, taking into account the nature of the procedures it performs and the anesthesia used, whether it will accept for admission patients who would have a classification of ASA PS IV or higher. For many patients classified as ASA PS level III, an ASC may also not be an appropriate setting, depending upon the procedure and anesthesia.

If a State establishes licensure limitations on the types of procedures an ASC may perform that are based on patient classifications and would permit ASCs to perform fewer procedures than they would under the CfCs, then the ASC must conform to those State requirements. However, State requirements that would expand the types of procedures an ASC may offer beyond what is permitted under the CfCs are superseded by the Federal CfC requirements.

Endnotes for Standard: Anesthetic Risk and Evaluation

[1]P. 636, Davenport et al., "National Surgical Quality Improvement Program Risk Factors Can Be Used to Validate American Society of Anesthesiologists Physical Status Classification Levels," Annals of Surgery, Vol. 243, No. 5, May 2006

Survey Procedures: §416.42(a)(1)

- Verify that there is evidence for every medical record in the survey sample of an assessment by a physician of the patient's risk for the planned surgery and anesthesia.

- Ask the ASC to provide you with its policies and procedures for assessment of anesthesia and procedural risk. Check to determine that the policies include the criteria the ASC's physicians are to use in making the assessments.

- Ask the ASC's leadership to demonstrate how they assure a consistent approach in the assessment.

- Ask the ASC's leadership whether they can point to any cases where an assessment resulted in a decision not to proceed with the surgery. If there are no such cases, ask the ASC to explain how its patient selection criteria assure that there is an acceptable level of anesthesia and procedural risk for every patient scheduled for surgery in the ASC – for example, do they use patient admission criteria that exclude higher risk patients? If so, ask to see those criteria.

- The survey sample should include cases where a patient died or needed to be transferred to a hospital; discuss the pre-surgical assessment of the patient in those cases, preferably with the physician who conducted the assessments, to explore the basis on which the patient was found to be suitable for the surgery and anesthesia.

Q-0062

(Rev. 56, Issued: 12-30-09, Effective/Implementation: 12-30-09)

§416.42(a) - Standard: Anesthetic Risk and Evaluation

(2) Before discharge from the ASC, each patient must be evaluated by a physician or by an anesthetist as defined at §410.69(b) of this chapter, in accordance with applicable State health and safety laws, standards of practice, and ASC policy, for proper anesthesia recovery.

Interpretive Guidelines: §416.42(a)(2)

An evaluation of the patient's recovery from anesthesia, to determine whether the patient is recovering appropriately, must be completed and documented before the patient is discharged from the ASC. The American Society of Anesthesiology (ASA) guidelines do not define moderate or conscious sedation as anesthesia. While current practice dictates that the patient receiving conscious sedation be monitored and evaluated before, during, and after the procedure by trained practitioners, a postanesthesia evaluation is not required.

The evaluation must be completed and documented by a physician or anesthetist, as

defined at 42 CFR 410.69(b), i.e., a certified registered nurse anesthetist (CRNA) or an anesthesiologist's assistant. See the discussion at §416.42(b) for more discussion of CRNA and anesthesiologist's assistant requirements.

ASCs would be well advised in developing their policies and procedures for postanesthesia care to consult recognized guidelines. For example, Practice Guidelines for Postanesthetic Care, Anesthesiology, Vol 96, No 3, March, 2002, provides the recommendations of the American Society of Anesthesiologists for routine postanesthesia assessment and monitoring, including monitoring/assessment of:

- Respiratory function, including respiratory rate, airway patency, and oxygen saturation;
- Cardiovascular function, including pulse rate and blood pressure;
- Mental status;
- Temperature;
- Pain;
- Nausea and vomiting; and
- Postoperative hydration.

Depending on the specific surgery or procedure performed, additional types of monitoring and assessment may be necessary.

Survey Procedures: §416.42(a)(2)

- Review the ASC's policies and procedures regarding postanesthesia recovery and evaluation to determine if they are consistent with the regulatory requirement. Determine whether the ASC is following its own policy.
- Review a sample of medical records for patients who had surgery or a procedure requiring anesthesia to determine whether a postanesthesia evaluation was conducted for each patient.
- Determine whether the evaluation was conducted by a practitioner who is qualified to administer anesthesia.
- Determine whether the evaluation was performed prior to the patient's discharge.

Q-0063

(Rev. 56, Issued: 12-30-09, Effective/Implementation: 12-30-09)

§416.42(b) - Standard: Administration of Anesthesia

Anesthetics must be administered by only-

(1) A qualified anesthesiologist, or

(2) A physician qualified to administer anesthesia, a certified registered nurse anesthetist (CRNA) or an anesthesiologist's assistant as defined in §410.69(b) of this chapter, or a supervised trainee in an approved educational program. In those cases in which a non-physician administers the anesthesia, unless exempted in accordance with paragraph (c) of this section, the anesthetist must be under the supervision of the operating physician, and in the case of an anesthesiologist's assistant, under the supervision of an anesthesiologist.

§416.42(c) - Standard: State Exemption

(1) An ASC may be exempted from the requirement for physician supervision of CRNAs as described in paragraph (b)(2) of this section, if the State in which the ASC is located submits a letter to CMS signed by the Governor, following consultation with the State's Boards of Medicine and Nursing, requesting exemption from physician supervision of CRNAs. The letter from the Governor must attest that he or she has consulted with State Boards of Medicine and Nursing about issues related to access to and the quality of anesthesia services in the State and has concluded that it is in the best interests of the State's citizens to opt-out of the current physician supervision requirement, and that the opt-out is consistent with State law.

(2) The request for exemption and recognition of State laws, and the withdrawal of the request may be submitted at any time, and is effective upon submission.

Interpretive Guidelines: §416.42(b) & (c)

The ASC's policies and procedures must include criteria, consistent with State law governing scope of professional practice and other applicable State law, for determining the anesthesia privileges to be granted by the governing body to an eligible individual practitioner and a procedure for applying the criteria to individuals requesting privileges. The ASC must specify the anesthesia privileges for each practitioner who administers anesthesia, or who supervises the administration of anesthesia by another practitioner. The privileges granted must be in accordance with State law and the ASC's policy. The type and complexity of procedures for which the practitioner may administer anesthesia, or supervise another practitioner supervising anesthesia, must be specified in the privileges granted to the individual practitioner.

When granting anesthesia privileges to a physician who is not an anesthesiologist, the ASC's governing body must consider the practitioner's scope of practice, State law, the individual competencies, education, and training of the practitioner and the practitioner's compliance with the ASC's other criteria for granting physician privileges.

When an ASC permits operating physicians to supervise CRNAs administering anesthesia, the governing body must adopt written policies that explicitly provide for this.

A CRNA is defined at §410.69(b) as a "…registered nurse who:

(1) is licensed as a registered professional nurse by the State in which the nurse practices;

(2) meets any licensure requirements the State imposes with respect to non-physician anesthetists;

(3) has graduated from a nurse anesthesia educational program that meets the standards of the Council on Accreditation of Nurse Anesthesia Programs, or such other accreditation organization as may be designated by the Secretary; and

(4) meets the following criteria:

(i) has passed a certification examination of the Council on Certification of Nurse Anesthetists, or any other certification organization that may be designated by the Secretary; or

(ii) is a graduate of a program described in paragraph (3) of this definition and within 24 months after that graduation meets the requirements of paragraph (4)(i) of this definition." A CRNA may administer anesthesia in an ASC when under the supervision of the operating physician.

If the ASC is located in a State where the Governor has submitted a letter to CMS attesting that he or she has consulted with State Boards of Medicine and Nursing about issues related to access to and the quality of anesthesia services in the State, and has concluded that it is in the best interests of the State's citizens to opt-out of the current physician supervision requirement, and that the opt-out is consistent with State law, then a CRNA may administer anesthesia without physician supervision.

An anesthesiologist's assistant is defined at §410.69(b) as a "…person who – (1) works under the direction of an anesthesiologist; (2) is in compliance with all applicable requirements of State law, including any licensure requirements the State imposes on nonphysician anesthetists; and (3) is a graduate of a medical school-based anesthesiologist's assistant education program that – (A) is accredited by the Committee on Allied Health Education and Accreditation; and (B) includes approximately two years of specialized basic science and clinical education in anesthesia at a level that builds on a premedical undergraduate science background." An anesthesiologist's assistant may administer anesthesia when under the direct supervision of an anesthesiologist. The anesthesiologist must be immediately available if needed, meaning the anesthesiologist is:

- Physically present in the ASC; and

- Prepared to immediately conduct hands-on intervention if needed.

A trainee who is a physician in training to be an anesthesiologist in a recognized graduate medical education program, or a student in a recognized nurse anesthesia or anesthesiologist's assistance educational program may administer anesthesia in an ASC when supervised by the operating physician, in the case of a nurse anesthetist trainee, or by an anesthesiologist, in the case of a physician trainee or an anesthesiologist's assistant trainee.

Survey Procedures: §§482.42(b) and (c)

- Prior to the survey, determine whether the State has exercised its CRNA physician supervision opt-out option.

- Review the qualifications of individuals authorized to deliver anesthesia in the ASC, to determine whether they are consistent with the regulatory requirements.

- Determine that there is documentation of current licensure or current certification status for all persons administering anesthesia.

- If the ASC uses CRNAs, anesthesiologist's assistants or trainees, interview the ASC's leadership to determine how they are supervised. Do the medical records indicate that required physician supervision is provided?

- When observing a procedure, look for evidence of appropriately trained practitioners with supervision as required by the regulations.

Q-0064

(Rev. 137, Issued: 04-01-15, Effective: 03-27-15, Implementation: 03-27-15)

Standard level tag for

§416.42 Condition for Coverage: Surgical Services

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

Interpretive Guidelines: §416.42

Qualified Physician: Surgery in an ASC may only be performed by a qualified physician. With respect to ASCs, a physician is defined in accordance with §1861(r) of the Social Security Act to include a doctor of medicine or osteopathy, a doctor of dental surgery or dental medicine, and a doctor of podiatric medicine. In all cases, the physician must be licensed in the State in which the ASC is located and practicing within the scope of his/her license.

In addition, the regulation requires that each physician who performs surgery in the ASC has been determined qualified and granted privileges for the specific surgical procedures he/she performs in the ASC. The ASC's governing body is responsible for reviewing the qualifications of all physicians who have been recommended by qualified medical personnel and granting surgical privileges as the governing body determines appropriate.

The ASC must have written policies and procedures that address the criteria for clinical staff privileges in the ASC and the process that the governing body uses when reviewing physician credentials and determining whether to grant privileges and the scope of the privileges for each physician. See the interpretive guidelines for §416.45(a), Medical Staff Membership and Clinical Privileges for further guidance.

Safe Manner: The surgical procedures that take place in the ASC must be performed in a "safe manner." "In a safe manner" means primarily that physicians and other clinical staff follow acceptable surgical standards of practice in all phases of a surgical procedure, beginning with the pre-operative preparation of the patient, through to the post-operative recovery and discharge. Acceptable standards of practice include maintaining compliance with applicable Federal and State laws, regulations and guidelines governing surgical services, as well as, any standards and recommendations promoted by or established by nationally recognized professional organizations (e.g., the American Medical Association, American College of Surgeons, Association of Operating Room Nurses, Association for Professionals in Infection Control and Epidemiology, etc.).

In addition, acceptable standards of practice include the use of standard procedures to ensure proper identification of the patient and surgical site, in order to avoid wrong site/wrong person/wrong procedure errors. Generally accepted procedures to avoid such surgical errors require:

- A pre-procedure verification process to make sure all relevant documents (including the patient's signed informed consent) and related information are available, correctly identified, match the patient, and are consistent with the procedure the patient and the ASC's clinical staff expect to be performed;

- Marking of the intended procedure site by the physician who will perform the procedure or another member of the surgical team so that it is unambiguously clear; and

- A "time out" before starting the procedure to confirm that the correct patient, site and procedure have been identified, and that all required documents and equipment are available and ready for use.

Conducting surgery in a safe manner also requires appropriate use of liquid germicides in the operating or procedure room. It is estimated that approximately 100 surgical fires occur each year in the United States, resulting in roughly 20 serious patient injuries, including one to two deaths annually. Fires occur when an ignition source, a fuel source, and an

oxidizer come together[1]. Heat-producing devices are potential ignition sources, while alcohol-based skin preparations provide fuel. Procedures involving electro-surgery or the use of cautery or lasers involve heat-producing devices. There is concern that an alcohol-based skin preparation, combined with the oxygen-rich environment of an anesthetizing location, could ignite when exposed to a heat-producing device in an operating room. Specifically, if the alcohol-based skin preparation is improperly applied, the solution may wick into the patient's hair and linens or pool on the patient's skin, resulting in prolonged drying time. Then, if the patient is draped before the solution is completely dry, the alcohol vapors can become trapped under the surgical drapes and channeled to the surgical site.

On the other hand, surgical site infections (SSI) also pose significant risk to patients; according to the Centers for Disease Control and Prevention (CDC)[2], such infections are the third most commonly reported healthcare associated infections. Although the CDC has stated that there are no definitive studies comparing the effectiveness of the different types of skin antiseptics in preventing SSI, it also states that "Alcohol is readily available, inexpensive, and remains the most effective and rapid-acting skin antiseptic."3 Hence, in light of alcohol's effectiveness as a skin antiseptic, there is a need to balance the risks of fire related to use of alcohol-based skin preparations with the risk of surgical site infection.

The use of an alcohol-based skin preparation in ASCs is not considered safe, unless appropriate fire risk reduction measures are taken, preferably as part of a systematic approach by the ASC to preventing surgery-related fires. A review of recommendations produced by various expert organizations concerning use of alcohol-based skin preparations in anesthetizing locations indicates there is general consensus that the following fire risk reduction measures are appropriate:

- Using skin prep solutions that are: 1) packaged to ensure controlled delivery to the patient in unit dose applicators, swabs, or other similar applicators; and 2) provide clear and explicit manufacturer/supplier instructions and warnings. These instructions for use should be carefully followed;

- Ensuring that the alcohol-based skin prep solution does not soak into the patient's hair or linens. Sterile towels should be placed to absorb drips and runs during application and should then be removed from the anesthetizing location prior to draping the patient;

- Ensuring that the alcohol-based skin prep solution is completely dry prior to draping. This may take a few minutes or more, depending on the

[1] *Tentative Interim Amendment (TIA 05-02) to (National Fire Protection Association) NFPA 99, 2005 edition, 13.4.1.2.2. Germicides and Antiseptics, issued July 29, 2005 and effective August 18, 2005. See also AORN Guidance Statement: Fire Prevention in the Operating Room; and Patient Safety Advisory June 2005 (Vol. 2 No. 2) 14, Prepared by ECRI for the Pennsylvania Patient Safety Reporting System.*
[2] *CDC Hospital Infection Control Practices Advisory Committee, "Guideline for Prevention of Surgical Site Infection, 1999," Infection Control and Hospital Epidemiology April 1999 (Vol. 20 No. 4) 251.*
3 Ibid, p. 257

amount and location of the solution. The prepped area should be inspected to confirm it is dry prior to draping; and

- Verifying that all of the above has occurred prior to initiating the surgical procedure. This can be done, for example, as part of a standardized pre-operative "time out" used to verify other essential information to minimize the risk of medical errors during the procedure.

ASCs that employ alcohol-based skin preparations in ORs or procedure rooms should establish appropriate policies and procedures to reduce the associated risk of fire. They should also document the implementation of these policies and procedures in the patient's medical record.

Failure by an ASC to develop and implement appropriate measures to reduce the risk of fires associated with the use of alcohol-based skin preparations in ORs or procedure rooms is cited as condition-level noncompliance with §416.44.

Requirements addressed in other ASC Conditions for Coverage are important components of the provision of surgical services in a "safe manner," and condition-level deficiencies in these other areas may also constitute condition-level noncompliance with the Surgical Services Condition. These other pertinent ASC regulatory requirements include:

- §416.44(a)(1), concerning operating room design and equipment – for example:

  - The surgical equipment and supplies are sufficient so that the type of surgery conducted can be performed in a manner that will not endanger the health and safety of the patient;

  - Surgical devices and equipment are monitored, inspected, tested, and maintained by the ASC in accordance with Federal and State law, regulations and guideline, and manufacturer's recommendations; and that

  - Access to the operative and recovery area is limited to authorized personnel and that the traffic flow pattern adheres to accepted standards of practice;

- §416.44(a)(2), concerning a separate recovery room;

- §416.44(a)(3) and §416.51, concerning infection control, for example:

  - The conformance to aseptic and, when applicable, sterile technique by all individuals in the surgical area;

  - That there is appropriate cleaning between surgical cases and appropriate terminal cleaning applied;

  - That operating room attire is suitable for the kind of surgical case

performed;

- That equipment is available for rapid "emergency" high-level disinfection or, as applicable, sterilization of operating room materials;

- That sterilized materials are packaged, handled, labeled, and stored in a manner that ensures sterility e.g., in a moisture- and dust-controlled environment, and policies and procedures for expiration dates have been developed and are followed in accordance with accepted standards of practice.

- That, as applicable, temperature and humidity are monitored and maintained within accepted standards of practice; and

- §416.44(c) & (d), concerning emergency equipment and personnel – for example:

  - That surgical staff are trained in the use of emergency equipment.

Survey Procedures: §416.42

- Determine whether the ASC has policies and procedures that establish the criteria and process the governing body uses when granting surgical privileges to a physician. Ask for documentation that the governing body approved these policies and procedures.

- Ask the ASC to identify each physician who currently has surgical privileges or has had surgical privileges within the previous 6 months. Ask the ASC for documentation of the governing body's action to grant privileges to each of these physicians. Conduct this review in conjunction with the review of compliance with §§416.45(a)&(b).

- For each surgical case record that is reviewed as part of the survey team's medical record review, verify that the individual performing the surgery was a physician who had been granted privileges by the ASC's governing body.

- Observe at least one surgical case from the pre-operative phase through to the recovery room and discharge phase in order to determine whether standard procedures are followed to avoid wrong site/procedure/patient surgical errors, and that the requirements described above are met.

- Determine whether the ASC employs appropriate measures to reduce the risk of surgical fires.

- Ask the ASC whether it has ever had a surgical fire, and if so, what follow-up actions did it take to prevent the recurrence of surgical fires.

Q-0080

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§416.43 Condition 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.

Interpretive Guidelines: §416.43

The QAPI CfC requires an ASC to take a proactive, comprehensive and ongoing approach to improving the quality and safety of the surgical services it delivers. The QAPI CfC presumes that ASCs employ a systems approach to evaluating their systems and processes, identifying problems that have occurred or that potentially might result from the ASC's practices and getting to root causes of problems rather than just superficially addressing one problem at a time.

From a survey perspective, the focus of the QAPI condition is not on whether an ASC has any deficient practices, but rather on whether it has an effective, ongoing system in place for identifying problematic events, policies, or practices and taking actions to remedy them, and then following up on these remedial actions to determine if they were effective in improving performance and quality. QAPI programs work best in an environment that fixes problems rather than assigning blame.

For surveyors this can sometimes pose difficult challenges, because it requires a balancing act. ASCs are not relieved of their obligation to comply with all Medicare CfCs, and surveyors are obligated when they find evidence of violations of a CfC to cite accordingly. However, surveyors generally should avoid using the ASC's own QAPI program data and analyses as evidence of violations of other CfCs. For example, an ASC that identifies problems with infection control through its QAPI program and takes effective actions to reduce the potential for transmission of infection would be taking actions consistent with the QAPI CfC. Absent evidence independently collected by the surveyors of current noncompliance with the infection control CfC, it would not be appropriate for surveyors to use the infection control information in the ASC's QAPI program as evidence of violations of the infection control CfC. There can be egregious cases under investigation where it might be appropriate to use QAPI program information as evidence of a deficiency, but these cases should be the exception rather than the rule.

CMS does not prescribe a particular QAPI program; it provides each ASC with the flexibility to develop its own program. Each program must, however, satisfy the regulatory criteria:

- Ongoing – i.e., the program is a continuing one, not just a one-time effort. Evidence of this would include, but is not limited to, things like collection by the ASC of quality data at regular intervals; analysis of the updated data at regular intervals; and updated records of actions taken to address quality problems

identified in the analyses, as well as new data collection to determine if the corrective actions were effective.

- Data-driven – i.e., the program must identify in a systematic manner what data it will collect to measure various aspects of quality of care; the frequency of data collection; how the data will be collected and analyzed; and evidence that the program uses the data collected to assess quality and stimulate performance improvement.

Survey Procedures: §416.43

When there is a team surveying the ASC, survey of the QAPI Condition should be coordinated by one surveyor.

Q-0081

(Rev.56, Issued: 12-30-09, Effective/Implementation: 12-30-09)

§416.43(a) & §416.43(c)(1)

§416.43(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 by the identification and reduction of medical errors.

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

§416.43(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.

Interpretive Guidelines: §416.43(a) & §416.43(c)(1)

There are a variety of types of indicators that are currently in use for measuring and improving quality of healthcare. This is also a rapidly changing field, as interest and research in patient safety and healthcare quality measurement grows. As a result of a recommendation of a 1998 Presidential Advisory Commission, the National Quality

Forum (NQF), a public-private not-for-profit membership organization, was created in 1999 to develop and implement a national strategy for healthcare quality measurement and reporting. Since then NQF has developed detailed recommendations for ways to promote and measure quality and patient safety, including in ASCs. The federal Agency for Healthcare Quality and Research (AHRQ) supports research assessing the effectiveness of care practices and procedures. A number of other organizations are also active in the field of healthcare quality improvement and patient safety. As a result, ASCs have many choices of indicators to use.

Indicators can be broken down into several types:

- **Outcomes Indicators** measure results of care; typical outcomes measures include risk-adjusted mortality rates, complication rates, healthcare-associated infection rates, length of stay, readmission rates, etc. In the ASC setting, outcomes measures might focus on things like complication rates, healthcare-associated infection rates, cases exceeding 24 hours, transfers to hospitals, wrong site surgeries, etc.

- **Process of Care Indicators** measure how often the standard of care was met for patients with a diagnosis related to that standard. For example, in the ASC setting, measures might focus on the administration and time of prophylactic antibiotics.

- **Patient Perception Indicators** measure a patient's experience of the care he/she received in the ASC. AHRQ sponsored development of one patient experience of care instrument, H-CAHPS, that CMS now uses in reporting on hospital quality. There may be similar patient survey instruments that could be used in the ASC setting.

The regulation at **§416.43(a)** requires that an ASC's QAPI program must improve both patient health outcomes and patient safety in the ASC. In order to achieve these goals, the ASC's QAPI program must:

1. Be ongoing – i.e., the program is a continuing one, not just a one-time effort or occasional effort. Evidence that the ASC's program is ongoing would include, for example, collection by the ASC of quality data at regular intervals; analysis of the updated data at regular intervals; and updated records of actions taken to address quality problems identified in the analyses, as well as new data collection to determine if the corrective actions were effective.

2. Use quality indicators or performance measures associated with improved health outcomes in a surgical setting. The quality and safety indicators available differ in terms of the weight and type of evidence for their effectiveness in measuring quality. For some indicators there is compelling peer-reviewed research of an association with improved health outcomes. For others, typically process of care indicators, consensus among experts in the field suggests a strong association with improved quality of care. Indicators also differ in terms of how the data is collected, and how frequently the data should be collected.

   For example, measures of how quickly an ASC produces error-free billing claims,

while relevant to the ASC's financial performance and of interest to ASC governing bodies, have no direct relationship to the quality of care the ASC provides. On the other hand, a measure of the frequency with which the ASC administers antibiotic prophylaxis consistent with generally accepted standards of care would be related to improved health outcomes, i.e., prevention of surgical site infections. Likewise, an ASC could choose to collect data measuring its compliance with applicable National Quality Forum Safe Practices, or with applicable Centers for Disease Control and Prevention (CDC) infection control guidelines, or with guidelines issued by national professional societies, such as the American College of Surgeons, or with recommended practices developed by national accreditation organizations or other organizations specializing in healthcare quality improvement, such as the Institute for Healthcare Improvement. CMS does not prescribe a certain set of indicators/measures for ASCs to use, but ASCs must be able to demonstrate that the indicators they are tracking will enable them to improve outcomes for ASC patients.

The regulations at §416.43(c)(1) also require the ASC to set priorities in choosing its quality indicators/measures, because what is measured will determine where the ASC focuses its efforts to make changes that improve performance. For example, if the ASC does not track measures related to infection control, it will not be in a position to determine whether or not its infection control program is working well or poorly, and thus will not be in a position to improve it.

The ASC is required to focus on high risk, high volume, and problem-prone areas. It is required to consider, when selecting the measures/indicators that will shape its improvement activities in these areas, the following:

- The incidence, i.e., the rate or frequency at which problems occur in the ASC related to area measured by the indicator. "Incidence" is a technical term used in epidemiology, referring to the frequency with which something, such as a disease, appears in a particular population or area. In disease epidemiology, the incidence is the number of newly diagnosed cases during a specific time period. Applying this concept in the ASC setting, as an example, the annual incidence of surgical site infections in an ASC would be the rate that results when dividing the number of such infections that occurred in a calendar year by the total number of surgical cases in the ASC during that same year. Likewise, the annual incidence of emergency transfers to a hospital would be the rate that results when dividing the number of such transfers by the total number of surgical cases during the same year;

- The prevalence, i.e., how widespread something is in an ASC at a given point in time. "Prevalence" is also a technical term used in epidemiology, and is a statistical concept referring to the number of cases of a disease that are present in a particular population at a given time. In an ASC setting, for example, it would make little sense to employ measures related to prevalence of pressure ulcers among ASC patients, since the limited amount of time a patient typically spends in an ASC makes it unlikely that the ASC's care processes contributes to pressure ulcers. On the other hand a more appropriate measure might be periodic

observation of the hand hygiene practices of all staff providing direct patient care, in order to assess the prevalence of good versus deficient practices; and

- The severity of problems. For example, any single instance of a transfer of a patient to a hospital represents a serious adverse, unplanned outcome of the surgical procedure, and it would be appropriate for an ASC to track and evaluate all such cases, due to their severity, even if they are low volume incidents.

Once having identified the quality indicators it will use, the ASC must collect and analyze data on these indicators.

3. Identify and reduce medical errors/adverse patient events. Although there is no single, standard definition of a medical error or adverse event, the Institute of Medicine created a series of definitions related to patient safety that are helpful in understanding the regulatory requirement:

"An **error** is defined as the failure of a planned action to be completed as intended (i.e., error of execution) or the use of a wrong plan to achieve an aim (i.e., error of planning)."

"An **adverse event** is an injury caused by medical management rather than the underlying condition of the patient."

"An adverse event attributable to error is a **preventable adverse event**."[1]

Using these definitions, if an ASC performing orthopedic procedures operates on the right shoulder of a patient with a left shoulder rotator cuff injury requiring surgery, then the ASC has committed an error. The patient suffered an adverse event – i.e., the harm to the patient of undergoing surgery on the wrong shoulder, and presumably having to undergo yet another surgery on the correct shoulder. Because the ASC's error resulted in the adverse event, it is a preventable adverse event that could and should have been avoided.

Not every adverse event is the result of an error. For example, the standard of practice might call for use of a particular medication when certain indications are present. A patient might have an allergy to that medication that is unknown to the patient and the patient's physicians. The patient develops an allergic reaction to the medication, requiring further medical intervention to counteract the reaction. Due to the unknown nature of the patient's allergy, there was no error, even though there was an injury resulting from medical management. On the other hand, if the allergy had been documented in the patient's medical record and the medication had been administered anyway, this would constitute an error.

Not every error results in an adverse event; for example, an ASC with two operating rooms might mix up the records of two ASC patients scheduled to have the same orthopedic procedure, e.g., foot surgery, on the same date, but on the opposite feet. This is an error. But the ASC employs a time-out procedure to verify the identity of the patients and site of the surgery and recognizes the error

before surgery begins. The error did not result in an adverse event, but it was a near miss.

ASCs must track all patient adverse events, in order to determine through subsequent analysis whether they were the result of errors that should have been preventable, to reduce the likelihood of such events in the future. ASCs are also expected to identify errors that result in near misses, since such errors have the potential to cause future adverse events.

ASCs seeking initial enrollment in the Medicare program are unlikely to have collected extensive data for their QAPI program indicators, since they likely have been in operation for a relatively brief period of time. Nevertheless, these initial applicants must have a QAPI program in place, and must be able to describe how the program functions, including which indicators/measures are being tracked, at what intervals, and how the information will be used by the ASC to improve quality and safety.

Examples of ASC Quality/Patient Safety Indicators

The following information is based on the National Quality Forum's (NQF) consensus standards for ASCs, and is provided only as an illustration of several types of measures an ASC might choose to include in its QAPI program. An ASC is free to use different measures, so long as the measures it chooses meets the regulatory criteria. ASCs are also expected to develop additional measures related to infection control, for example to enable it to comply with the requirement at §416.51(b)(2) for its infection control program to be integrated into its QAPI program, and at §416.44(a)(3) to have a program to identify healthcare associated infections and report diseases as required under State law. Depending on the individual characteristics of the ASC, including problems it had experienced in the past, it may be necessary to track other additional indicators as well.

More information on these and other NQF ASC measures is available at: **http://www.qualityforum.org/pdf/ambulatory/tbAMBALLMeasuresendorsed%2012-10-07.pdf**

- **Patient Burn** – Percentage of ASC admissions experiencing a burn prior to discharge. Approximately 100 surgical fires occur each year nationally, in all surgical settings, with about 20 resulting in serious injuries to patients.

- **Prophylactic Intravenous Antibiotic Timing** – Percentage of ASC patients who received appropriate antibiotics ordered for surgical site infection prophylaxis on time.

- **Hospital Transfer/Admission** – Percentage of ASC admissions requiring a hospital transfer or hospital admission prior to being discharged from the ASC.

- **Patient Fall** – Percentage of ASC admissions experiencing a fall in the ASC.

- **Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant**

- Percentage of ASC admissions experiencing a wrong site, wrong side, wrong patient, wrong procedure, or wrong implant.

Survey Procedures: §416.43(a)

- Ask the ASC's leadership to describe the QAPI program, including staff responsibilities for QAPI and the quality/safety indicators being tracked.

- Ask what the rationale is for the particular indicators that the ASC has chosen to track. Are they based on nationally-recognized recommendations? If not, what evidence does the ASC have that the indicators it has chosen are associated with improvement in patient health outcomes and safety?

  - At a minimum, do the indicators include cases of patients transferred from the ASC to a hospital?
  - At a minimum, do the indicators include measures appropriate for surgery and infection control measures?

  - At a minimum, does the ASC have a system for tracking adverse patient events?

- Ask the staff responsible for QAPI what the method and frequency is for data collection for each QAPI program indicator.

[1]P. 28, ToErr is Human, Institute of Medicine, November, 1999.

Q-0082

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§416.43(b) and §416.43(c)(2) & (3)

§416.43(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.

(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.

§416.43(c) Standard: Program Activities

(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.

Interpretive Guidelines: §416.43(b)& §416.43(c)(2) & (3)

Active Data Collection

The ASC must not only have identified a number of indicators or measures of quality and patient safety, but it must actively collect data related to those measures at the intervals called for by its QAPI program. Staff responsible for collection of the data should be trained in appropriate techniques to collect and maintain the data.

Data Analysis

Once having collected the data, the ASC must analyze it to monitor ASC performance, i.e., to determine what the data suggests about the ASC's quality of care and the effectiveness and safety of its services. Analysis must take place at regular intervals, in order to avoid too much time elapsing before the ASC is able to detect problem areas. In the case of data related to adverse events, the ASC must use the data to analyze the cause(s) of the adverse events. Data collection and analysis must be conducted by personnel with appropriate qualifications to collect and interpret quantitative data. CMS does not expect ASCs to engage in sophisticated statistical modeling of data, but calculation of incidence rates should be within the skill set of individual(s) conducting the analysis. On the other hand, CMS does expect ASCs to conduct thorough analyses that focus on systemic issues. For example, if the ASC's adverse event tracking system identifies a medication error that resulted in serious injury to a patient, the ASC would not be taking the type of systems approach mandated under the QAPI regulations if it states that the event was caused by the staff member who administered the medication incorrectly, and that its method for improving performance was to fire that staff member. An acceptable analysis would look at the root causes that facilitated the error by the staff member: Were medications stored in a manner that increased the possibility of error? Were the physician's orders clearly written? Was the staff member appropriately trained? Is there any evidence of similar errors made by other staff members, including errors that did not result in adverse events? There are probably additional issues that should be investigated in order to fully understand the causes of the adverse event. Once there is a thorough analysis of these causes, the ASC would then be in a better position to identify improvement strategies that are appropriately designed to address the underlying causes.

The ASC may choose to use contractors for technical aspects of the QAPI program, including analysis of data, but the ASC is also expected to actively involve ASC staff in the program and the ASC's leadership retains the responsibility for the ongoing management of the program, even when a contractor is used.

Analysis of the monitoring data must be used to identify areas where there is room for

improvement in the ASC's performance, as well as follow-up actions taken to improve performance. A good monitoring system, even in a good ASC surgical program, is likely to always find some areas of performance that are weaker than others. These identified areas of weakness present opportunities for the ASC to make changes in its systems, policies or procedures that result in improved patient care.

Implement Improvements/Preventive Strategies

Once the ASC's analysis of its data has identified opportunities for improvement, the ASC must develop specific changes in its policies, procedures, equipment, etc., as applicable, to accomplish improvements in the identified areas of weakness. In particular, an ASC must implement preventive strategies designed to reduce the likelihood of adverse events throughout the ASC. For example, if an ASC has three operating or procedure rooms, and it has an adverse event in a case in one of these rooms that is attributable in part to a confusing storage of emergency medications, the ASC should review the set up in each of the rooms to ensure that the same problem does not occur elsewhere.

Sustaining Improvements

The ASC must also have a method to ensure that the improvements it makes are sustained over time. For example, if an ASC's QAPI program identifies problems with hand hygiene in ASC staff providing care to patients, the ASC must be able to demonstrate that whatever solution it adopted to address this problem continues to work over time. Generally this means that the ASC must collect data on indicators that measure staff hand hygiene on an ongoing basis.

Staff Training

The ASC is required to make all staff aware of the strategies it has adopted for prevention of adverse events. For example, all staff who are involved in the preparation of a patient for the surgical procedure, as well as in the conduct of the surgical procedure, must be familiar with the ASC's strategies for avoiding wrong patient, wrong site, wrong side, wrong procedure, wrong implant, and adverse surgical events. All staff involved in the preparation and administration of injectable medications should be aware of standard safe injection practices designed to avoid the transmission of infectious disease. Staff should be encouraged to ask questions when they observe a practice, or receive an order, etc. that they believe might compromise patient safety or quality of care in the ASC.

Prospective ASC's Applying for Initial Certification in Medicare

A facility seeking initial certification as an ASC may not have been in operation long enough to demonstrate extensive data collection or the identification of opportunities for improvement based on the monitoring data. However, it must be able to show that it has an active data collection and analysis infrastructure in place as well as to indicate when it expects to have sufficient data to begin analysis and what procedures it has put in place to consider the results of QAPI program analyses.

Survey Procedures: §416.43(b)

- Ask the ASC to show you examples of quality and adverse event data it is collecting. Is the ASC collecting data on all of the indicators/measures it identified for its QAPI program? Is it collecting the data at the frequency specified in its QAPI program?

- Ask the ASC who is responsible for the data collection and analysis, and what their qualifications are? In particular, ask the ASC how it determines the causes of adverse events – does the ASC stop with the immediate cause (staff error, equipment failure, etc.) or does it probe to discover the underlying root causes of the adverse events?

- If ASC staff handle these duties, do they have education or training that equips them to conduct analyses of the data?

- Ask the ASC to provide examples of instances where it used QAPI data to identify opportunities for improving processes for providing care. Ask how it evaluated whether the improvements were effective and sustained.

- Ask the ASC how it trains staff on ways to prevent adverse events from occurring.

- Ask ASC staff what they know about the ASC's QAPI program, focusing in particular on staff awareness of policies and procedures for preventing adverse events.

Q-0083

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§416.43(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.

Interpretive Guidelines: §416.43(d)

Every ASC must undertake one or more specific quality improvement projects each year. Larger ASCs with multiple ORs or procedure rooms, multiple types of surgical procedures offered, or high volume of cases are expected to undertake more or more complex projects. Furthermore, a highly complex improvement project might be of such scope that it could reasonably be the only project an ASC undertakes in a given year.

CMS does not specify particular projects that each ASC must undertake, but instead expects the projects to be based on the types of services the ASC furnishes, as well as other aspects of the ASC's operations. The requirement for annual projects does not mean that an ASC may not undertake a complex project that is expected to require more than 1 year in order to be completed.

The ASC must keep records on its performance improvement projects. Each project must, at a minimum, include an explanation of why the project was undertaken. The explanation must indicate what data collected in the ASC or based on recommendations of nationally recognized organizations leads the ASC to believe that the project's activities will actually result in improvements in patient health outcomes and safety in the ASC. For projects that are still underway, the ASC must be able to explain what activities the project entails, and how the impact of the project is being monitored. Unless the project has just begun, the ASC must be able to provide evidence that it is collecting data that will enable it to assess the project's effectiveness. For projects that are completed, the ASC must be able to show documentation that explains what the results of the project were, and what actions, if any, the ASC took in response to those results.

Survey Procedures: §416.43(d)

- Ask the ASC to show you documentation for performance improvement projects currently underway, as well as those completed in the prior year.

- If a large, complex, or high volume ASC has only one project underway, is the scope of that project such that it is likely to have a significant impact on the ASC's quality of care or patient safety?

- Does the ASC's documentation indicate the rationale for undertaking each project? Does the ASC have data indicating it had a problem in the area targeted for improvement, or could the ASC point to recommendations from a nationally recognized expert organization suggesting the activities?

- Does the documentation for the completed project(s) include the project's results? If a project was unsuccessful, ask the ASC what actions it took as a result of that information. If the project was successful, ask the ASC how it is sustaining the improvement.

Q-0084

(Rev.56, Issued: 12-30-09, Effective/Implementation: 12-30-09)

§416.43(e) Governing body responsibilities.

The governing body must ensure that the QAPI program –

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

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

(3) Specifies data collection methods, frequency, and details.

(4) Clearly establishes its expectations for safety.

(5) Adequately allocates sufficient staff, time, information systems and training to implement the QAPI program.

Interpretive Guidelines: §416.43(e)

An ongoing, successful QAPI program requires the support and direction of the ASC's leadership. This regulation makes clear CMS' expectations that the ASC's governing body must assume responsibility for all aspects of the design and and implementation of every phase of the QAPI program. The governing body must assure that the ASC's QAPI program:

- Is defined, in writing, for example in the minutes of a meeting where the governing body established the program;
- Is actually implemented, with written evidence of this implementation, as well as evidence of knowledge of the program by the ASC's staff;
- Is implemented on an ongoing basis;
- Employs quality and patient safety indicators that reflect appropriate prioritization, as required by §416.43(c);
- Describes in detail the indicator data to be collected, how it will be collected, how frequently it will be collected;
- Uses the data collected and analyzed to improve the ASC's performance;
- Evaluates changes designed to improve the ASC's performance to determine whether they are effective, and takes appropriate actions to make further changes as needed;
- Is designed to establish clearly the governing body's expectations that patient safety is a priority, not only by the tracking of all adverse events, but also by the program's processes for analyzing and making changes in ASC operations to prevent future such events; and
- Has sufficient resources, i.e., the ASC's governing body must allocate sufficient and qualified staff (including consultants)**,** staff time, information systems and training to support the program. Given the great variety in size and complexity among ASCs, the extent of resources required will vary as well. However, the resources dedicated to the QAPI program must be commensurate with the ASC's

overall scope and complexity. The ASC must also be able to identify in detail the resources that it dedicates to the QAPI program.

Survey Procedures: §416.43(e)

- Does the ASC's QAPI program include all of the essential elements described above?

- Ask the ASC's leadership to explain how the governing body is involved in the QAPI program. Does the ASC's leadership display ready knowledge of the program's structure and activities. If a contractor is used for some portions of the program, does the ASC's leadership monitor closely the contractor's activities?

- Is there evidence of a governing body review of all elements of the QAPI program, e.g., meeting minutes?

- Ask the ASC's leadership how it uses the program to improve performance. Ask for evidence of changes made as a result of QAPI program activities.

- Ask the ASC's leadership for documentation of the details of the resources that are dedicated to the QAPI program. Is there evidence that these resources were actually made available as planned? For example, interview staff identified as having a role in the QAPI program to determine whether they actually perform QAPI functions, and for what percentage of their time. Is there evidence that planned data collections and analyses actually took place?

Q-0100

(Rev.56, Issued: 12-30-09, Effective/Implementation: 12-30-09)

§416.44 Condition for Coverage: Environment

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

Interpretive Guidelines: §416.44

The ASC must comply with requirements governing the construction and maintenance of a safe and sanitary physical plant, safety from fire, emergency equipment and emergency personnel.

Survey Procedures: §416.44

A surveyor trained in surveying for the applicable Life Safety Code standards must survey for compliance with the Safety from Fire Standard; the rest of the standards under this Condition are surveyed by Health surveyors.

Q-0101
(Rev. 137, Issued: 04-01-15, Effective: 03-27-15, Implementation: 03-27-15)

§416.44(a) Standard: Physical Environment

The ASC must provide a functional and sanitary environment for the provision of surgical services.

(1) Each operating room must be designed and equipped so that the types of surgery conducted can be performed in a manner that protects the lives and assures the physical safety of all individuals in the area.

Interpretive Guidelines: §416.44(a)(1)

State Agencies may wish to assign surveyors who are trained in evaluating healthcare facility design and construction assist in evaluating compliance with this standard. "Operating room" (OR) in an ASC includes not only traditional ORs, but also procedure rooms, including those where surgical procedures that do not require a sterile environment are performed.

ORs must be designed in accordance with industry standards for the types of surgical procedures performed in the room, including whether the OR is used for sterile and/or non-sterile procedures. Existing ORs must meet the standards in force at the time they were constructed, while new or reconstructed ORs must meet current standards. Although the term "OR" includes both traditional ORs and procedure rooms, this does not mean that procedure rooms must meet the same design and equipment standards as traditional operating rooms. In all cases, the OR design and equipment must be appropriate to the types of surgical procedures performed in it.

National organizations, such as the Facilities Guidelines Institute, may be used as a source of guidance to evaluate OR design and construction in an ASC. If a State's licensure requirements include specifications for OR design and construction, the ASC must, in accordance with §416.40, comply with those State requirements.

The location of the OR within the ASC and the access to it must conform to accepted standards of practice, particularly for infection control, with respect to the movement of people, equipment and supplies in and out of the OR. The movement of staff and patients on stretchers must proceed safely, uninhibited by obstructions.

The OR must also be appropriately equipped for the types of surgery performed in the ASC. Equipment includes both facility equipment (e.g., lighting, generators or other back-up power, air handlers, medical gas systems, air compressors, vacuum systems, etc.) and medical equipment (e.g., biomedical equipment, radiological equipment if applicable, OR tables, stretchers, IV infusion equipment, ventilators, etc.). Medical equipment for the OR includes the appropriate type and volume of surgical and anesthesia equipment, including surgical instruments. Surgical instruments must be available in a quantity that is commensurate with the ASC's expected daily procedure volume, taking into

consideration the time required for appropriate cleaning and, if applicable, sterilization. In addition, emergency equipment determined to be necessary in accordance with §416.44(c) must be either in or immediately available to the OR.

The OR equipment must be inspected, tested and maintained appropriately by the ASC, in accordance with Federal and State law (including regulations) and manufacturers' recommendations.

Temperature, humidity and airflow in ORs must be maintained within acceptable standards to inhibit microbial growth, reduce risk of infection, control odor, and promote patient comfort. ASCs must maintain records that demonstrate they have maintained acceptable standards.

An example of an acceptable humidity standard for ORs is the American Society for Heating, Refrigerating, and Air Conditioning Engineers (ASHRAE) Standard 170, Ventilation of Health Care Facilities. Addendum D of the ASHRAE standard requires RH in ORs to be maintained between 20 - 60 percent. In addition, this ASHRAE standard has been incorporated into the Facility Guidelines Institute (FGI) 2010 Guidelines for Design and Construction of Health Care Facilities, and has been approved by the American Society for Healthcare Engineering of the American Hospital Association and the American National Standards Institute. ASCs must also ensure, however, that the OR humidity level is appropriate for all of their surgical and anesthesia equipment, and that supplies which require a different level of humidity than that in the OR are appropriately stored until used.

Each operating room should have separate temperature control. Acceptable standards for OR temperature, such as those recommended by the Association of Operating Room Nurses (AORN) or the FGI, should be incorporated into the ASC's policy.
Equipment for rapid emergency sterilization of OR equipment/materials whose sterility has been compromised must be available on-site. However, an ASC that routinely uses sterilization procedures intended for emergency use only as its standard method of sterilization between cases, in order to reuse surgical instruments, must be cited for violating §§416.44(a)(1) & (3) and the Infection Control Condition at §416.51.

It is not necessary for the ASC to have equipment for routine sterilization of equipment and supplies on-site, so long as this service is provided to the ASC under arrangement.

Survey Procedures: §416.44(a)

- Verify the ASC's ORs meet applicable design standards.
- Verify the ASC has the right kind of equipment in the ORs for the types of surgery it performs.
- Verify the ASC has enough equipment, including surgical instrument sets, for the volume of procedures it typically performs.

- Verify the ASC has evidence, such as logs on each piece of electrical or mechanical equipment, indicating that it routinely inspects, tests, and maintains the equipment.

- Verify who within the ASC is responsible for equipment testing and maintenance.

- Considering the size of the OR and the amount and size of OR equipment, verify there is sufficient space for the unobstructed movement of patients and staff.

- Review the ASC's temperature and humidity records for ORs, to ensure that appropriate levels are maintained and that, if monitoring determined temperature or humidity levels were not within acceptable parameters, that corrective actions were performed in a timely manner to achieve acceptable levels.

Q-0102

(Rev.56, Issued: 12-30-09, Effective/Implementation: 12-30-09)

§416.44(a) Standard: Physical Environment

[The ASC must provide a functional and sanitary environment for the provision of surgical services.]

(2) **The ASC must have a separate recovery room and waiting area**.

Interpretive Guidelines: §416.44(a)(2)

The ASC is required to have both a waiting area and a recovery room, which must be separate from each other as well as other parts of the ASC. They may not be shared with another healthcare facility or physician office. (See the interpretive guidelines for §416.2 concerning sharing of physical space by an ASC and another entity.)

There must be a room within the ASC where patients recover immediately after surgery. A "room" consists of an area with at least semi-permanent walls from floor to ceiling separating it from other areas of the ASC. The recovery room must be equipped to allow appropriate monitoring of the patient's recovery. The type of equipment required depends on the type(s) of surgery performed in the ASC. The size of the recovery room must be commensurate with the number of ORs in the ASC and the expected volume of patients who will be in recovery simultaneously.

The recovery room may also be used for preoperative preparation of patients as well as for post-operative recovery, consistent with accepted standards of practice. Under no circumstances, however, may the recovery room also be used as a general waiting area for patients awaiting preoperative preparation or for people who accompany patients. Likewise, patients recovering from surgery may not be placed in a waiting room or area,

unless they have already been discharged from the ASC and are, for example, waiting briefly while the adult who accompanied them brings a car to the ASC's entrance.

Consistent with accepted standards of practice, including infection control standards, and protection of patients' rights to privacy and confidentiality of their clinical information the ASC may permit individuals who accompany patients to be present in the recovery room during the patient's recovery from surgery.

Survey Procedures: §416.44(a)(2)

- Observe whether there is a separate room in which patients recover from their surgery, and whether it is appropriately equipped.
- Observe whether there is a separate waiting area for visitors and patients who have not yet begun preoperative preparation.

Q-0104

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§416.44(b) Standard: Safety From Fire

(1) Except as otherwise provided in this section, the ASC must meet the provisions applicable to Ambulatory Health *Care Occupancies, regardless of the number of patients served, and must proceed in accordance with* the Life Safety Code *(NFPA 101 and Tentative Interim Amendments TIA 12-1, TIA 12-2, TIA 12-3, and TIA 12-4).*

(2) In consideration of a recommendation by the State survey agency *or Accrediting Organization or at the discretion of the Secretary, may waive, for periods deemed appropriate,* specific provisions of the Life Safety Code, which would result in unreasonable hardship upon an ASC, but only if the waiver will not adversely affect the health and safety of the patients.

(3) The provisions of the Life Safety Code do not apply in a State if CMS finds that a fire and safety code imposed by State law adequately protects patients in an ASC.

Interpretive Guidelines: §416.44(b)*(1)-(3)*

Guidance pending and will be updated in future release.

Q-0105

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

(4) An ASC may place alcohol-based hand rub dispensers in its facility if the dispensers are installed in a manner that adequately protects against inappropriate access.

Interpretive Guidelines: §416.44(*b*)*(4)*

Guidance pending and will be updated in future release.

Q-0106

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

(5) When a sprinkler system is shut down for more than 10 hours, the ASC must:

> ***(i) Evacuate the building or portion of the building affected by the system outage until the system is back in service, or***
>
> ***(ii) Establish a fire watch until the system is back in service.***

Interpretive Guidelines: §416.44(*b*)*(5)*

Guidance pending and will be updated in future release.

Q-0107

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

(6) Beginning July 5, 2017, an ASC must be in compliance with Chapter 21.3.2.1, Doors to hazardous areas.

Interpretive Guidelines: §416.44(b)(6)

Guidance pending and will be updated in future release.

Q-0108

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§416.44(c) Standard: Building Safety.

Except as otherwise provided in this section, the ASC must meet the applicable provisions and must proceed in accordance with the 2012 edition of the Health Care Facilities Code (NFPA 99, and Tentative Interim Amendments TIA 12-2, TIA 12-3, TIA 12-4, TIA 12-5 and TIA 12-6).

> ***(1) Chapters 7, 8, 12, and 13 of the adopted Health Care Facilities Code do not apply to an ASC.***
>
> ***(2) If application of the Health Care Facilities Code required under paragraph (c) of this section would result in unreasonable hardship for the ASC, CMS may waive specific provisions of the Health Care Facilities Code, but only if the waiver does not adversely affect the health and safety of patients.***

Interpretive Guidelines §416.44(c)

Guidance pending and will be updated in future release.

Q-0109

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§416.44(d) Standard: Emergency Equipment

The ASC medical staff and governing body of the ASC coordinates, develops, and revises ASC policies and procedures to specify the types of emergency equipment required for use in the ASC's operating room. The equipment must meet the following requirements:

(1) ***Be immediately available for use during emergency situations.***

(2) ***Be appropriate for the facility's patient population.***

(3) ***Be maintained by appropriate personnel.***

Interpretive Guidelines §416.44(d)

Guidance pending and will be updated in future release.

Q-0110

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§416.44(e) Standard: Emergency Personnel

Personnel trained in the use of emergency equipment and in cardiopulmonary resuscitation must be available whenever there is a patient in the ASC.

Interpretive Guidelines: §416.44(e)

Guidance pending and will be updated in future release.

Q-0111

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§416.44(f) The standards incorporated by reference in this section are approved for incorporation by reference by the Director of the Office of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may inspect a copy at the CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html. If any changes in this edition of the Code are incorporated by reference, CMS will publish a document in the FEDERAL REGISTER to announce the changes.

(1) National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02169, www.nfpa.org, 1.617.770.3000.

(i) NFPA 99, Standards for Health Care Facilities Code of the National Fire Protection Association 99, 2012 edition, issued August 11, 2011.

(ii) TIA 12-2 to NFPA 99, issued August 11, 2011.

(iii) TIA 12-3 to NFPA 99, issued August 9, 2012.

(iv) TIA 12-4 to NFPA 99, issued March 7, 2013.

(v) TIA 12-5 to NFPA 99, issued August 1, 2013.

(vi) TIA 12-6 to NFPA 99, issued March 3, 2014.

(vii) NFPA 101, Life Safety Code, 2012 edition, issued August 11, 2011;

(viii) TIA 12-1 to NFPA 101, issued August 11, 2011.

(ix) TIA 12-2 to NFPA 101, issued October 30, 2012.

(x) TIA 12-3 to NFPA 101, issued October 22, 2013.

(xi) TIA 12-4 to NFPA 101, issued October 22, 2013.

(2) [Reserved]

Q-0120

(Rev.56, Issued: 12-30-09, Effective/Implementation: 12-30-09)

§416.45 Condition for Coverage: Medical Staff

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

Interpretive Guidelines §416.45

The organization of the medical staff is left to the discretion of the governing body, but however the staff is organized, the ASC must have an explicit, written policy that indicates how the medical staff is held accountable by the governing body. The policy must address all requirements in this condition. Medical staff privileges may be granted both to physician and non-physician practitioners, consistent with their permitted scope of practice in the State, as well as their training and clinical experience.

It is possible for an ASC to be owned and operated by one physician, who could be both

the sole member of the governing body and also the sole member of the ASC's medical staff. In such cases the physician owner must nevertheless implement a formal process for complying with all medical staff regulatory requirements.

Survey Procedures §416.45

Ask the ASC's leadership for its policy detailing how the governing body holds the medical staff accountable.

Q-0121

(Rev. 56, Issued: 12-30-09, Effective/Implementation: 12-30-09)

§416.45(a) Standard: Membership and Clinical Privileges

Members of the medical staff must be legally and professionally qualified for the positions to which they are appointed and for the performance of privileges granted. The ASC grants privileges in accordance with recommendations from qualified medical personnel.

Interpretive Guidelines §416.45(a)

All members of the ASC's medical staff and all clinicians granted medical staff privileges must be appointed to their position within the ASC by the ASC's governing body. They must be granted privileges by the governing body, in writing, that specify in detail the types of procedures they may perform within the ASC. It is not sufficient for the governing body to grant privileges to "perform surgery" or even to perform "orthopedic surgery." For example, an ASC that specializes in orthopedic surgery of various types must specify which types of procedures each surgeon is privileged to perform.

The ASC's governing body must assure that medical staff privileges are granted only to legally and professionally qualified practitioners.

"Legally qualified" means the practitioner has a current license to practice within the State where the ASC is located, and that the privileges to be granted fall within that State's permitted scope of practice. The ASC must verify that each practitioner has a current professional license and document the license in the practitioner's file.

"Professionally qualified" means that the practitioner has demonstrated competence in the area for which privileges are sought. Competence is demonstrated through evidence of specialized training and experience, e.g., certification by a nationally recognized professional board.

The governing body is also required to solicit the opinion of qualified medical personnel on the competence of applicants for privileges. The recommendation provided must be in writing, and should include a supporting rationale. The qualified medical personnel may be current members of the ASC's medical staff, but may also be physicians not practicing in the ASC. ASCs should consider seeking the recommendations of qualified outside

physicians when they do not have appropriate expertise in-house to evaluate the competency of an applicant for privileges. This is particularly advisable when the ASC's governing body consists of one physician owner who is also the sole member of the medical staff. The ASC's governing body is not required to accept the recommendation provided by the qualified medical personnel to grant, deny, or restrict privileges to a practitioner. However, when the ASC's governing body makes a decision contrary to the recommendation, it is expected to document its rationale for doing so.

The ASC should document the process by which the governing body grants medical staff privileges, including the documentation, or credentials, it reviews for each candidate, the criteria it uses in evaluating the candidate, how it selects the qualified medical personnel who make recommendations on the practitioner's qualifications, and whether and under what circumstances the governing body may make a privileging decision contrary to the recommendation of the qualified medical staff.

Survey Procedures: §416.45(a)

Ask the ASC's leadership to explain its process for granting clinical privileges.

Review the personnel records for all medical staff that have been granted clinical privileges.

There must at a minimum be documentation of:

- State licensure, registration, or state certification, as applicable;
- Certification by a specialty organization, as appropriate;
- Other training or pertinent experience;
- Evidence of a recommendation by qualified medical personnel concerning the practitioner's competence;
- The scope of the privileges granted to the practitioner; and
- If the governing body granted privileges against the recommendation of the qualified medical personnel, its rationale for doing so.

Does the review of each practitioner's record provide evidence that they are legally and professionally qualified to exercise the privileges granted them by the ASC?

Q-0122

(Rev. 137, Issued: 04-01-15, Effective: 03-27-15, Implementation: 03-27-15)

§416.45(b) Standard: Reappraisals

Medical staff privileges must be periodically reappraised by the ASC. The scope of procedures performed in the ASC must be periodically reviewed and amended as

appropriate.

Interpretive Guidelines: §416.45(b)

The ASC's governing body must have a process reappraising the medical staff privileges granted to each practitioner. CMS recommends a reappraisal at least every 24 months. The reappraisal must include:

- Review of the practitioner's current credentials; and

- The practitioner's ASC-specific case record, including measures employed in the ASC's quality assurance/performance improvement program, such as emergency transfers to hospitals, post-surgical infection rates, other surgical complications, etc.

The ASC's governing body should use a similar process, including the recommendation of qualified medical personnel, for the periodic reappraisal as it used when initially granting privileges.

Based on the evidence, the ASC's governing body must decide whether to continue the practitioner's current privileges without change, or to amend those privileges by contracting or expanding them, or by withdrawal of the practitioner's privileges entirely.

The ASC must also reappraise a practitioner any time the practitioner seeks to perform procedures outside the scope of previously granted procedures.

The ASC should also develop triggers for reappraisal of privileges outside the periodic reappraisal schedule.

In the case of an ASC whose sole member of the governing body is also a member of the ASC's medical staff, it would be advisable to seek the recommendation of outside qualified medical personnel who review not only the physician's credentials, but also evidence of the physician's performance in the ASC.

Survey Procedures: §416.45(b)

- Does the ASC periodically reappraise all practitioners granted clinical privileges?

- Ask the ASC's leadership how it re-evaluates the professional qualifications of practitioners with privileges to practice in the ASC?

- Review the personnel records for all practitioners with privileges to practice in the ASC to determine whether they have been reappraised within the timeframe specific in the medical staff policy.

- Do the reappraisals include evidence that data on the practitioner's

practice within the ASC is considered along with the practitioner's credentials?

Q-0123

(Rev. 56, Issued: 12-30-09, Effective/Implementation: 12-30-09)

§416.45(c) Standard: Other Practitioners

If the ASC assigns patient care responsibilities to practitioners other than physicians, it must have established policies and procedures, approved by the governing body, for overseeing and evaluating their clinical activities.

Interpretive Guidelines: §416.45(c)

Patient care responsibilities (which may or may not include formal medical staff privileges, but excluding nursing care services) may be assigned to licensed practitioners not meeting the definition of physician in §1861(r) of the Act. "Physician" is defined in §1861(r) of the Social Security Act as:

- Doctor of medicine or osteopathy;
- Doctor of dental surgery or of dental medicine;
- Doctor of podiatric medicine;
- Doctor of optometry with respect to services legally authorized to be performed in the State; and
- Chiropractor with respect to treatment by manual manipulation of the spine (to correct subluxation diagnosed by x-ray).

When an ASC uses licensed practitioners to provide patient care, other than nursing care, the ASC's governing body must approve written policies and procedures that establish a system for overseeing and evaluating the quality of the clinical services provided by other practitioners. The policies must address:

- The specific types of clinical activities that each class of practitioner, e.g., Nurse Practitioner, Physician's Assistant, CRNA, will be eligible to perform. The ASC may not permit performance of any activities that are outside the licensed practitioner's permitted scope of practice under applicable State law;
- The process by which the ASC exercises oversight over each class of practitioner. Depending on the practitioner's scope of practice, physician supervision of the practitioner may be required; in other cases oversight through collaborative practice with a physician or some other means may suffice;
- The process and criteria for reviewing the qualifications of each individual practitioner before he/she is permitted to provide patient care; and

- The process, criteria and frequency for evaluating the performance in providing clinical services by practitioners other than physicians. Evaluations must take place at regular intervals specified in the ASC's policy.

Survey Procedures: §416.45(c)

- Determine whether the ASC uses licensed practitioners other than physicians to provide care, other than nursing care, within the ASC. If it does:

  - Ask to see the ASC's policy governing the oversight and evaluation of practitioners other than physicians. Does the policy address all required issues?

  - Review the personnel files for each licensed practitioner who is not a physician providing patient care in the ASC. Does each file contain evidence of the practitioner's qualifications, consistent with the ASC's policy? Does each file contain evidence of periodic evaluation of the practitioner's performance?

Q-0140

(Rev. 56, Issued: 12-30-09, Effective/Implementation: 12-30-09)

§416.46 Condition for Coverage: Nursing Service

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

Interpretive Guidelines: §416.46

The ASC must ensure that the nursing service is directed under the leadership of an RN. The ASC must have documentation that it has designated an RN to direct nursing services.

There must be sufficient nursing staff with the appropriate qualifications to assure the nursing needs of all ASC patients are met. This implies that there is ongoing assessment of patients' needs for nursing care, and that identified needs are addressed. The number and types of nursing staff needed will depend on the volume and types of surgery the ASC performs.

Survey Procedures: §416.46

- Ask the ASC's leadership to identify the person responsible for the direction of nursing services within the ASC. Is that person an RN?

- Review the staffing available for patients undergoing surgery during the survey; is there sufficient staff to address each patient's nursing needs?

Do nursing staff have the appropriate qualifications for the tasks they are asked to perform?

Q-0141

(Rev. 56, Issued: 12-30-09, Effective/Implementation: 12-30-09)

§416.46(a) Standard: Organization and Staffing

Patient care responsibilities must be delineated for all nursing service personnel. Nursing services must be provided in accordance with recognized standards of practice. There must be a registered nurse available for emergency treatment whenever there is a patient in the ASC.

Interpretive Guidelines: §416.46(a)

Every nurse in the ASC must have clearly delineated assigned responsibilities for providing nursing care to patients. These assignments must be in writing; job descriptions would suffice for a general articulation of the responsibilities for each nurse. Individual patient assignments on a given day must be documented clearly in the assignment sheet.

The ASC's nursing services must be consistent with recognized standards of practice. "Recognized standards of practice" means that the services provided are consistent with State laws governing nursing scope of practice, as well as with nationally recognized standards or guidelines for nursing care issued by organizations such as the American Nurses Association, the Association of Operating Room Nurses, etc.

An RN with specialized training or experience in emergency care must be available to provide emergency treatment whenever there is a patient in the ASC. "Available" means on the premises and sufficiently free from other duties that the nurse is able to respond rapidly to emergency situations. In accordance with the requirements at §416.44(d), the ASC must have personnel present who are trained in the use of the required emergency equipment specified at §416.44(c) and in cardiopulmonary resuscitation whenever there is a patient in the ASC. The RN(s) designated to provide emergency treatment must be able to use any of the required equipment, so long as such use falls within an RN's scope of practice. ASC's would be well advised to assure that the RN(s) designated to provide emergency treatment have training in advanced cardiac life support interventions.

Survey Procedures: §416.46(a)

- Are the general responsibilities for each ASC nurse for providing patient care clearly documented?

- Ask the nursing staff to explain what their duties for the day of the survey are; can they articulate clearly what their patient care responsibilities are?

- Ask the ASC to explain how it evaluates the nursing care provided in the ASC for conformance to acceptable standards of practice.

- Ask the ASC to identify the RN(s) who are available for emergency treatment. Is there documentation of their qualifications to provide emergency treatment? Do staff in the ASC know which RN(s) (as well as medical staff) to call when a patient develops an emergency?

- Ask the ASC for evidence that one or more RN(s) are readily available to provide emergency treatment. How do they assure that an RN can leave their current task to respond to the emergency without putting another patient at risk of harm?

Q-0160

(Rev. 95, Issued: 12-12-13, Effective: 06-07-13, Implementation: 06-07-13)

§416.47 Condition for Coverage: Medical Records

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

Interpretive Guidelines: §416.47

The ASC must have a complete, comprehensive and accurate medical record for each patient. Material required under other Conditions, such as the history and physical examination or documentation of allergies to drugs and biologicals required under §416.52, must be incorporated into the medical record in a timely fashion. The ASC must use the information contained in each medical record in order to assure that adequate care is delivered to each ASC patient. In accordance with the provisions of the Patients' Rights Condition at §416.50(g), the ASC must ensure the confidentiality of each patient's medical record.

Survey Procedures: §416.47

Review a sample of active and closed medical records for completeness and accuracy in accordance with Federal and State laws and regulations and ASC policy. If patient records are not collected in a systematic manner for easy access, annotate this on the survey report form.

Q-0161

(Rev. 56, Issued: 12-30-09, Effective/Implementation: 12-30-09)

§416.47(a) Standard: Organization. The ASC must develop and maintain a system for the proper collection, storage, and use of patient records.

Interpretive Guidelines: §416.47(a)

The ASC must have a documented system that enables it to systematically develop a

unique medical record for each patient, permit timely access to the medical record to support the delivery of care, and to store records. Records may exist in hard copy, electronic format, or a combination of the two media.

The regulation does not prescribe how long a closed record is to be maintained by the ASC, but many States have laws governing retention of medical records.

Survey Procedures: §416.47(a)

- Review the ASC's medical record policy and interview the person responsible for the medical records to ascertain that the system is structured appropriately.

- If the ASC employs a fully or partially electronic medical record system, ask clinical personnel to demonstrate how they use the system in order to determine whether they are able to make entries and access needed information in order to support the provision of care.

- Determine that closed records are retained in accordance with applicable State law.

- Review a sample of active and closed medical records for completeness and accuracy in accordance with Federal and State laws and regulations and ASC policy. If patient records are not collected in a systematic manner for easy access, annotate this on the survey report form.

Q-0162

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§416.47(b) Standard: Form and Content of Record

The ASC must maintain a medical record for each patient. Every record must be accurate, legible, and promptly completed. Medical records must include at least the following:

(1) Patient identification;
(2) Significant medical history and results of physical examination *(as applicable)*;
(3) Pre-operative diagnostic studies (entered before surgery), if performed;
(4) Findings and techniques of the operation, including a pathologist's report on all tissues removed during surgery, except those exempted by the governing body;
(5) Any allergies and abnormal drug reactions;
(6) Entries related to anesthesia administration;
(7) Documentation of properly executed informed patient consent; and
(8) Discharge diagnosis.

Interpretive Guidelines: §416.47(b)

The medical record must contain all of the required elements listed in the regulation. Specifically:

• The identity of the patient must be clear through use of identifiers such as name, date of birth, social security number, etc.

• A medical history and physical assessment (H&P), completed *as applicable* and entered into the medical record in accordance with the requirements at §416.52, as well as the results of the pre-surgical assessments specified at §416.42 and §416.52.

• If pre-operative diagnostic studies were performed, they must be included in the medical record prior to the start of surgery.

• An operative report that describes the surgical techniques and findings. A pathologist's report on all tissues removed during surgery must also be included, unless the governing body has adopted a written policy exempting certain types of removed tissue from this requirement. Depending on the type of surgery performed in the ASC, tissue may or may not routinely be removed during surgery; no pathologist's report is required when no tissue has been removed. The governing body's policy on exemption should provide the clinical rationale supporting the exemption decision. For example, an ASC that performs cataract removal and implantation of an artificial lens might exempt from the pathologist's report requirement the ocular lens removed in routine procedures where there is no indication suggesting the presence of other disease for which a pathology analysis should be required. On the other hand, it generally would not be reasonable to exempt intestinal polyps removed during a colonoscopy, since a pathologist's analysis of the tissue would be required to confirm whether or not the polyp(s) were malignant growths.

• The patient's history of allergies or abnormal drug reactions prior to the surgery, as well as any allergies or abnormal drug reactions that occurred during or after the surgery prior to discharge.

• Information related to the administration of anesthesia during the procedure and the patient's recovery from anesthesia after the procedure.

• Documentation of a properly executed informed patient consent. A well-designed informed consent process would most likely include a discussion of the following elements:

> • A description of the proposed surgery, including the anesthesia to be used;
>
> • The indications for the proposed surgery;
>
> • Material risks and benefits for the patient related to the surgery and anesthesia, including the likelihood of each, based on the available clinical evidence, as informed by the responsible practitioner's clinical judgment. Material risks could

include risks with a high degree of likelihood, but a low degree of severity, as well as those with a very low degree of likelihood, but a high degree of severity;

• Treatment alternatives, including the attendant material risks and benefits;

• Who will conduct the surgical intervention and administer the anesthesia;

• Whether physicians other than the operating practitioner will be performing important tasks related to the surgery. Important surgical tasks include: opening and closing, dissecting tissue, removing tissue, harvesting grafts, transplanting tissue, administering anesthesia, implanting devices and placing invasive lines; and

• Whether, as permitted by State law, qualified medical practitioners who are not physicians will perform important parts of the surgery or administer the anesthesia, and if so, the types of tasks each type of practitioner will carry out; and that such practitioners will be performing only tasks within their scope of practice for which they have been granted privileges by the ASC.

• Documentation of the patient's discharge diagnosis. The record should also include the patient's disposition, i.e., whether the patient was discharged to home (including to a nursing home for patients already resident in a nursing home at the time of surgery), or transfer to another healthcare facility, including emergent transfers to a hospital.

Survey Procedures: §416.47(b)

• Evaluate the sample of open and closed records selected for review to determine whether they contain all of the required elements. For open records of patients whose surgery has not yet begun, focus on the elements that must be present before surgery, e.g., H&P *(as applicable)*, immediate pre-surgical assessment, informed consent, etc. The absence of any required element must be cited as standard-level noncompliance. The absence of a number of elements from a number of medical records might warrant citation of condition-level noncompliance. Likewise the absence of one element from a number of medical records – e.g., lack of informed consent to surgery – should warrant citation of condition-level noncompliance.

Ask the ASC's leadership if the ASC removes tissue during surgery and, if so, does it exempt any or all classes of tissue removed from the requirement for analysis by a pathologist? If yes, ask to see the policy and its rationale, to determine whether it was adopted by the governing body and whether the clinical rationale for the exemption is reasonable.

Q-0180

(Rev. 56, Issued: 12-30-09, Effective/Implementation: 12-30-09)

§416.48 Condition for Coverage: Pharmaceutical Services

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

Interpretive Guidelines: §416.48

Drugs and biologicals used within the ASC must be provided safely and in an effective manner, consistent with generally accepted professional standards of pharmaceutical practice and with the requirements specified in the Standards within this Condition.

The ASC must designate a specific licensed healthcare professional to provide direction to the ASC's pharmaceutical service. That individual must be routinely present when the ASC is open for business, but continuous presence is not required, particularly when the ASC is open for longer periods of time to accommodate the recovery of patients for up to 24 hours. Ideally the ASC should have available a pharmacist who provides oversight or consultation on the ASC's pharmaceutical services, but this is not required by the regulation, unless the ASC is performing activities which under State law may only be performed by a licensed pharmacist.

Survey Procedures: §416.48

- Ask the ASC's leadership for evidence that a qualified individual has been designated to direct pharmaceutical services in the ASC.

- Ask how often and for how long this individual is on-site at the ASC. Determine whether there is any documentation indicating that the individual is providing active direction and oversight to the program.

Q-0181

(Rev. 56, Issued: 12-30-09, Effective/Implementation: 12-30-09)

§416.48(a) Standard: Administration of Drugs

Drugs must be prepared and administered according to established policies and acceptable standards of practice

Interpretive Guidelines: §416.48(a)

Drugs and biologicals used within the ASC must be administered to patients in accordance with formal policies the ASC has adopted, and those policies and the ASC's actual practices must conform to acceptable standards of practice for medication administration.

"**Accepted professional practice**" and **"acceptable standards of practice"** mean that drugs and biologicals are handled and provided in the ASC in accordance with applicable State and Federal laws as well as with standards established by organizations with nationally recognized expertise in the clinical use of drugs and biologicals. This would

include organizations such as the National Association of Boards of Pharmacy, the Institute for Safe Medication Practices, the American Society of Health-System Pharmacists, etc.

The ASC must have policies and procedures designed to promote medication administration consistent with acceptable standards of practice. The policies and procedures should address issues including, but not limited to:

- A physician or other qualified member of the medical staff acting within their scope of practice must issue an order for all drugs or biologicals administered in the ASC. The administration of the drugs or biologicals must be by, or under the supervision of, nursing or other personnel in accordance with applicable laws, standards of practice and the ASC's policies.

- Following the manufacturer's label, including storing drugs and biologicals as directed; disposing of expired medications in a timely manner; using single-dose vials of medication for one ASC patient only; etc.
- Avoiding preparation of medications too far in advance of their use. For example, while it may appear efficient to pre-draw the evening before all medications that will be used for surgeries scheduled the following day, this practice may, depending on the particular drug or biological, promote loss of integrity, stability or security of the medication.

- Any pre-filled syringes must be initialed by the person who draws it, dated and timed to indicate when they were drawn, and labeled as to both content and expiration date.

- Employing standard infection control practices when using injectable medications.

There must be records of receipt and disposition of all drugs listed in Schedules II, III, IV, and V of the Comprehensive Drug Abuse Prevention and Control Act of 1970, if the ASC uses any such scheduled drugs. The ASC's policies and procedures should also address the following:

- Accountability procedures to ensure control of the distribution, use, and disposition of all scheduled drugs.

- Records of the receipt and disposition of all scheduled drugs must be current and must be accurate.

- Records to trace the movement of scheduled drugs throughout the ASC.

- The licensed health care professional who has been designated responsible for the ASC's pharmaceutical services is responsible for determining that all drug records are in order and that an account of all scheduled drugs is maintained and reconciled.

- The record system, delineated in policies and procedures, tracks movement of all scheduled drugs from the point of entry into the ASC to the point of departure, either through administration to the patient, destruction, or return to the manufacturer. This system provides documentation on scheduled drugs in a readily retrievable manner to facilitate reconciliation of the receipt and disposition of all scheduled drugs.

- All drug records are in order and an account of all scheduled drugs is maintained and any discrepancies in count are reconciled promptly.

- The ASC's system is capable of readily identifying loss or diversion of all controlled substances in such a manner as to minimize the time frame between the actual loss or diversion to the time of detection and determination of the extent of loss or diversion?

Survey Procedures: §416.48(a)

- Is there evidence in the medical records reviewed that there is an order, signed by a physician or other qualified practitioner, for every drug or biological administered to the patient?
- Are drugs or biologicals administered only by nurses or other qualified individuals, or under the supervision of nurses or other qualified individuals, as permitted under Federal or State law and the ASC's policy?

- Determine whether medications are properly labeled, stored, and have not expired.

- Using the infection control survey tool, determine whether the ASC employs safe injection practices.

- If the ASC uses scheduled drugs:

  - Determine if there is a record system in place that provides information on controlled substances in a readily retrievable manner.

  - Review the records to determine that they trace the movement of scheduled drugs throughout the ASC.

  - Determine if there is a system, delineated in policies and procedures, that tracks movement of all scheduled drugs from the point of entry into the ASC to the point of departure, either through administration to the patient, destruction or return to the manufacturer. Determine if this system provides documentation on scheduled drugs in a readily retrievable manner to facilitate reconciliation of the receipt and disposition of all scheduled drugs.

  - Determine if the licensed health care professional who is in charge of the

ASC's pharmaceutical services is responsible for determining that all drug records are in order and that an account of all scheduled drugs is maintained and periodically reconciled.

- Is the ASC's system capable of readily identifying loss or diversion of all controlled substances in such a manner as to minimize the time between the actual losses or diversion to the time of detection and determination of the extent of loss or diversion?

- Determine if facility policy and procedures minimize scheduled drug diversion.

Q-0182

(Rev. 56, Issued: 12-30-09, Effective/Implementation: 12-30-09)

§416.48(a) Standard: Administration of Drugs

(1) Adverse reactions must be reported to the physician responsible for the patient and must be documented in the record.

Interpretive Guidelines: §416.48(a)(1)

Every adverse reaction to a drug or biological that a patient experiences while in the ASC must be reported promptly to the physician on the ASC's medical staff who is responsible for that patient. This permits that physician to assess the patient in a timely manner and determine whether additional treatment is required in order to counteract the adverse reaction.

All adverse drug reactions experienced by patients while in the ASC must be documented in the patient's medical record.

The ASC's policies and procedures must incorporate these requirements and ASC staff must be aware of and comply with them.

Survey Procedures: §416.48(a)(1)

- Interview clinical staff to ask them what steps they would take if a patient experiences an adverse reaction to a drug? Are staff aware of the requirement to promptly report this information to the physician on the ASC's medical staff who is responsible for the patient?

- Look for documentation of adverse drug reactions in the sample of records selected for review. If no adverse drug reactions are noted, ask ASC staff whether they recall any patients having adverse drug reactions, and if so, whether they could pull a medical record containing documentation of an adverse drug reaction.

- Determine whether the ASC's policies and procedures address adverse drug

reactions and are consistent with the regulatory requirements.

Q-0183

(Rev. 56, Issued: 12-30-09, Effective/Implementation: 12-30-09)

§416.48(a) Standard: Administration of Drugs

(2) Blood and blood products must be administered only by physicians or registered nurses.

Interpretive Guidelines: §416.48(a)(2)

If the ASC ever administers blood or blood products to patients, it may permit only a physician on the ASC's medical staff or an RN working in the ASC to administer blood and blood products. The ASC's policies and procedures must specifically address this requirement, unless the ASC does not keep blood or blood products on hand and never administers such products to ASC patients.

Survey Procedures: §416.48(a)(2)

- Determine whether the ASC administers blood or blood products to patients. If yes,
  - Determine from the record review whether anyone other than a physician on the ASC's medical staff or an ASC RN administered the blood or blood product.
  - Determine whether the ASC's policies specifically restrict administration of blood and blood products to a physician or RN.

Q-0184

(Rev. 56, Issued: 12-30-09, Effective/Implementation: 12-30-09)

§416.48(a) Standard: Administration of Drugs

(3) Orders given orally for drugs and biologicals must be followed by a written order and signed by the prescribing physician.

Interpretive Guidelines: §416.48(a)(3)

Orders for drugs and biologicals that are transmitted as oral, spoken communications between the prescribing physician and the ASC's nursing staff, delivered either face-to-face or via telephone, commonly called "verbal orders," must be followed by a written order that is signed by the prescribing physician.

CMS expects ASC policies and procedures for verbal orders to include a read-back and verification process whereby the nurse receiving the order repeats it back to the prescribing physician, who verifies that it is correct. When administering a drug or biological per a verbal order, the nurse should include in the medical record entry

covering the administration of the drug or biological a note that it was prescribed orally, indicating the name of the prescribing physician.

The prescribing physician must sign, date, and time the written order in the patient's medical record confirming the verbal order. This should be done as soon as possible after the verbal order is issued.

In the ASC setting medications prescribed for patients in recovery present a particular area of vulnerability in terms of the potential failure to follow-up a verbal order with a written order signed by the prescribing physician. Careful attention must be given to compliance with the regulatory requirement for medications administered during recovery room.

Survey Procedures: §416.48(a)(3)

- Does the ASC have policies and procedures addressing verbal orders? Does it require the prescribing practitioner to sign, date, and time a written order as soon as possible after issuing the verbal order?

- Do the ASC's policies and procedures for verbal orders include a "read back and verify" process where the nurse who receives the order repeats it back to the prescribing physician to verify that the order was understood accurately?

- Ask ASC nursing staff how they handle verbal orders. Does their practice conform to the regulatory requirements? Do they use a read-back and verify process?

- Is there evidence in the medical records reviewed that each verbal order was followed by a written order signed by the prescribing physician?

Q-0200

(Rev. 56, Issued: 12-30-09, Effective/Implementation: 12-30-09)

§416.49 Condition for Coverage: Laboratory and Radiologic Services

Interpretive Guidelines: §416.49(a)

Lack of substantial compliance with either the laboratory or the radiologic standard within this condition could provide a basis for citing a condition-level deficiency.

Q-0201

(Rev. 56, Issued: 12-30-09, Effective/Implementation: 12-30-09)

§416.49(a) Standard: Laboratory Services

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.

Interpretive Guidelines: §416.49(a)

ASC policies and procedures should list the kinds of laboratory services that are provided directly by the facility, and services that are provided through a contractual agreement. Review the contractual agreements and determine if the referral laboratory is a CLIA-approved laboratory. The ASC procedures must include the following:

- A well-defined arrangement (need not be contractual) with outside services;
- Laboratory services that are provided by the ASC;
- Routine procedures for requesting lab tests; and
- Language that requires the incorporation of lab/radiological reports into patient records.

When laboratory tests are performed prior to admission, the results should be readily available to the attending physician in the ASC.

Q-0202

(Rev. 137, Issued: 04-01-15, Effective: 03-27-15, Implementation: 03-27-15)

§416.49(b) Standard: Radiologic Services.

(1) Radiologic services may only be provided when integral to procedures offered by the ASC …

Interpretive Guidelines: §416.49(b)(1)

An ASC may only provide radiological services as an integral part of the surgical procedures it performs. Radiological services integral to the procedure itself are those imaging services performed immediately before, during or after the procedure that are medically necessary to the completion of the procedure.

If the ASC does not provide these radiological services directly, i.e., utilizing its own staff, then it must obtain them via a contract or other formal arrangement.

Survey Procedures: §416.49(b)(1)

- Does the ASC provide, either directly or under arrangement, radiologic services? If yes, verify that it performs only those radiologic services that are integral to its surgical services?

Q-0203
(Rev. 137, Issued: 04-01-15, Effective: 03-27-15, Implementation: 03-27-15)

§416.49(b)(1) [Radiologic services…]

. . . must meet the requirements specified in § 482.26(b), (c)(2), and (d)(2) of this chapter.

Interpretive Guidelines §416.49(b)(1)

The scope and complexity of radiological services provided within the ASC, either directly or under arrangement, as an integral part of the ASC's surgical services must be specified in writing and approved by the governing body. The ASC must also ensure that the provision of radiological services in the ASC complies with the hospital radiologic services requirements at § 482.26(b), (c)(2), and (d)(2), regardless of whether the service is provided directly by the ASC or under arrangement.

The interpretive guidelines for § 482.26(b), (c)(2), and (d)(2) in Appendix A, Survey Protocol, Regulations and Interpretive Guidelines for Hospitals of the State Operations Manual, provide the following guidance in determining compliance:

§482.26(b) Standard: Safety for Patients and Personnel

The radiologic services, particularly ionizing radiology procedures, must be free from hazards for patients and personnel.

Interpretive Guidelines §482.26(b)

The hospital must adopt and implement policies and procedures that provide safety for patients and personnel.

Survey Procedures §482.26(b)

Observe locations where radiological services are provided. Are they safe for patients and personnel? Are any hazards to patients or personnel observed?

§482.26(b)(1) Proper safety precautions must be maintained against radiation hazards. This includes adequate shielding for patients, personnel, and facilities, as well as appropriate storage, use and disposal of radioactive materials.

Interpretive Guidelines §482.26(b)(1)

The hospital policies must contain safety standards for at least:

- Adequate shielding for patients, personnel and facilities;

- Labeling of radioactive materials, waste, and hazardous areas;
- Transportation of radioactive materials between locations within the hospital;
- Security of radioactive materials, including determining who may have access to radioactive materials and controlling access to radioactive materials;
- Testing of equipment for radiation hazards;
- Maintenance of personal radiation monitoring devices;
- Proper storage of radiation monitoring badges when not in use;
- Storage of radio nuclides and radio pharmaceuticals as well as radioactive waste; and
- Disposal of radio nuclides, unused radio pharmaceuticals, and radioactive waste.
- Methods of identifying pregnant patients.

The hospital must implement and ensure compliance with its established safety standards.

Survey Procedures §482.26(b)(1)

- Verify that patient shielding (aprons, etc.) are properly maintained and routinely inspected by the hospital.
- Verify that hazardous materials are stored properly in a safe manner.
- Observe areas where testing is done for violations in safety precautions.

§482.26(b)(2) Periodic inspection of equipment must be made and hazards identified must be properly corrected.

Interpretive Guidelines §482.26(b)(2)

The hospital must have policies and procedures in place to ensure that periodic inspections of radiology equipment are conducted, current and that problems identified are corrected in a timely manner. The hospital must ensure that equipment is inspected in accordance with manufacturer's instructions, Federal and State laws, regulations, and guidelines, and hospital policy. The hospital must have a system in place, qualified employees or contracts, to correct hazards. The hospital must be able to demonstrate current inspection and proper correction of all hazards.

Survey Procedures §482.26(b)(2)

- Review the inspection records (logs) to verify that periodic inspections are conducted in accordance with manufacturer's instructions, Federal and State laws, regulations, and guidelines and hospital policy.

- Determine that any problems identified are properly corrected in a timely manner.

§482.26(b)(3) Radiation workers must be checked periodically, by the use of exposure meters or badge tests, for amount of radiation exposure.

Interpretive Guidelines §482.26(b)(3)

The requirement that "radiation workers must be checked periodically, by use of exposure meters or badge tests, for amount of radiation exposure" would include radiological services personnel, as well as, other hospital employees who may be regularly exposed to radiation due to working near radiation sources. This could include personnel such as certain nursing and maintenance staff.

Survey Procedures §482.26(b)(3)

- Verify that the hospital requires periodic checks on all radiology personnel and any other hospital staff exposed to radiation and that the personnel are knowledgeable about radiation exposure for month, year, and cumulative/entire working life.

- Observe that appropriate staff have a radiation-detecting device and that they appropriately wear their radiation detecting device.

- Review records to verify that periodic tests of radiology personnel by exposure meters or test badges are performed.

§482.26(b)(4) Radiologic services must be provided only on the order of practitioners with clinical privileges or, consistent with State law, of other practitioners authorized by the medical staff and the governing body to order the services.

Survey Procedures §482.26(b)(4)

Review medical records to determine that radiological services are provided only on the orders of practitioners with clinical privileges and to practitioners outside the hospital who have been authorized by the medical staff and the governing body to order radiological services, consistent with State law.

§482.26(c)(2) Only personnel designated as qualified by the medical staff may use

the radiologic equipment and administer procedures.

Interpretive Guidelines §482.26(c)(2)

There should be written policies, developed and approved by the medical staff, consistent with State law, to designate which personnel are qualified to use the radiological equipment and administer procedures.

Survey Procedures §482.26(c)(2)

Determine which staff are using differing pieces of radiological equipment and/or administering patient procedures. Review their personnel folders to determine they meet the qualifications established by the medical staff for the tasks they perform.

§482.26(d)(2) The hospital must maintain the following for at least 5 years:

(i) Copies of reports and printouts

(ii) Films, scans, and other image records, as appropriate.

Interpretive Guidelines §482.26(d)(2)

Patient radiology records are a type of patient medical record. The hospital must maintain radiology records in compliance with the medical records CoP and this CoP. Medical records, including radiology records, must be maintained for 5 years.

Survey Procedures §482.26(d)(2)

- Verify that the hospital maintains records for at least 5 years.

- Verify that radiology records are maintained in the manner required by the Medical Records…." [CfC].

Survey Procedures: §416.49(b)(1)

- If the ASC provides radiologic services as an integral part of surgical procedures, does it comply with the requirements of §482.26(b), (c)(2), and (d)(2) in its provision of those services, using the hospital radiologic services interpretive guidelines cited above?

- Interview the individual designated responsible for assuring compliance with this CfC and review related documentation to assess how these responsibilities have been implemented in the ASC. For example, is there evidence that this individual monitors and/or oversees the monitoring of compliance with all of the requirements in §482.26(b), (c)(2), and (d)(2)? What steps are available to this individual to remedy the situation if there is evidence of noncompliance with any of the requirements?

Q-0204

(Rev. 137, Issued: 04-01-15, Effective: 03-27-15, Implementation: 03-27-15)

§416.49(b)(2) If radiologic services are utilized, the governing body must appoint an individual qualified in accordance with State law and ASC policies who is responsible for assuring all radiologic services are provided in accordance with the requirements of this section.

Interpretive Guidelines: §416.49(b)(2)

If the ASC provides radiologic services, the ASC's governing body must appoint an individual who has appropriate qualifications, in accordance with State law and Federal regulations, to provide oversight of these services. The appointed individual is responsible for assuring the ASC's compliance with §§482.26(b), (c)(2), and (d)(2). In order to assure compliance with these requirements the individual is expected to be qualified, through training and/or experience, to oversee areas including, but not limited to: use of safety precautions (shielding, and appropriate storage, use and disposal of radioactive materials) against radiation hazards; regular equipment inspection and hazard correction; regular review of radiation worker radiation exposure; assuring use of radiologic equipment only by qualified personnel; and maintenance of imaging results or records. The person appointed to oversee radiologic services could be someone already working in the ASC who is qualified in accordance with State law and Federal regulations. Under the medical staff credentialing and privileging requirements at §416.45, the ASC's governing body will continue to be required to ensure that the operating surgeon is competent both to perform the surgical procedures for which privileges have been issued by the ASC and to appropriately and safely use the imaging modalit(ies) that are integral to the procedures s/he performs.

Survey Procedures: §416.49(b)(2)

- Can the ASC demonstrate that the individual responsible for assuring all radiologic services are provided in accordance with the requirements of this section:
    - Is qualified for this role in accordance with State and/or Federal law and regulations and ASC policies?
    - Was appointed by the ASC's governing body?

Q-0219

(Rev. 95, Issued: 12-12-13, Effective: 06-07-13, Implementation: 06-07-13)

§416.50 Condition for Coverage - Patient Rights

The ASC must inform the patient or the patient's representative or surrogate of the patient's rights and must protect and promote the exercise of these rights, as set forth in this section. The ASC must also post the written notice of patient rights in a

place or places within the ASC likely to be noticed by patients waiting for treatment or by the patient's representative or surrogate, if applicable.

Interpretive Guidelines: §416.50

The ASC must inform each of its patients, or the patient's representative or surrogate in the case of minor patients or other situations where there is a designated representative for the patient, of their rights as an ASC patient. Further, all of the ASC's policies, procedures and actions must be consistent with the protection of the patients' rights articulated in this Condition. Further, the ASC must actively promote the patient's exercise of their rights.

In addition, the ASC must ensure that the written notice of patient rights is posted in one or more places where it is likely to be seen by patients waiting for treatment, or the patient's representative or surrogate, if applicable. Such areas include, but are not limited to, waiting rooms or pre-operative preparation areas where patients are awaiting care. Notices must be posted in at least one area. Whether the ASC must post more than one notice depends on the size and physical layout of the areas where notices are posted. The determining factor is whether the notice(s) are posted in a manner that all patients (or their representatives or surrogates, as applicable) are likely to see the notice.

The patient's representative or surrogate is an individual designated by the patient, in accordance with applicable State law, to make health care decisions on behalf of the individual or to otherwise assist the patient during his/her stay in the ASC. Designation may be in writing, as in an advance directive or medical power of attorney, or may be oral (verbal). Written designation may occur before the patient presents to the ASC, or during the ASC registration process. Oral designation may take place at any time during the patient's visit in the ASC. The patient's representative or surrogate includes, but is not limited to, an individual who could be a family member or friend who accompanies the patient. Depending on the designation the patient has made, the patient's representative or surrogate may make all health care decisions for the patient during his/her ASC visit, or may act in a more limited role, for example, as a liaison between the patient and the ASC to help the patient communicate, understand, remember, and cope with the interactions that take place during the visit, and explain any instructions to the patient that are delivered by the ASC staff. If a patient is unable to fully communicate directly with the ASC staff, then the ASC may give patient rights information to the patient's representative or surrogate.

Survey Procedures: §416.50

When there is a team surveying the ASC, survey of the Patients' Rights Condition should be coordinated by one surveyor. However, each surveyor, as he or she conducts his/her survey assignments, should assess the ASC's compliance with the Patient's Rights regulatory requirements. It is particularly important for the surveyor who will be following one or more patients from the start of their case to discharge to be observing how the ASC's actions protect and promote those patients' exercise of their rights.

- Determine whether the ASC provides patients (or their representatives or

surrogates, as applicable), with notice of their rights, consistent with the standards under this condition.

- Determine whether the ASC promotes the patients' exercise of their rights (or their representatives or surrogates, as applicable), consistent with the standards under this condition.

Review posted notices to determine if they contain the same information as the individual written notice provided to patients or their representatives/surrogates, as required under §416.50(a). Deficiencies related to posting of the notice are to be cited using tag -Q0219.

Q-0220

(Rev. 95, Issued: 12-12-13, Effective: 06-07-13, Implementation: 06-07-13)

§416.50…. The ASC must also post the written notice of patient rights in a place or places within the ASC likely to be noticed by patients waiting for treatment or by the patient's representative or surrogate, if applicable.

Interpretive Guidelines: §416.50 (standard-level citation only)

Since the condition concerning posting the written notice does not have a counterpart in a standard within the patient rights condition, a second tag is provided for this portion of the condition for citations at the standard level. Deficiencies related solely to posting of the notice must be cited at the standard level, using tag Q-0220. The condition-level tag, Q-0219, must be cited whenever the manner and degree of noncompliance on the part of an ASC represents substantial noncompliance.

Survey Procedures: §416.50(standard-level citation only)

Observe waiting rooms and pre-operative areas where patients await care to see if notice of patient rights is posted in a manner where all patients awaiting care are likely to see a notice. Ensure that the notices are posted in conspicuous locations in the waiting rooms, pre-operative preparation areas, recovery rooms, or other common areas. If only one notice is posted, verify that it is conspicuously located in an area use by every ASC patient. Deficiencies related to posting of the notice are to be cited using tag -Q0219.

Q-0221

(Rev. 137, Issued: 04-01-15, Effective: 03-27-15, Implementation: 03-27-15)

§416.50(a) Standard: Notice of Rights

An ASC must, prior to the start of the surgical procedure, provide the patient, or the patient's representative, or the patient's surrogate with verbal and written notice of the patient's rights in a language and manner that ensures the patient, the representative, or the surrogate understand all of the patient's rights as set forth in this section. The ASC's notice of rights must include the address and telephone number of the State agency to which patients may report complaints, as well as the

Web site for the Office of the Medicare Beneficiary Ombudsman.

Interpretive Guidelines: §416.50(a)

The ASC must inform each patient, or the patient's representative or surrogate of the patient's rights. This notice must be provided both verbally and in writing prior to the start of the surgical procedure, i.e., prior to the patient's movement out of the pre-operative area, and, if applicable, before the patient is medicated with a drug(s) that suppresses the patient's consciousness. It is not acceptable for the ASC to provide the notice when the patient has already been moved into the operating room (including procedure room) or has been medicated in such a manner that he or she is not able to follow or remember the provision of notice.

This regulation does not require that in every instance notice be delivered just prior to the start of the surgical procedure. Instead, the regulation indicates the latest acceptable time for delivery of the notice. It would be acceptable for the ASC to mail or e-mail the notice of patient rights in advance of the date of the scheduled procedure, or at the time the patient appears in the registration area on the date of the procedure. CMS recommends that ASCs provide patients notice of their rights as soon as possible after the procedure is scheduled, but so long as notice is provided prior to the start of the surgical procedure, the ASC is in compliance with the regulation.

Notice must be provided regardless of the type of procedure scheduled to be performed.

The regulation does not require a specific form or wording for the written notice, so it is acceptable for the ASC to develop a generic, pre-printed notice for use with all of its patients, as long as the notice includes all of the patient rights established under the regulation.

The notice must include the address and telephone number of the appropriate State agency to which patients may report complaints about the ASC. If available, an e-mail or web address for submission of complaints to the State agency should also be provided.

The notice must also include, with respect to ASC patients who are Medicare beneficiaries, the Web site for the Office of the Medicare Beneficiary Ombudsman: http://www.medicare.gov/claims-and-appeals/medicare-rights/get-help/ombudsman.html

Patients who are Medicare beneficiaries, or their representative or surrogates, should be informed that the role of the Medicare Beneficiary Ombudsman is to ensure that Medicare beneficiaries receive the information and help they need to understand their Medicare options and to apply their Medicare rights and protections. These Medicare rights are in addition to the rights available to all ASC patients under this CfC.

The notice must:

- Address all of the patient's rights under this Condition.
- Be provided and explained in a language and manner that the patient or the

patient's representative or surrogate understands, including patients who do not speak English or with limited communication skills. The patient has the choice of using an interpreter of his or her own, or one supplied by the ASC. A professional interpreter is not considered to be a patient's representative or surrogate. Rather, it is the professional interpreter's role to pass information from the ASC to the patient. In following translation practices, CMS recommends, but does not require, that a written translation be provided in languages that non-English speaking patients can read, particularly for languages that are most commonly used by non-English-speaking patients of the ASC. We note that there are many hundreds of languages (not all written) that are used by one or more residents of the United State, but that in most geographic areas the most common non-English language generally is Spanish. We note there are other applicable legal requirements, most notably, those under title VI of the Civil Rights Act of 1964. The Department of Health and Human Services' (HHS) guidance related to Title VI of the Civil Rights Act of 1964, ''Guidance to Federal Financial Assistance Recipients Regarding Title VI Prohibition Against National Origin Discrimination Affecting Limited English Proficient Persons'' (68 FR 47311, Aug. 8, 2003) applies to those entities that receive federal financial assistance from HHS, including ASCs. This guidance may assist ASCs in ensuring that patient rights information is provided in a language and manner the patient understands. The regulation at §416.50(a) is compatible with guidance on Title VI.

Survey Procedures: §416.50(a)

- Determine what the ASC's policy and procedures are for providing all patients and/or their representatives or surrogates notice of their rights prior to the start of the surgical procedure. Are the policies and procedures consistent with the regulatory requirements?

- Determine whether the information provided in the written notice to the patients and/or their representatives or surrogates by the ASC is complete and accurate:

o Does the notice address all of the patients' rights listed in this Condition?

o Does the notice provide the required information about where to file complaints or how to contact the Medicare Ombudsman?

- Is the staff who are responsible for advising patients of their rights aware of the ASC's policies and procedures for providing such notice, including to those patients with special communication needs?

- Review records, interview staff, and observe staff/patient interaction to examine how the ASC communicates information about patient rights to diverse patients, including patients who need assistive devices or translation services.

- Does the ASC provide all patients with verbal and written notice of their rights prior to the start of the surgical procedure?

- Does the ASC have a significant number of patients with limited English proficiency? If so, are there written notice materials available for patients who have a primary language other than English? If not, does the ASC have translators available to provide verbal notice of their rights to ASC patients?

- Ask patients to tell you how, when and what the ASC has told them about their rights.

Q-0222

(Rev. 137, Issued: 04-01-15, Effective: 03-27-15, Implementation: 03-27-15)

§416.50(a) Standard: Notice of rights

(1)[…] In addition, the ASC must –

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

Interpretive Guidelines: §416.50(a)(1)(i)

The ASC must ensure that a written notice of patient rights is posted in one or more places where they are likely to be noticed. This would include waiting rooms, recovery rooms, or any other areas where patients and/or their representatives are likely to be. Notices must be posted in at least one area. Posting in more than one area increases the likelihood that patients will see the notice, but an ASC may post only one notice and comply with the requirement, so long as the notice is posted in an area used by every ASC patient and where it is likely to be noticed.

The notice must include the name, address, and telephone number of a representative in the State survey agency to whom patients and/or their representatives can report complaints. Because there can be staff turnover in the State survey agency, creating a burden for both States and ASCs to keep current the names of State staff, it is sufficient if the notice provides the title of the individual in the State survey agency to whom complaints may be reported, as well as the address and telephone number.

The notice must also include, with respect to ASC patients who are Medicare beneficiaries, the Web site for the Office of the Medicare Beneficiary Ombudsman: http://www.medicare.gov/claims-and-appeals/medicare-rights/get-help/ombudsman.html

Patients who are Medicare beneficiaries, or their representative, should be informed that the role of the Medicare Beneficiary Ombudsman is to ensure that Medicare beneficiaries receive the information and help they need to understand their Medicare options and to apply their Medicare rights and protections. These Medicare rights are in addition to the rights available to all ASC patients under this CfC.

Survey Procedures: §416.50(a)(1)(i)

- Observe waiting rooms, recovery rooms, and other common areas used by patients to see if one or more notices of patient rights are posted. Ensure that the notices are posted in conspicuous locations in the waiting rooms, recovery rooms, or other common areas. If only one notice is posted, verify that it is conspicuously located in an area used by every ASC patient.

- Observe notices to see that each notice contains all required information.

Q-0223

(Rev. 95, Issued: 12-12-13, Effective: 06-07-13, Implementation: 06-07-13)

§416.50(b) Standard: Disclosure of physician financial interest or ownership

The ASC must disclose, in accordance with Part 420 of this subchapter, and where applicable, provide a list of physicians who have financial interest or ownership in the ASC facility. Disclosure of information must be in writing.

Interpretive Guidelines: §416.50(b)

An ASC that has physician owners or investors must provide written notice to the patient, the patient's representative or surrogate, prior to the start of the surgical procedure, that the ASC has physician-owners or physicians with a financial interest in the ASC. CMS considers the disclosure of physician financial interest or ownership to be part of the overall "patient rights information" that is now required to be given prior to the start of the procedure. 42 CFR Part 420 provides definitions and requirements concerning ownership and control of Medicare-participating providers and suppliers. Surveyors are not expected to have expert knowledge of what constitutes ownership and control, but ASCs are required to comply with the provisions of Part 420. ASCs that meet the physician ownership and control threshold specified in 42 CFR Part 420 must disclose their physician ownership to patients and provide them with a list of physicians who have a financial interest or ownership in the ASC. The intent of this disclosure requirement is to assist the patient in making an informed decision about his or her care by making the patient, or the patient's representative or surrogate, aware when physicians who refer their patients to the ASC for procedures, or physicians who perform procedures in an ASC also have an ownership or financial interest in the ASC.

The written notice must disclose, in a manner designed to be understood by all patients,

that physicians have an ownership or financial interest in the ASC. Information should be provided in a manner that is not only technically correct, but also easily understood by persons not familiar with financial statements, legal documents or technical language. The ASC should also be aware of the age and the cognitive abilities of its patients in developing its written notice. (72 FR 50475, August 31, 2007)

Survey Procedures: §416.50(b)

- Ask the ASC whether it is has reported in accordance with 42 CFR Part 420 to the Medicare program whether the ASC has any physicians with ownership/financial interests. (Surveyors are not required to make an independent determination regarding whether an ASC has physicians with ownership or financial interests.) If the answer is yes, then the ASC is required to comply with the requirement for disclosure to patients. If the ASC's response is no, then the ASC has no disclosure requirement and the surveyor does not have to investigate further.

- If the ASC indicates it has physicians with ownership/financial interests in the ASC:

    - Does the ASC have policies and procedures in place to make the required disclosures to patients? Are the policies and procedures consistent with the regulatory requirements?

    - Does the ASC provide a written notice of disclosure to all patients prior to the start of the surgical procedure, including a list of physicians with financial interests or ownership in the ASC?

- Interview ASC staff to assess their knowledge and understanding of the physician ownership notice requirements, including the ASC's process for delivering the notice.

- Interview patients to ask them whether they were aware that the ASC has physician owners/investors. Ask them if they recall getting a written notice about this prior to the start of their surgical procedure.

Q-0224

(Rev. 95, Issued: 12-12-13, Effective: 06-07-13, Implementation: 06-07-13)

§416.50(c) Standard: Advance Directives

The ASC must comply with the following requirements:

(1) Provide the patient or, as appropriate, the patient's representative with written information concerning its policies on advance directives, including a description of applicable State health and safety laws and, if requested, official State advance directive forms.

(2) Inform the patient or, as appropriate, the patient's representative of the patient's

rights to make informed decisions regarding the patient's care.

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

Interpretive Guidelines: §416.50(c)

Information on Advance Directives

An advance directive is a written instruction, such as a living will or durable power of attorney for healthcare, recognized under State law (whether statutory or as recognized by the courts of the State), relating to the provision of healthcare when the individual who has issued the directive is incapacitated. (See 42 CFR 489.100.)

Each ASC patient has the right to formulate an advance directive consistent with applicable State law and to have ASC staff implement and comply with the advance directive, subject to the ASC's limitations on the basis of conscience. To the degree permitted by State law, and to the maximum extent practicable, the ASC must respect the patient's wishes and follow that process.

The facility must provide the patient or the patient's representative, as appropriate, the following information in writing, prior to the start of the surgical procedure:

- Information on the ASC's policies on advance directives;
- A description of the applicable State health and safety laws. (Note that CMS does not determine whether this description is accurate. State Survey Agencies are responsible for making this accuracy determination.); and
- If requested, official State advance directive forms, if such exist.

The ASC must include in the information concerning its advance directive policies a clear and precise statement of limitation if the ASC cannot implement an advance directive on the basis of conscience or any other specific reason that is permitted under State law. A blanket statement of refusal by the ASC to comply with any patient advance directives is not permissible. However, if and to the extent permitted under State law, the ASC may decline to implement elements of an advance directive on the basis of conscience or any other reason permitted under State law if it includes in the information concerning its advance directive policies a clear and precise statement of limitation. A statement of limitation must:

- Clarify any differences between ASC-wide conscience objections and those that may be raised by individual ASC staff;
- Identify the state legal authority permitting such objection; and
- Describe the range of medical conditions and procedures affected by the objection

For example, the ASC's notice of limitation could, if permitted by State law, indicate that it would always attempt to resuscitate a patient and transfer that patient to a hospital in the event of deterioration.

The patient may wish to delegate his/her right to make informed decisions to another person, even though the patient is not incapacitated. To the extent permitted by State law, the ASC must respect such delegation. In some cases, the patient may be unconscious or otherwise incapacitated. If the patient is unable to make a decision, the ASC must consult the patient's advance directives, medical power of attorney, or patient representative or surrogate, if any of these are available. In the advance directive or the medical power of attorney, the patient may provide guidance as to his or her wishes in certain situations, or may delegate decision-making to another individual as permitted by State law. If such an individual has been selected by the patient, or if a person willing and able under applicable State law is available to make treatment decisions, relevant information should be provided to the representative or surrogate, so that informed healthcare decisions can be made for the patient. However, as soon as the patient is able to be informed of his or her rights, the ASC should also provide that information to the patient.

The right to make informed decisions presumes that the patient, or the patient's representative or surrogate, has been provided information about the patient's health status, diagnosis and prognosis. It includes providing consent to the surgical procedure(s) to be performed in the ASC. The patient, or the patient's representative or surrogate, must receive adequate information, provided in a manner that the patient or the patient's representative or surrogate can understand, to assure that the patient can effectively exercise the right to make informed decisions about care in the ASC. In many cases, the informed consent may take place in a physician office outside the ASC and prior to the patient's visit to the ASC. Nevertheless, the ASC is responsible for ensuring an informed process is in place for each patient. (See discussion of fully informing the patient under §416.50(e)(iii).)

Documentation of Advance Directives

The ASC must document in the patient's current medical record, i.e., the record for the current ASC visit, whether or not the patient has executed an advance directive. This documentation must be placed in a prominent part of the medical record where it will be readily noticeable by any ASC staff providing clinical services to the patient. The documentation requirement applies, even if the ASC is unable to comply with the patient's advance directive on the basis of conscience or a State law limitation.

If the patient with an advance directive is transferred from the ASC to another healthcare facility, e.g., if there is an emergency transfer to a hospital, the ASC must ensure that a copy of the patient's advance directive is provided with the medical record when the patient is transferred.

The ASC should provide education to its staff concerning the facility's policies and procedures on advance directives.

Survey Procedures: §416.50(c)

- Review the ASC's policies and procedures related to the advance directive requirements. Do they conform to the regulatory requirements?

- Ask to see a copy of the written notice of the ASC's advance directive policies and applicable State law. Does it contain all required information? If there is a statement of limitations based on conscience or State law, does it include all required information?

- If the State has an official advance directive form, ask the ASC to demonstrate how it provides these forms upon request to patients.

- Ask the ASC how it documents that required advance directive information is provided to the patient prior to the start of the surgical procedure. Review each record in the survey sample to determine if there is evidence that the information was provided to the patient or the patient's representative prior to the start of the surgical procedure.
- Review each record in the survey sample to determine if advance directive information was provided prior to the start of the surgical procedure.

- Does the ASC advise patients, or the patient's representative or surrogate, of their right to make informed decisions about their care in the ASC?

- Review each record in the survey sample to determine if information is prominently displayed as to whether or not there is an advance directive in effect for the patient. Is the information displayed in a manner such that patients with advance directives can be readily distinguished from patients without an advance directive?

- Determine to what extent the ASC educates its staff regarding advance directives and promoting informed decisions. Does the ASC have a training class or any educational materials available for the staff regarding advance directives and informed patient decision-making? Interview staff to determine their knowledge of the advance directives of the patients in their care.

Q-0225

(Rev. 95, Issued: 12-12-13, Effective: 06-07-13, Implementation: 06-07-13)

§416.50(d) Standard: Submission and investigation of grievances

The ASC must establish a grievance procedure for documenting the existence, submission, investigation, and disposition of a patient's written or verbal grievance to the ASC. The following criteria must be met:

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(3) The grievance process must specify timeframes for review of the grievance and

the provisions of a response.

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

(5) The ASC must document how the grievance was addressed, as well as provide the patient, the patient's representative, or the patient's surrogate 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 result of the grievance process and the date the grievance process was completed.

Interpretive Guidelines: §§416.50(d)(4), (5), & (6)

What is a Grievance?

A "patient grievance" is a formal or informal written or verbal complaint that is made to the ASC by a patient or a patient's representative or surrogate, regarding a patient's care (when such complaint is not resolved at the time of the complaint by the staff present), abuse, neglect, or ASC compliance issues.

- A complaint from someone other than a patient or a patient's representative or surrogate is not a grievance.

- A complaint that is presented to the ASC's staff and resolved at that time is not considered a grievance; the grievance process requirements do not apply to such complaints. For example, a complaint that discharge instructions are unclear may be resolved relatively quickly before the patient is discharged, and would not usually be considered a "grievance."

If a patient care complaint cannot be resolved at the time of the complaint by the staff present, is postponed for later resolution, is referred to other staff for later resolution, requires an investigation, and/or requires additional actions for resolution, the complaint is then considered a grievance for purposes of these requirements.

Billing issues are not usually considered grievances for the purposes of this grievance requirement.

Although complaints may be both written and verbal, a written complaint is always considered a grievance. This includes written complaints from a current patient, a released/discharged patient, or a patient's representative or surrogate regarding the patient care provided, abuse or neglect, or the ASC's compliance with the CfCs. For the purposes of this requirement, an email or fax is considered written.

Information obtained from patient satisfaction surveys conducted by the ASC usually is not considered a grievance. However, if an identified patient writes or attaches a written complaint on the survey and requests resolution, the complaint must be treated as a grievance. If an identified patient writes or attaches a complaint to the survey, but does

not request resolution, the ASC should treat this as a grievance if the ASC would usually treat such a complaint as a grievance.

Patient complaints that are considered grievances also include situations where a patient or a patient's representative or surrogate telephones the ASC with a complaint regarding the patient's care or with an allegation of abuse or neglect, or a failure of the ASC to comply with one or more of the CfCs.

Whenever the patient or the patient's representative or surrogate requests that his or her complaint be handled as a formal complaint or grievance, or when the patient requests a response from the ASC, the complaint is considered a grievance and all the grievance requirements apply.

Grievance Process

The ASC must have an established procedure in place for documenting the existence, submission, investigation, and disposition of a grievance.

As part of its obligation to notify patients of their rights, the ASC must inform the patient and/or the patient's representative or surrogate of the ASC's grievance process, including how to file a grievance.

All grievances submitted to any ASC staff member, whether verbally or in writing, must be reported by the staff to an ASC official who has authority to address grievances. The ASC's grievance policies and procedures must identify the person(s) in the ASC who have the authority to respond to grievances. The ASC is expected to educate staff on their obligation to report all grievances, including whom they should report the grievance to.

All grievances must be investigated, but the regulation stresses this in particular for grievances related to treatment or care that the ASC provided or allegedly failed to provide. In its investigation the ASC should not only respond to the substance of the grievance, but should also use the grievance to determine if there are systemic problems indicated by the grievance that require resolution. An ASC would be well-advised to integrate its grievance process into its overall quality assessment and performance improvement program.

The ASC's grievance process must include a timeframe for the completion of the ASC's review of the grievance allegations, as well as for the ASC to provide a response to the person filing the grievance. The timeframe must be reasonable, i.e., allowing the ASC sufficient but not excessive time to conduct its review and issue its response. CMS does not mandate a particular timeframe. The application of the ASC's timeframe begins with the date of the receipt of the grievance by the ASC.

The ASC must document for each grievance how it was addressed. The ASC must also notify the patient or the patient's representative or surrogate, in writing, of the ASC's decision regarding each grievance.

The ASC may use additional methods to resolve a grievance, such as meeting with the patient's family. There are no restrictions on the ASC's use of additional effective methods to handle a patient's grievance. However, in all cases, the ASC must provide a written notice of its decision on each patient's grievance. The written notice must include the name of an ASC contact person, the steps the ASC took to investigate the grievance, the results of the grievance process, and the date the process was completed.

When a patient communicates a grievance to the ASC via email, the ASC may respond to the patient via email, pursuant to the ASC's policy. (Some ASC may have policies prohibiting communication to patients via email.) If the patient requests a response via email, the ASC may respond via email. If the email response contains the name of an ASC contact person, the steps taken to investigate the grievance, the results of the grievance process, and the date the process was completed, the email meets the requirements for a written response.
In its written response to any grievance, the ASC is not required to include statements that could be used in a legal action against the ASC, but the ASC should provide adequate information to address the specific grievance. A form letter with generic statements about grievance process steps and results is not acceptable.

Survey Procedures: §§416.50(d)(4)(5), & (6):

- Determine whether the ASC has a written policy addressing the grievance process. Does the process specifically address how grievances are documented, how they are to be submitted, how they are to be investigated, and how the findings are to be used to dispose of the grievance? Does the policy comply with the regulatory requirements concerning reporting of grievances,, timeframe, and notice of disposition?

- Ask the ASC how many grievances it received during the past year. Ask how it documents the existence of grievances. Ask what the disposition was of grievances processed during that period. Ask to see a sample of grievance files. If this is a complaint survey concerning a grievance, ask to see grievances submitted at the time of the grievance that triggered the complaint survey.

- Review a sample of grievance files to determine if grievances are properly documented and handled in accordance with the ASC's policy and the regulatory requirements.

- Interview staff to see if staff is aware of the ASC's grievance policies. Do staff know the difference between a complaint handled on the spot and a grievance?

- Interview patients and/or representatives or surrogates to determine if they know how to file a grievance and who to contact if they have a complaint/grievance.

- Interview staff and patients to see how staff and patients are educated regarding to whom grievances and allegations should be reported.

Q-0226

(Rev. 95, Issued: 12-12-13, Effective: 06-07-13, Implementation: 06-07-13)

§416.50(d) Standard: Submission and investigation of grievances

…. The following criteria must be met:

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

(2) All allegations must be immediately reported to a person in authority in the ASC.

(3) Only substantiated allegations must be reported to the State authority or the local authority, or both.

Interpretive Guidelines: §§416.50(d)(1), (2), & (3)

Grievances making allegations related to mistreatment; neglect; verbal, mental, sexual or physical abuse; or other serious allegations of harm must be fully documented. This means that all pertinent details of the allegation must be recorded and retained in the ASC's files. Documentation of the allegation should include, at a minimum, the date and time of the alleged occurrence, the location, the names of all individuals involved, and a description of the behavior that is alleged to have occurred within the ASC and to have constituted mistreatment, neglect or abuse or other serious harm.

The ASC regulation does define the terms "mistreatment," "neglect," or "abuse." However, the following definitions from long term care regulations may be helpful in making common sense judgments about whether an allegation fits into one of these categories:

- Neglect - Failure to provide goods and services necessary to avoid physical harm, mental anguish, or mental illness (42 CFR 488.301).

- Abuse - The willful infliction of injury, unreasonable confinement, intimidation, or punishment with resulting physical harm, pain or mental anguish (42 CFR 488.301).

In addition, according to the Merriam Webster dictionary, "mistreatment" means to treat badly. It is also a synonym for abuse.

Finally, if there is applicable State law defining mistreatment, neglect or abuse in a healthcare facility, including ASCs, those definitions will apply.

All grievances alleging mistreatment, neglect or abuse that are submitted to any ASC staff member, whether verbally or in writing, must be reported immediately, i.e., as soon as possible, and at least on the same day, by the staff member to an ASC official who has authority to address grievances. The ASC's grievance policies and procedures must

identify the person(s) in the ASC who have the authority to respond to grievances. The ASC is expected to educate staff on their obligation to immediately report all grievances alleging mistreatment, neglect or abuse, including whom they should report the grievance to.

Grievances alleging mistreatment, neglect, abuse or other behavior that endangers a patient should be investigated as soon as possible, given the seriousness of the allegations and the potential for harm to patients. The ASC must conduct a careful investigation, balancing the need for speedy resolution with the need to ascertain all pertinent facts.

If the ASC confirms that the alleged mistreatment, abuse, neglect or other serious harm took place, then the ASC is obligated to report the event to the appropriate local or State authority, or even both. Depending on the specifics of the case and State or local law, the appropriate authority(ies) might include the local police, a State healthcare professional licensing board, a State agency that licenses the ASC, a State ombudsman, etc. The ASC should contact the appropriate authority promptly after it concludes its investigation of the grievance.

Survey Procedures: §§416.50(d)(1)(2), & (3)

- Do the ASC's grievance policies and procedures separately address the process for investigating grievances alleging mistreatment, abuse, neglect or other serious harm? Do the policies and procedures conform to the regulatory requirement?

- Interview staff to determine how they would handle a grievance alleging mistreatment, abuse, neglect or other serious harm? Do they know who to report the grievance to? Do they know that it should be reported immediately?

- Ask the ASC who is the person authorized to handle such grievances. Interview that person to determine if he/she understands the requirements to fully document the allegation, conduct a prompt investigation, and to report substantiated grievances to the proper authority.

- Ask the person authorized to handle such grievances if the ASC has had any grievances alleging mistreatment, neglect, abuse or other serious harm? If the answer is yes, ask to review the files for one or more such grievances. If such grievances were substantiated, verify whether there is documentation that the findings were reported to the appropriate authority.

Q-0227

(Rev. 95, Issued: 12-12-13, Effective: 06-07-13, Implementation: 06-07-13)

§416.50(e) Standard: Exercise of rights and respect for property and person.

(1) The patient has the right to the following:

(i) Be free from any act of discrimination or reprisal.

Interpretive Guidelines: §416.50(e)(1)(i)

The ASC may not take punitive action as a reprisal or discriminate against a patient. This includes reprisals or discrimination against a patient merely because he or she has exercised her rights. The ASC's patients' rights policies and procedures must indicate that the ASC does not engage in reprisals or discriminatory behavior.

Survey Procedures: §416.50(e)(1)(i)

- Interview staff to determine whether they are aware that the ASC may not discriminate against patients, or take punitive actions against any patient as a reprisal for some act on the patient's part.

- Review the ASC's policies and procedures to determine whether it is clear that patients, or their representatives, or surrogates may exercise their rights without fear of reprisal.

- Interview staff about how a patient who has filed a grievance or otherwise exercises his/her rights is treated. Is staff aware that they should not treat patients differently if the patient files a grievance?

Q-0228

(Rev. 95, Issued: 12-12-13, Effective: 06-07-13, Implementation: 06-07-13)

§416.50(e) Standard: Exercise of rights and respect for property and person.

[(1) The patient has the right to the following:]

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

Interpretive Guidelines: §416.50(e) (1)(ii)

This requirement complements the requirement for the ASC to have a grievance system. Patients have the right to express a grievance regarding the treatment or care they receive in the ASC.

The patient, or the patient's representative or surrogate, as appropriate, may file a grievance, verbally or in writing, before the date of the scheduled procedure, on the date of the procedure, or after the date of the procedure. The regulation does not prescribe any limitation as to when a patient may submit a grievance. However, it is understood that, if a substantial amount of time has passed since the care episode addressed in the grievance, e.g., several years, that it may, depending on the nature of the grievance, be harder for the ASC to investigate the grievance and ascertain the pertinent facts.

Survey Procedures: §416.50(e) (1)(ii)

- Interview ASC staff to determine if they are aware of the patient's right to file a grievance.

- If the survey is related to a complaint alleging that an ASC ignored a patient's grievance, include that medical record in the sample and review it to determine if there is any evidence of a grievance as well as of action to respond to the grievance.

Q-0229

(Rev. 137, Issued: 04-01-15, Effective: 03-27-15, Implementation: 03-27-15)

§416.50(e) Standard: Exercise of rights and respect for property and person.

[(1) The patient has the right to the following:]

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

Interpretive Guidelines: §416.50(e)(1)(iii)

As in the case of advance directives, the patient has the right to make an informed decision regarding his/her care in the ASC. The right to make informed decisions means that the patient or patient's representative or surrogate is given the information needed in order to make "informed" decisions regarding his/her care. The right to make informed decisions regarding care presumes that the patient has been provided information about his/her health status, diagnosis, and prognosis. Furthermore, it includes the patient's participation in the development of their plan of care, including providing consent to, or refusal of, medical or surgical interventions, and in planning for care after discharge from the ASC. The patient or the patient's representative or surrogate should receive adequate information, provided in a manner that the patient or the patient's representative or surrogate can understand, to assure that the patient can effectively exercise the right to make informed decisions.

ASCs must utilize an informed consent process that assures patients or their representatives or surrogates are given the information and disclosures needed to make an informed decision about whether to consent to a surgical procedure in the ASC. The primary purpose of the informed consent process in the ASC is to ensure that the patient, or the patient's representative or surrogate, is provided information necessary to enable him/her to evaluate a proposed surgery before agreeing to the surgery. Typically, this information would include potential short- and longer-term risks and benefits to the patient of the proposed intervention, including the likelihood of each, based on the available clinical evidence, as informed by the responsible physician's professional judgment. Informed consent must be obtained and the informed consent form must be signed by the patient, or as appropriate, the patient's representative, and placed in the

patient's medical record, prior to surgery. It would be acceptable if the ASC required the physician(s) who perform procedures in the ASC to obtain the patient's informed consent outside of the ASC, prior to the date of the surgery, since this might allow more time for discussion between the patient and physician than would be feasible on the date of the surgery. In such cases, the physician must follow the ASC's informed consent process. In all cases, the ASC must ensure that the patient's informed consent is secured prior to the start of the surgical procedure, and that this consent is documented in the patient's medical record. (See the interpretive guidelines for §416.47(b)(7) concerning documentation in the medical record of informed consent.)

Given that ASC surgical procedures generally entail use of some form of anesthesia, and that there are risks as well as benefits associated with the use of anesthesia, ASCs should assure that their informed consent process provides the patient with information on anesthesia risks and benefits as well as the risks and benefits of the surgical procedure. The ASC's surgical informed consent policy should describe the following:

- Who may obtain the patient's informed consent;
- The circumstances when a patient's representative, rather than the patient, may give informed consent for a surgery (see guidance for §416.50(e)(2) & (3);
- The content of the informed consent form and instructions for completing it;
- The process used to obtain informed consent, including how informed consent is to be documented in the medical record;
- Mechanisms that ensure that the informed consent form is properly executed and is in the patient's medical record prior to the surgery; and
- If the informed consent process and informed consent form are obtained outside the ASC, how the properly executed informed consent form is incorporated into the patient's medical record prior to the surgery.

If there are additional requirements under State law for informed consent, the ASC must comply with those requirements.

Example of a Well-Designed Informed Consent Process

A well-designed informed consent process would include discussion of the following elements:

- A description of the proposed surgery, including the anesthesia to be used;
- The indications for the proposed surgery;
- Material risks and benefits for the patient related to the surgery and

anesthesia, including the likelihood of each, based on the available clinical evidence, as informed by the responsible practitioner's clinical judgment. Material risks could include risks with a high degree of likelihood but a low degree of severity, as well as those with a very low degree of likelihood but high degree of severity;

- Treatment alternatives, including the attendant material risks and benefits;

- The probable consequences of declining recommended or alternative therapies;

- Who will conduct the surgical intervention and administer the anesthesia;

- Whether physicians other than the operating practitioner will be performing important tasks related to the surgery, in accordance with the ASC's policies. Important surgical tasks include: opening and closing, dissecting tissue, removing tissue, harvesting grafts, transplanting tissue, administering anesthesia, implanting devices and placing invasive lines;

- Whether, as permitted by State law, qualified medical practitioners who are not physicians will perform important parts of the surgery or administer the anesthesia, and if so, the types of tasks each type of practitioner will carry out; and that such practitioners will be performing only tasks within their scope of practice for which they have been granted privileges by the ASC.

Survey Procedures: §416.50(e)(1)(iii)

- Determine whether the ASC has an informed consent policy that meets the regulatory requirements.

- Verify in the survey sample of medical records that there is documentation that informed consent was given prior to the surgical procedure. Was the consent signed by the patient or as appropriate, the patient's representative?

- As part of the process of following one or more cases from start to finish, determine whether there is an informed consent that was executed prior to the surgery date on file, and if not, observe whether the ASC obtains informed consent.

- Check the records of patients who are in recovery on the date(s) of the survey to verify that there is documentation of informed consent.

- Interview patients to determine whether they recall being asked to consent to the procedure, and whether the risks and benefits were discussed with them at that time.

Q-0230

(Rev. 95, Issued: 12-12-13, Effective: 06-07-13, Implementation: 06-07-13)

§416.50(e) Standard: Exercise of rights and respect for property and person.

(2) If a patient is adjudged incompetent under applicable State laws 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 or surrogate designated by the patient in accordance with State law may exercise the patient's rights to the extent allowed by State law.

Interpretive Guidelines: §§416.50(e)(2)& (3)

A patient who has been determined to be incompetent under a State legal process is not capable of exercising his or her rights independently. For such patients, the person appointed under State law to act on the patient's behalf may exercise any and all of the rights afforded to any ASC patient.

In addition, a competent patient may wish to delegate his/her right to make informed decisions to another person. To the degree permitted by State law, and to the maximum extent practicable, the ASC must respect the patient's wishes and follow that process. In some cases, the patient may be unconscious or otherwise incapacitated, for example, if a complication requiring a treatment decision arises during a procedure. If the patient is unable to make a decision, the ASC must consult the patient's advance directives, medical power of attorney or patient representative or surrogate, if any of these are available. In the advance directive or the medical power of attorney, the patient may provide guidance as to his/her wishes in certain situations, or may delegate decision-making to another individual as permitted by State law. If such an individual has been selected by the patient, or if a person willing and able under applicable State law is available to make treatment decisions, relevant information should be provided to the representative or surrogate so that informed healthcare decisions can be made for the patient.

Survey Procedures: §§416.50(e)(2) &(3)

- Verify that there is a policy addressing the exercise of rights on behalf of a patient judged legally incompetent.

- Verify that there is a policy addressing the delegation by a patient of the exercise of rights to a representative.

Q-0231

(Rev. 95, Issued: 12-12-13, Effective: 06-07-13, Implementation: 06-07-13)

§416.50(f) Standard: Privacy and Safety.

The patient has the right to –

(1) Personal privacy.

Interpretive Guidelines: §416.50(f)(1)

The underlying principle of this requirement is the patient's basic right to respect, dignity, and comfort. "The right to personal privacy" includes at a minimum, that patients have privacy during personal hygiene activities (e.g., toileting, dressing), during medical/surgical treatments, and when requested as appropriate.

People not involved in the care of the patient should not be present without the patient's consent while the patient is being examined or treated. Video or other electronic monitoring or recording methods should not be used when the patient is being examined without the patient's consent. If a patient requires assistance during toileting and other personal hygiene activities, staff should assist, giving the utmost attention to the patient's need for privacy. Privacy should also be afforded when staff visits the patient to discuss clinical care issues or conduct any examination.

A patient's right to privacy may be limited in situations where a person must be continuously observed, such as when there is an emergency and transfer to a hospital is pending.

In most situations, security cameras in non-patient care areas such as stairwells, public waiting areas, outdoor areas, entrances, etc. are not generally affected by this requirement.

Survey Procedures: §416.50(f)(1)

- Observe whether patients are provided privacy during examinations, activities concerning personal hygiene, and discussions regarding the patient's health status or healthcare, and any other appropriate situations.

Q-0232

(Rev. 95, Issued: 12-12-13, Effective: 06-07-13, Implementation: 06-07-13)

§416.50(f) Standard: Privacy and Safety.

The patient has the right to –

(2) Receive care in a safe setting.

Interpretive Guidelines: §416.50(f)(2)

Each patient should receive care in an environment that a reasonable person would

consider to be safe. The ASC staff should follow current standards of practice for patient environmental safety, infection control, and security. The ASC staff should also provide protection for the patient's emotional health and safety as well as the patient's physical safety. Respect, dignity, and comfort would be components of an emotionally safe environment.

Survey Procedures: §416.50(f)(2)

- Review and analyze patient and staff incident and accident reports to identify any incidents or patterns of incidents concerning a safe environment. Expand your review if you suspect a problem with safe environment in the ASC.

- Review safety, infection control and security documentation to determine if the ASC is identifying problems, evaluating those problems, and taking steps to ensure a safe patient environment.

- Observe the environment where care and treatment are provided.

- Review policy and procedures to see what steps the facility takes to curtail unwanted visitors and/or contaminated materials.

- Interview staff and patients to see if either have any concerns about the safety of the setting.

Q-0233

(Rev. 95, Issued: 12-12-13, Effective: 06-07-13, Implementation: 06-07-13)

§416.50(f) Standard: Privacy and Safety.

The patient has the right to –

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

Interpretive Guidelines: §416.50(f)(3)

An ASC must prohibit all forms of abuse, neglect (as a form of abuse), and harassment from staff, other patients, or visitors. The ASC must have mechanisms/methods in place ensure that patients are free from all forms of abuse, neglect, or harassment.

As discussed in the guidance for §416.50(d), abuse is the willful infliction of injury, unreasonable confinement, intimidation, or punishment with resulting physical harm, pain or mental anguish or mental illness and neglect is the failure to provide goods and services necessary to avoid physical harm, mental anguish, or mental illness. The Merriam Webster Dictionary defines "harassment" as creating an unpleasant or hostile situation, especially by uninvited and unwelcome verbal or physical conduct.

The following components are suggested as necessary for effective protection from

abuse, neglect or harassment:

Prevent - Persons with a record of abuse or neglect should not be hired or retained as employees. It is recommended that the ASC have a process in place to screen all applicants for employment or privileges to practice in the ASC.

Identify - The ASC should create and maintain a proactive approach to identify events and occurrences that may constitute or contribute to abuse and neglect.
Train - The ASC, during its orientation program, and through an on-going training program, should provide all employees with information regarding patient abuse and neglect, including who in the ASC is authorized to receive and handle allegations of abuse and neglect.

Investigate - The ASC ensures, in a timely and thorough manner, an objective investigation of all allegations of abuse, neglect, or mistreatment. This includes investigation not only of grievances from patients or their representatives, for which the grievance process prescribed in §416.50(d) must be used, but also allegations from any other source.

Respond - The ASC should assure that any and all incidents of abuse, neglect, or harassment are reported and analyzed, and the appropriate corrective, remedial or disciplinary action occurs, in accordance with the applicable local, State, or Federal law.

Survey Procedures: §416.50(f)(3)

Examine the extent to which the ASC has a system in place to protect patients from abuse, neglect, and harassment of all forms, whether from staff, other patients, visitors, or other persons. In particular, determine the extent to which the ASC addresses the following issues:

- Does the ASC have policies and procedures for investigating allegations of abuse and neglect in addition to the required grievance process that applies to allegations from patients or their representatives?

- Does the ASC use the same process as for grievances alleging abuse and neglect? If not, what is the ASC's policy and process, including the process for training staff?

- Interview staff to determine if staff members know what to do if they witness abuse and neglect.

- Ask the ASC if it has had any allegations of patient abuse or neglect from any source during the past year? If it has, ask the ASC to provide the files and to describe how the matter was handled.

- Review the records to see if the appropriate agencies were notified in accordance with State and Federal laws regarding incidents of substantiated abuse and

neglect?

Q-0234

(Rev. 95, Issued: 12-12-13, Effective: 06-07-13, Implementation: 06-07-13)

§416.50(g) Standard: Confidentiality of Clinical Records

The ASC must comply with the Department's rules for the privacy and security of individually identifiable health information, as specified at 45 CFR Parts 160 and 164.

Interpretive Guidelines: §416.50(g)

Section 45 CFR Parts 160 and 164, generally known as the Health Insurance Portability and Accountability Act (HIPAA) Privacy and Security rules, establish standards for health care providers and suppliers that conduct covered electronic transactions, such as ASCs, among others, for the privacy of protected health information (phi), as well as for the security of electronic phi (ephi).

> **45 CFR 160.103** defines "Protected health information" as "individually identifiable health information" with specified exceptions and limitations.
>
> **45 CFR 160.103** defines "Individually identifiable health information" as "information that is a subset of health information, including demographic information collected from an individual, and:
>
> (1) Is created or received by a healthcare provider, health plan, employer, or healthcare clearinghouse; and
>
> (2) Relates to the past, present, or future physical or mental health or condition of an individual; the provision of healthcare to an individual; or the past, present, or future payment for the provision of healthcare to an individual; and
>
> (i) That identifies the individual; or
>
> (ii) With respect to which there is a reasonable basis to believe the information can be used to identify the individual."

Privacy Rule

Individually identifiable health information that is held by HIPAA Covered Entities is protected under the Privacy Rule. Such information held by the "business associates" of Covered Entities is protected through contractual requirements in their contracts with the Covered Entities.

The Privacy Rule requires ASCs that are HIPAA Covered Entities to engage in activities such as:

- Notifying patients about their privacy rights and how their information can be used;

- Adopting and implementing privacy procedures for the ASC;

- Training employees so that they understand the privacy procedures;

- Designating an individual to be responsible for seeing that the privacy procedures are adopted and followed within the ASC; and

- Securing patient records containing individually identifiable health information so that they are not readily available to those who do not need them.

To ease the burden of complying with these requirements, the Privacy Rule gives needed flexibility for ASCs to create their own privacy procedures, tailored to fit their size and needs. This scalability provides a more efficient and appropriate means of safeguarding protected health information than would any single standard. For example:

- The privacy official at a small ASC may be the office manager, who will have other non-privacy related duties; the privacy official at a very large, high volume ASC may be a full-time position.

- The training requirement may be satisfied by a small ASC's providing each new member of the workforce with a copy of its privacy policies and documenting that new members have reviewed the policies; whereas a very large ASC may provide training through live instruction, video presentations, or interactive software programs.
- The policies and procedures of small ASCs may be more limited under the Rule than those of a very large ASC, based on the volume of health information maintained and the number of interactions with those within and outside of the healthcare system.

The Department of Health and Human Services Office of Civil Rights, which is charged with responsibility for enforcing the Privacy Rule, provides more detailed information at the following website: http://www.hhs.gov/ocr/privacy/hipaa/understanding/index.html
A summary of the Privacy Rule's requirements may be found at:
http://www.hhs.gov/ocr/privacy/hipaa/understanding/summary/index.html

Security Rule

The Department of Health and Human Services (HHS), Office of Civil Rights, also established standards, as required under HIPAA, for the security of health information. The Security Rule specifies a series of administrative, technical, and physical security standards with which covered entities must comply to ensure the confidentiality, integrity, and availability of all ephi that the covered entity creates, receives, maintains, or transmits. The standards include required and addressable implementation specifications. Unlike the Privacy Rule, which applies to protected health information in

both electronic and non-electronic forms, the Security Rule only applies to phi in electronic form. More information on the Security Rule may be found at the following Web site:
http://www.hhs.gov/ocr/privacy/hipaa/administrative/securityrule/securityruleguidance.html

Expectations for Surveyors

Surveyors are not expected to have detailed knowledge of the requirements of the Privacy and Security Rules, but instead are to focus on the steps the ASC takes to protect the confidentiality of clinical records, as well as to assure a patient's access to his/her own clinical record. If broader violations of the Privacy Rule are suspected, the case may be referred to the Regional Office, which may in turn forward the information to the Office of Civil Rights.

The ASC must have sufficient safeguards to ensure that access to all clinical records is limited to those individuals designated by law, regulation, and policy, or duly authorized by the patient to have access. No unauthorized access or dissemination of clinical records is permitted. Clinical records must be kept secure and only viewed when necessary by those persons participating in some aspect in the patient's care.
The right to the confidentiality of clinical records means safeguarding the content of information, including patient paper records, video, audio, and/or computer-stored information from unauthorized disclosure without the specific informed consent of the patient or patient's representative.

Confidentiality applies to both central storage of the closed clinical records and to open clinical records in use throughout the ASC.

Survey Procedures: §416.50(g)

- What policies and procedures does the ASC have in place to prevent the release or disclosure of individually identifiable patient information?

- Observe whether patient information is visible in areas where it can be viewed by visitors or other patients? How likely is it that an unauthorized individual could read and/or remove a patient's medical record?

- What security measures are in place to protect the patient's medical records?

Q-0240

(Rev. 56, Issued: 12-30-09, Effective/Implementation: 12-30-09)

§416.51 Condition for Coverage – Infection control

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

Interpretive Guidelines: §416.51

This regulation requires the ASC to maintain an active program for the minimization of infections and communicable diseases. The National Institute of Allergy and Infectious Diseases (NIAID) defines an infectious disease as a change from a state of health to a state in which part or all of a host's body cannot function normally because of the presence of an infectious agent or its product. An infectious agent is defined by the NIAID as a living or quasi-living organism or particle that causes an infectious disease, and includes bacteria, viruses, fungi, protozoa, helminthes, and prions. NIAID defines a communicable disease as a disease associated with an agent that can be transmitted from one host to another. (See NIAID website glossary)

The ASC's infection control program must:

- Provide a functional and sanitary environment for surgical services, to avoid sources and transmission of infections and communicable diseases;
- Be based on nationally recognized infection control guidelines;
- Be directed by a designated health care professional with training in infection control;
- Be integrated into the ASC's QAPI program;
- Be ongoing;
- Include actions to prevent, identify and manage infections and communicable diseases; and
- Include a mechanism to immediately implement corrective actions and preventive measures that improve the control of infection within the ASC.

The ambulatory care setting, such as an ASC, presents unique challenges for infection control, because: patients remain in common areas, often for prolonged periods of time; surgical prep, recovery rooms and ORs are turned around quickly; patients with infections/communicable diseases may not be identified; and there is a risk of infection at the surgical site. Furthermore, due to the short period of time patients are in an ASC, the follow-up process to identify infections associated with the ASC requires gathering information after the patient's discharge rather than directly. It is essential that ASCs have a comprehensive and effective infection control program, because the consequences of poor infection control can be very serious. In recent years, for example, poor infection control practices related to injections of medications, saline or other infusates in some ASCs have resulted in the transmission of communicable diseases, such as hepatitis C, from one patient infected with the disease prior to his/her ASC visit to other ASC patients, and a requirement to notify thousands of other ASC patients of their potential exposure.

Survey Procedures: §416.51

One surveyor is responsible for completion of the Infection Control Surveyor Worksheet, Exhibit 351, which is used to facilitate assessment of compliance with this Condition. However, each member of the survey team, as he or she conducts his/her survey assignments, should assess the ASC's compliance with the Infection Control regulatory

requirements.

Q-0241
(Rev. 56, Issued: 12-30-09, Effective/Implementation: 12-30-09)

§416.51(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.

Interpretive Guidelines: §416.51(a)

The ASC must provide and maintain a functional and sanitary environment for surgical services, to avoid sources and transmission of infections and communicable diseases. All areas of the ASC must be clean and sanitary. This includes the waiting area(s), the pre-surgical prep area(s), the recovery room(s), and the operating or procedure rooms. The ASC must appropriately monitor housekeeping, maintenance (including repair, renovation, and construction activities), and other activities to ensure a functional and sanitary environment. Policies and procedures for a sanitary and functional environment should address the following:

- Ventilation and water quality control issues, including measures taken to maintain a safe environment during internal or external construction/renovation;
- Maintaining safe air handling systems in areas of special ventilation, such as operating rooms;
- Techniques for food sanitation if employee food storage and eating areas are provided;
- Techniques for cleaning and disinfecting environmental surfaces, carpeting, and furniture;
- Techniques for disposal of regulated and non-regulated waste; and
- Techniques for pest control.

These activities must be conducted in accordance with professionally recognized standards of infection control practice. Examples of national organizations that promulgate nationally recognized infection and communicable disease control guidelines, and/or recommendations include: the Centers for Disease Control and Prevention (CDC), the Association for Professionals in Infection Control and Epidemiology (APIC), the Society for Healthcare Epidemiology of America (SHEA), and the Association of periOperative Registered Nurses (AORN).

Survey Procedures: §416.51(a)

Using the specific questions on the infection control survey worksheet related to environmental infection control to guide you:

- Observe throughout the ASC the cleanliness of the waiting area(s), the recovery room(s), the OR/procedure rooms, floors, horizontal surfaces, patient equipment,

air inlets, mechanical rooms, supply, storage areas, etc.

- Interview staff to determine whether cleaning/disinfection takes place at the appropriate frequencies, using suitable EPA-registered agents. Ask for supporting documentation to confirm what staff say in interviews.

- Determine whether the ASC has a procedure for decontamination after gross spills of blood or other bodily fluids.

- Determine whether used sharps are disposed of properly.

- Determine whether the ASC re-uses devices marketed for single use, and if so, does it send them to an FDA-approved vendor for reprocessing?

Q-0242

(Rev. 56, Issued: 12-30-09, Effective/Implementation: 12-30-09)

§416.51(b) Standard: Infection control program.

The ASC must maintain an ongoing program designed to prevent, control, and investigate infections and communicable diseases. In addition, the infection control and prevention program must include documentation that the ASC has considered, selected, and implemented nationally recognized infection control guidelines. […]

Interpretive Guidelines: §416.51(b)

The ASC must maintain an ongoing program to prevent, control, and investigate infections and communicable diseases. As part of this ongoing program, the ASC must have an active surveillance component that covers both ASC patients and personnel working in the facility. Surveillance includes infection detection through ongoing data collection and analysis.

The ongoing program must be based on nationally recognized infection control guidelines that the ASC has selected, after a deliberative process. Examples of national organizations that promulgate nationally recognized infection and communicable disease control guidelines, and/or recommendations include: the Centers for Disease Control and Prevention (CDC), the Association for Professionals in Infection Control and Epidemiology (APIC), the Society for Healthcare Epidemiology of America (SHEA), and the Association of periOperative Registered Nurses (AORN).

The ASC should select one or more sets of guidelines that enable it to address the following key functions of an effective infection control program:

- Maintenance of a sanitary ASC environment (see requirements of §416.51(a));

- Development and implementation of infection control activities related to ASC personnel, which, for infection control purposes, includes all ASC medical staff,

employees, and on-site contract workers (e.g., nursing staff employed by associated physician practice who also work in the ASC, housekeeping staff, etc);

- Mitigation of risks associated healthcare-associated infections:
- Identifying infections;
- Monitoring compliance with all policies, procedures, protocols and other infection control program requirements;
- Program evaluation and revision of the program, when indicated;

The following provides a more detailed overview of the types of activities related to these key functions.

ASC staff-related activities:

- Evaluating ASC staff immunization status for designated infectious diseases, for example, as recommended by the CDC and its Advisory Committee on Immunization Practices (ACIP);
- Policies articulating the authority and circumstances under which the ASC screens its staff for infections likely to cause significant infectious disease or other risk to the exposed individual, and for reportable diseases, as required under local, state, or federal public health authority;
- Policies articulating when infected ASC staff are restricted from providing direct patient care or required to remain away from the facility entirely;
- New employee and regular update training in preventing and controlling healthcare-associated infections and methods to prevent exposure to and transmission of infections and communicable diseases; and
- Methods to evaluate staff exposed to patients with infections and communicable diseases.

Mitigation of risks contributing to healthcare-associated infections (HAI):

For the purposes of its surveillance activities in an acute care setting, the CDC defines an HAI as a localized or systemic condition resulting from an adverse reaction to the presence of an infectious agent(s) or its toxin(s). There must be no evidence that the infection was present or incubating at the time of admission to the ASC.

HAIs may be caused by infectious agents from endogenous or exogenous sources. Endogenous sources are body sites, such as the skin, nose, mouth, gastrointestinal (GI) tract, or vagina that are normally inhabited by microorganisms. Exogenous sources are those external to the patient, such as patient care personnel, visitors, patient care

equipment, medical devices, or the health care environment.

HAI risk mitigation measures include:

Surgery-related infection risk mitigation measures:

- Implementing appropriate prophylaxis to prevent surgical site infection (SSI), such as protocol to assure that antibiotic prophylaxis to prevent SSI for appropriate procedures is administered at the appropriate time, done with an appropriate antibiotic, and discontinued appropriately after surgery; and

- Addressing aseptic technique practices used in surgery, including sterilization or high-level disinfection of instruments, as appropriate.

- Other ASC healthcare-associated infection risk mitigation measures:

- Promotion of hand hygiene among staff and employees, including utilization of alcohol-based hand sanitizers;

- Measures specific to the prevention of infections caused by organisms that are antibiotic-resistant;

- Measures specific to safe practices for injecting medications and saline or other infusates;

- Requiring disinfectants and germicides to be used in accordance with the manufacturers' instructions;

- Appropriate use of facility and medical equipment, including air filtration equipment, UV lights, and other equipment used to control the spread of infectious agents;

- Educating patients, visitors, and staff, as appropriate, about infections and communicable diseases and methods to reduce transmission in the ASC and in the community.

Identifying Infections

The ASC must conduct monitoring activities throughout the entire facility in order to identify infection risks or communicable disease problems. The ASC should document its monitoring/tracking activities, including the measures selected for monitoring, and collection and analysis methods. Activities should be conducted in accordance with recognized infection control surveillance practices, such as, for example, those utilized by the CDC's National Healthcare Safety Net (NHSN). Monitoring includes follow-up of patients after discharge, in order to gather evidence of whether they have developed an infection associated with their stay in the ASC. See discussion of §416.44(a)(3).

The ASC must develop and implement appropriate infection control interventions to address issues identified through its detection activities, and then monitor the effectiveness of interventions through further data collection and analysis.

Monitoring Compliance

It is not sufficient for the ASC to have detailed policies and procedures governing infection control; it must also take steps to determine whether the staff of the ASC adhere to these policies and procedures in practice. Are staff washing their hands prior to providing care to patients? Do personnel who prepare injections comply with all pertinent protocols? Is equipment properly sterilized or disinfected? Is the facility clean? The ASC must demonstrate that it has a process in place for regularly assessing infection control compliance.

Program Evaluation

See the guidance for §416.51(b)(2), which requires that the infection control program must be an integral part of the ASC's quality assessment and performance improvement program.

An ASC presents different challenges for infection control as patients at varying levels of wellness are gathered in waiting or recovery areas, including the elderly, immuno-compromised patients, pre- and post-operative patients, and individuals with active or incubating infectious and communicable diseases. The length of stay for such individuals can range from brief to all day. Additionally, as ASCs are performing more invasive procedures, the level of risk for developing and transmitting infections and communicable diseases for patients and heath care workers increases. The ASC should design its infection control program with these challenges in mind. For instance, the ASC should take appropriate control measures for those individuals who may present risk for the transmission of infectious agents by the airborne or droplet route. When such individuals are identified, the ASC could, for example, implement such prevention measures that would include prompt physical separation, implementation of respiratory hygiene/cough etiquette protocols, and appropriate isolation precautions based on the routes of transmission of the suspected infection.

Survey Procedures: §416.51(b)

- Use the infection control tool to assist in assessing compliance with this standard.
- Determine that there is an ongoing program for the prevention, control, and investigation of infections and communicable diseases among patients and ASC personnel, including contract workers and volunteers.
- Determine whether the policies and procedures of the program of the infection control program are implemented correctly. Specifically, surveyors should determine whether the ASC:

- Mitigates risks contributing to healthcare-associated infections (for example, observe whether staff exhibit good hand hygiene);

- Performs monitoring/tracking activities to identify infections; and

- Monitors compliance with all infection control program requirements.

- Review the parameters of the program to determine whether it is consistent with nationally recognized infection control guidelines. Is there documentation that the ASC has developed the procedures and policies of the program based on nationally recognized infection control guidelines?

Q-0243

(Rev. 56, Issued: 12-30-09, Effective/Implementation: 12-30-09)

§416.51(b) Standard: Infection control program.

[…] The program is –

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

Interpretive Guidelines: §416.51(b) (1)

The ASC must designate in writing, a qualified licensed health care professional who will lead the facility's infection control program. The ASC must determine that the individual has had training in the principles and methods of infection control. Note that certification in infection control, such as that offered by the Certification Board of Infection Control and Epidemiology Inc. (CIBC), while highly desirable, is not required, so long as there is documentation that the individual has training that qualifies the individual to lead an infection control program. The individual selected to lead the ASC's infection control program must maintain his/her qualifications through ongoing education and training, which can be demonstrated by participation in infection control courses, or in local and national meetings organized by recognized professional societies, such as APIC and SHEA.

Although CMS does not specify the number of hours that the qualified individual must devote to the infection control program, resources must be adequate to accomplish the tasks required for the infection control program. The ASC should consider the type of surgical services offered at the facility as well as the patient population in determining the size and scope of the resources it commits to infection control. The CDC's HICPAC as well as professional infection control organizations, such as the APIC and the SHEA, publish studies and recommendations on resource allocation that ASCs may find useful.

Survey Procedures: §416.51(b) (1)

- Determine whether a qualified individual has been designated with the responsibility for leading the infection control program.

- Review the personnel file of the infection control individual to determine whether he/she is qualified through ongoing education, training, or certification to oversee the infection control program.

Q-0244

(Rev. 56, Issued: 12-30-09, Effective/Implementation: 12-30-09)

§416.51(b) Standard: Infection Control Program.

[…The program is –]

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

Interpretive Guidelines: §416.51(b)(2)

To reflect the importance of infection control the regulations specifically require that the ASC's infection control program must be integrated into its QAPI program. Among other things this means that infection control data and program activities are an ongoing component of the QAPI program, and that actions are taken in response to data analyses to improve the ASC's infection control performance. See the discussion related to §416.43, which articulates the ASC QAPI requirements.

Survey Procedures: §416.51(b)(2)

- Determine whether the ASC's quality assessment and performance program includes measures/indicators and activities related to infection control on an ongoing basis.

- Determine whether there is evidence that the QAPI infection control activities result in specific actions designed to improve infection control within the ASC.

Q-0245

(Rev. 95, Issued: 12-12-13, Effective: 06-07-13, Implementation: 06-07-13)

§416.51(b) Standard: Infection control program.

The program is –]

(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.

Interpretive Guidelines: §416.51(b)(3)

The ASC's infection control professional must develop and implement a comprehensive plan that includes actions to prevent, identify and manage infections and communicable diseases within the ASC. The plan of action must include mechanisms that result in immediate action to take preventive or corrective measures that improve the ASC's infection control outcomes. The plan should be specific to each particular area of the ASC, including, but not limited to, the waiting room(s), the recovery room(s), and the surgical areas. The designated infection control professional must assure that the program's plan of action addresses the activities discussed in the interpretive guidelines for §416.51(b), i.e.,

- Maintenance of a sanitary environment; (See discussion of §416.51(a))
- Development and implementation of infection control measures related to ASC personnel;
- Mitigation of risks associated with patient infections present upon admission;
- Mitigation of risks contributing to healthcare-associated infections;
- Active surveillance;
- Monitoring compliance with all policies, procedures, protocols, and other infection control program requirements;
- Plan evaluation and revision of the plan, when indicated;
- Coordination as required by law with federal, state, and local emergency preparedness and health authorities to address communicable and infectious disease threats and outbreaks; and
- Compliance with reportable disease requirements of the local health authority. (See discussion of §416.44(a)(3))

ASCs are required to have a process to follow up on each patient after discharge, in order to identify and track infections associated with the patient's stay in the ASC. An ASCs is not expected to establish routine post-surgical laboratory testing for infectious diseases, but if it learns of an infection in the post-discharge period from the patient or patient's physician, the ASC might consider inquiring whether there is a lab confirmation of an infectious disease, and, if there are indications that the infection was associated with the patient's stay in the ASC. If the ASC learns of a disease that is reportable under State law (including regulations), they must report it to the appropriate State authorities.

ASCs may delegate portions of this follow-up responsibility to the physicians on the ASC's staff who will see the patients in their office post-discharge only if the ASC's process includes a mechanism for ensuring that the results of the follow-up are reported back to the ASC and documented in the patient's medical record.

Survey Procedures: §416.51(b)(3)

- Ask the infection control professional to describe actual examples of how, as a result of the action plan, infection control issues were identified and corrective or preventive actions were taken.
- Ask for documentation of how those actions were evaluated to assure that they resulted in improvement.
- Ask the infection control professional to review the ASC's infection control plan of action with you, explaining how it addresses the fundamental elements of an infection control program.
- Does the plan address all the basic elements of infection control?
- Ask the ASC's leadership how it tracks infections among patients and staff.
- Ask for documentation of this tracking – is there tracking of all patients?
- Ask the ASC's leadership what diseases are reportable to the State to verify the ASC's awareness of applicable reporting requirements.
- Ask the ASC if it has ever reported a reportable disease to the State. If yes, review the ASC's documentation of the case.

Q-0260

(Rev. 56, Issued: 12-30-09, Effective/Implementation: 12-30-09)

§416.52 Condition for coverage – Patient Admission, Assessment and Discharge

The ASC must ensure each patient has the appropriate pre-surgical and post-surgical assessments completed and that all elements of the discharge requirements are completed.
Interpretive Guidelines §416.52

The core objectives of this condition are to ensure that:

- The patient can tolerate a surgical experience;
- The patient's anesthesia risk and recovery are properly evaluated
- The patient's post-operative recovery is adequately evaluated;
- The patient received effective discharge planning; and

- The patient is successfully discharged from the ASC

(See 72 FR 50477, August 31, 2007.)

All elements of the specific requirements of this condition concerning pre- and post-surgical assessments, together with the patient assessment requirements in the surgical services CfC at§416.42(a) , must be met. Deficiencies related to §416.42(a), concerning the need for a physician to evaluate the patient for anesthesia risk and surgical procedure risk prior immediately before surgery, and for anesthesia recovery prior to discharge are to be considered when determining whether the requirements of this Condition have been met.

Q-0261

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§416.52(a): Standard: ***Patient Assessment and Admission.***

(1) The ASC must develop and maintain a policy that identifies those patients who require a medical history and physical examination prior to surgery. The policy must--

(i) Include the timeframe for medical history and physical examination to be completed prior to surgery.

(ii) Address, but is not limited to, the following factors: patient age, diagnosis, the type and number of procedures scheduled to be performed on the same surgery date, known comorbidities, and the planned anesthesia level.

(iii) Be based on any applicable nationally recognized standards of practice and guidelines, and any applicable State and local health and safety laws.

Interpretive Guidelines §416.52(a)(1)

Guidance pending and will be updated in future release.

Q-0262

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§416.52(a) Standard: Admission and Pre-surgical Assessment

(2) Upon admission, each patient must have a pre-surgical assessment completed by a physician who will be performing the surgery or other qualified practitioner in accordance with applicable State health and safety laws, standards of practice, and ASC policy.

(3) The pre-surgical **assessment** ***must include*** **documentation of any allergies to drugs and biologicals.**
Interpretive Guidelines: §416.52(a)(2)-*(3)*

Guidance pending and will be updated in future release.

Q-0263

(Rev. 200, Issued: 02-21-20; Effective: 02-21-20, Implementation: 02-21-20)

§416.52(a) Standard: Admission and Pre-surgical Assessment

(4) **The patient's medical history and physical examination (if any) must be placed in the patient's medical record prior to the surgical procedure.**

Interpretive Guidelines: §416.52(a)(*4*)

Guidance pending and will be updated in future release.

Q-0264

(Rev.56, Issued: 12-30-09, Effective/Implementation: 12-30-09)

§416.52(b) Standard: Post-surgical Assessment.

(1) The patient's post-surgical condition must be assessed and documented in the medical record by a physician, other qualified practitioner, or a registered nurse with, at a minimum, post-operative care experience in accordance with applicable State health and safety laws, standards of practice, and ASC policy.

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

Interpretive Guidelines: §416.52(b)

Each patient must be assessed after the surgery is completed. In accordance with the requirements of §416.42(a)(2), a physician or anesthetist must assess each patient for recovery from anesthesia after the surgery. See the interpretive guidelines for §416.42(a)(2) for a discussion of the requirements for a post-anesthesia assessment.

In addition, each post-surgical patient's overall condition must be assessed and documented in the medical record, in order to determine how the patient's recovery is proceeding, what needs to be done to facilitate the patient's recovery, and whether the patient is ready for discharge or in need of further treatment or monitoring.

Except for the assessment of the patient's recovery from anesthesia, the assessment may be performed by a physician, another qualified practitioner, or a registered nurse with post-operative care experience who is permitted, under applicable State laws as well as general standards of practice and the ASC's clinical policy, to assess patients' post-operatively.
If the assessment identifies post-surgical patient needs that must be addressed in order for the patient to be safely discharged, or, in the case of patients who develop needs that

exceed the capabilities of the ASC, appropriately and timely transferred to a hospital for further care, the ASC must address those patient needs. This must be documented in the discharge notes in the patient's medical record.

Survey Procedures: §416.52(b)

- Verify through observation of post-surgical patient care and through record review whether the ASC evaluates each patient after surgery, both for recovery from anesthesia, as required under §416.42(a)(2), and for his/her overall recovery from the surgery and suitability for discharge.

- Are the post-surgical assessments performed by qualified personnel, i.e., a physician or anesthetist assesses the recovery from anesthesia, while the overall assessment is performed by a physician, other licensed practitioner or RN with appropriate experience in post-operative care? Where an RN performs an assessment, is there documentation of the RN's qualifications to do so?

- Does the ASC identify patient needs related to safe discharge, or, as applicable, does it identify patients who require transfer to a hospital for further treatment that exceeds the ASC's capabilities? Do the records reflect actions by the ASC to address the needs it has identified?

- Do the medical records reflect the post-surgical assessment, needs identified, and actions taken by the ASC to address those needs in the medical record's discharge notes?

Q-0265

(Rev.56, Issued: 12-30-09, Effective/Implementation: 12-30-09)

§416.52(c) Standard: Discharge. The ASC must -

(1) Provide each patient with written discharge instructions and overnight supplies. When appropriate, make a follow-up appointment with the physician, and ensure that all patients are informed, either in advance of their surgical procedure or prior to leaving the ASC, of their prescriptions, post-operative instructions and physician contact information for follow-up care.

Interpretive Guidelines: §416.52(c)(1)

Each patient, or the adult who accompanies the patient upon discharge, must be provided with written discharge instructions.

Either before the surgery or before discharge each patient must be provided with:

- Prescriptions they will need to fill associated with their recovery from surgery;

- Written instructions that specify actions the individual should take in the immediate post-operative, post-discharge period to promote their recovery from the surgery; warning signs of complications to be alert for, etc.

- How to contact the physician who will provide follow-up care to the patient. When appropriate, the ASC must make an appointment with the physician for follow-up care.

The ASC must also provide supplies, such as gauze, bandages, etc., sufficient for the patient's needs through the first night after the surgery.

Survey Procedures: §416.52(c)(1)

- Determine whether there is a copy of the discharge instructions provided to the patient in the patient's medical record.

- Look at the discharge instructions in the sample of records under review, as well as for patients being discharged while the ASC is being surveyed. Do the discharge instructions include post-operative care instructions for the patient? Do they indicate if the patient was provided prescriptions, if applicable? Do they provide physician contact information?

- Ask the ASC when and how it schedules follow-up appointments with the physician for patients.

- Ask the ASC what types of supplies it typically provides to patients upon discharge. Observe whether patients being discharged during the survey are provided any supplies to cover their overnight needs.

Q-0266

(Rev. 137, Issued: 04-01-15, Effective: 03-27-15, Implementation: 03-27-15)

§416.52(c) Standard: Discharge.

The ASC must -

(2) Ensure each patient has a discharge order, signed by the physician who performed the surgery or procedure in accordance with applicable State health and safety laws, standards of practice, and ASC policy.

Interpretive Guidelines: §416.52(c)(2)

No patient may be discharged from the ASC unless the physician who performed the surgery or procedure signs a discharge order. The ASC must ensure that physicians follow applicable State laws as well as generally accepted standards of practice and ASC policy when determining that a patient has recovered sufficiently from surgery and may be discharged from the ASC, or, as applicable, that the patient must be transferred to

another healthcare facility that can provide the ongoing treatment that the patient requires and that the ASC is unable to provide. It is permissible for the operating physician to write a discharge order indicating "the patient may be discharged when stable." (73 FR 68721). In such cases there must be documentation of when patient was stable. It is expected that a patient will actually leave the ASC within 15 – 30 minutes of the time when the physician signs the discharge order or when he or she was found to be stable, whichever happens later.

Survey Procedures: §416.52(c)(2)

- Determine whether there is a discharge order, signed by the physician who performed the surgery/procedure, in the sample of medical records being reviewed.

- Determine whether there is a discharge order signed by the physician for patients being discharged while the survey takes place.

Q-0267

(Rev.56, Issued: 12-30-09, Effective/Implementation: 12-30-09)

§416.52(c) Standard: Discharge.

The ASC must -

(3) Ensure all patients are discharged in the company of a responsible adult, except those patients exempted by the attending physician.

Interpretive Guidelines: §416.52(c)(3)

Unless the physician who is responsible for the patient's care in the ASC has exempted the patient, the ASC may not discharge any patient who is not accompanied by a responsible adult who will go with the patient after discharge. ASCs would be well-advised to develop policies that address what criteria a physician should consider when deciding a patient does not need to be discharged in the company of a responsible adult. Exemptions must be specific to individual patients, not blanket exemptions to a whole class of patients.

Survey Procedures: §416.52(c)(3)

- Do the medical records being review identify for each patient the responsible adult who will accompany the patient after discharge or, alternatively, a specific exemption or this patient from this requirement by the physician?

- Observe whether the ASC ensures an adult accompanies patients discharged while the survey is taking place, unless the patient has been specifically exempted from this requirement.

Transmittals Issued for this Appendix

Rev #	Issue Date	Subject	Impl Date	CR#
R200SOMA	02/21/2020	Revisions to the State Operations Manual (SOM) Appendix A - Hospitals, Appendix AA – Psychiatric Hospitals, Appendix B – Home Health Agency, Appendix D - Portable X-Ray, Appendix G - Rural Health Clinics/Federally Qualified Health Centers, Appendix H- End Stage Renal Disease Facilities (ESRD), Appendix K – Comprehensive Outpatient Rehabilitation Facility, Appendix L - Ambulatory Surgical Centers, Appendix M – Hospice, Appendix U - Religious Nonmedical Healthcare Institutions, Appendix W - Critical Access Hospitals (CAHs), Appendix X-Organ Transplant Program and Appendix Z - Emergency Preparedness	02/21/2020	N/A
R137SOM	04/01/2015	Revisions to State Operations Manual (SOM) Appendices A, G, L and T related to Hospitals, Rural Health Clinics, Ambulatory Surgical Centers and Swing Beds	03/27/2015	N/A
R99SOM	01/31/2014	Revised State Operations Manual (SOM) Appendices A, I, L, and W	01/31/2014	N/A
R95SOM	12/12/2013	Revised Appendix A, Interpretive Guidelines for Hospitals, Appendix L, Interpretive Guidelines for Ambulatory Surgical Centers and Appendix W, Interpretive Guidelines for Critical Access Hospitals	06/07/2013	N/A
R89SOM	08/30/2013	Revised State Operations Manual (SOM) Appendices A, I, L, and W – Rescinded and replaced by Transmittal 99	08/30/2013	N/A
R84SOM	06/07/2013	Revised Appendix A, Interpretive Guidelines for Hospitals, Appendix L, Interpretive Guidelines for Ambulatory Surgical Centers and Appendix W, Interpretive Guidelines for Critical Access Hospitals – Rescinded and replaced by Transmittal 95	06/07/2013	N/A
R76SOM	12/22/2011	Clarifications to Appendix L, Ambulatory Surgical Center Interpretive Guidelines – Obtaining Consent Before Observing Surgical Procedures	12/22/2011	N/A

R71SOM	05/13/2011	Clarifications to Appendix L, Ambulatory Surgical Center Interpretive Guidelines – Comprehensive Medical History and Physical (H&P) Assessment and Anesthetic Risk and Evaluation	05/13/2011	N/A
R56SOM	12/30/2009	Revised Appendix L, "Interpretive Guidelines for Ambulatory Surgical Centers"	12/30/2009	N/A
R01SOM	05/24/2004	Initial Release of Pub 100-07	N/A	N/A