

# CMS Manual System

## Pub. 100-07 State Operations Provider Certification

Department of Health &  
Human Services (DHHS)  
Centers for Medicare &  
Medicaid Services (CMS)

Transmittal 206

Date: June 17, 2022

**SUBJECT: Revisions to the State Operations Manual (SOM) Appendix L - Ambulatory Surgical Centers and Chapter 9 Exhibits – Exhibit 351.**

**I. SUMMARY OF CHANGES:** This Transmittal includes revisions based on recent federal regulation changes (CMS–3346–F; CMS–3334–F; CMS–3277–CN; CMS-1715-F) and is a follow up to memo QSO 20-07 released on December 20, 2019. Additionally, Appendix L was updated to clarify sections of the guidance based on stakeholder feedback. Minor technical corrections were also made to SOM Chapter 9, Exhibit 351.

**NEW/REVISED MATERIAL - EFFECTIVE DATE: June 17, 2022**  
**IMPLEMENTATION DATE: June 17, 2022**

*The revision date and transmittal number apply to the red italicized material only. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.*

**II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual not updated.)**  
**(R = REVISED, N = NEW, D = DELETED) – (Only One Per Row.)**

<b>R</b>	Appendix L/Ambulatory Surgical Center Survey Protocol
<b>R</b>	Appendix L/Q-0002/§416.2 Definitions
<b>R</b>	Appendix L/Q-0042/§416.41(b) Standard: Hospitalization
<b>R</b>	Appendix L/Q-0061/§416.42(a) Standard: Anesthetic Risk and Evaluation
<b>N</b>	Appendix L/Q-0065/§416.42(a)(1) Standard: Anesthetic Risk and Evaluation
<b>R</b>	Appendix L/Q-0101/§416.44(a) Standard: Physical Environment
<b>R</b>	Appendix L/Q-0104/§416.44(b) Standard: Safety From Fire
<b>R</b>	Appendix L/Q-0105/§416.44(b)(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.
<b>R</b>	Appendix L/Q-0106/§416.44(b)(5) When a sprinkler system is shut down for more than 10 hours, the ASC must:
<b>R</b>	Appendix L/Q-0107/§416.44(b)(6) Beginning July 5, 2017, an ASC must be in compliance with Chapter 21.3.2.1, Doors to hazardous areas.
<b>R</b>	Appendix L/Q-0108/§416.44(c) Standard: Building Safety.
<b>R</b>	Appendix L/Q-0109/§416.44(d) Standard: Emergency Equipment
<b>R</b>	Appendix L/Q-110/§416.44(e) Standard: Emergency Personnel
<b>R</b>	Appendix L/Q-0121/§416.45(a) Standard: Membership and Clinical Privileges
<b>R</b>	Appendix L/Q-0141/§416.46(a) Standard: Organization and Staffing

<b>R</b>	Appendix L/Q-0160/§416.47 Condition for Coverage: Medical Records
<b>R</b>	Appendix L/Q-0161/§416.47(a) Standard: Organization.
<b>R</b>	Appendix L/Q-0162/§416.47(b) Standard: Form and Content of Record
<b>R</b>	Appendix L/Q-0221/§416.50(a) Standard: Notice of Rights
<b>D</b>	Appendix L/Q-0222/§416.50(a) Standard: Notice of rights
<b>R</b>	Appendix L/Q-0225/§416.50(d) Standard: Submission and investigation of grievances
<b>R</b>	Appendix L/Q-0234/§416.50(g) Standard: Confidentiality of Clinical Records
<b>R</b>	Appendix L/Q-0240/§416.51 Conditions for Coverage – Infection control
<b>R</b>	Appendix L/Q-0242/§416.51(b) Standard: Infection control program.
<b>R</b>	Appendix L/Q-0245/§416.51(b)(3) Responsible for providing a plan of action for preventing...
<b>R</b>	Appendix L/Q-0261/§416.52(a): Standard: Patient assessment and admission.
<b>R</b>	Appendix L/Q-0262/§416.52(a)(2)(3) 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.
<b>R</b>	Appendix L/Q-0263/§416.52(a)(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.
<b>N</b>	Appendix L/No Tag – Informational Only – please place after tag Q-0267 so it shows as the last tag in Appendix L
<b>R</b>	Chapter 9/Exhibits Table of Contents/Exhibit 351

**III. FUNDING:** No additional funding will be provided by CMS; contractor activities are to be carried out within their FY 2023 operating budgets.

**IV. ATTACHMENTS:**

	<b>Business Requirements</b>
<b>X</b>	<b>Manual Instruction</b>
	<b>Confidential Requirements</b>
	<b>One-Time Notification</b>
	<b>Recurring Update Notification</b>

# **State Operations Manual**

## **Appendix L - Guidance for Surveyors: Ambulatory Surgical Centers**

*(Rev.206; Issued: 06-17-22)*

[Transmittals for Appendix L](#)

# Ambulatory Surgical Center Survey Protocol

## Introduction

*(Rev. 206; Issued: 06-17-22; Effective: 06-17-22; Implementation: 06-17-22)*

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 ASC survey is to determine if the ASC is in compliance with the definition of an ASC, ASC general conditions and requirements, and the 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 *Location (formerly known as the 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 *CMS Location* 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 (*LSC*) 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 *CMS Location* concurs, the *CMS Location* initiates appropriate enforcement action. SAs may only survey a deemed ASC when authorized to do so by the CMS *Location*.

**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 *CMS Location* 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 *Location* 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, and 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 *Location* 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 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. All 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 *CMS Location*) 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 databases 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 (*LSC*) 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 *CMS Location* (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 - *Core Guidelines for Determining Immediate Jeopardy* in the SOM;
- *Appendix Z- Emergency Preparedness for All Provider and Certified Supplier Types Interpretive Guidance 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 *CMS Location* 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 *CMS Location* 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 *Team* 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. *At least one surgical case must be observed to evaluate compliance with the CfCs.* 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 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 CfC 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. *If the survey team identifies an immediate jeopardy situation, the team should follow the guidance in Appendix Q of the State Operations Manual.*



## 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
- Review *contracts with outside services, if applicable*, to verify these are current *and that services are being provided in safe and effective manner*.

## 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 *CMS Location* (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 medical history and physical assessment, *as applicable, if required by the ASC's policy*;
- Pre-surgical assessments – update of the H&P upon admission, *as applicable, if required by the ASC's policy*, 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 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 *ASC* wishes to audio *record* the conference, it must provide *a copy of the recording, or transmit a copy, to the survey team in a format the survey team can utilize. If the survey team has the capability to record the discussion, the team may use its own recording device for its purposes.* 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. *Any videotaping must also comply with all applicable state and federal privacy laws.*

## **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 *national data system* 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, *Core* 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 *CMS Location* 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 *CMS Location* 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 *the national data system*, 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 *national data system* Complaint Tracking System:

- Description of sample selection;
- Summary listing of sample cases;
- Summary of interviews;
- Complaint investigation narrative;
- For all surveys with a LSC 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-0002

*(Rev. 206; Issued: 06-17-22; Effective: 06-17-22; Implementation: 06-17-22)*

#### §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 *requirements* in Subparts B and C, i.e., 42 CFR 416.25-54.

#### ***A. 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.

#### ***Distinct Entity - Physical or Temporal Separation***

*CMS's long-standing interpretation of the “distinct entity” requirement is that the ASC must be physically and administratively distinct (47 FR 34085) from any other entity. 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.** During the hours that the ASC is closed, its records must be secure and not accessible by non-ASC personnel.

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.

### ***Life Safety Code Implications of Sharing Space***

*If the ASC is located in a building that is shared with other entities, the ASC must be physically separated from the other tenants by walls with at least a one-hour fire resistance rating* in accordance with National Fire Protection Association (NFPA) *LSC* requirements (incorporated by cross-reference at §416.44(b)). *If State licensure requires walls with more than a one-hour fire resistance rating*, the ASC must comply with the more stringent requirement. *The fact that an ASC is permitted to use the same space as other entities at different times* does not mean that the ASC is relieved of its obligation to comply with the *physical separation, fire alarm and all other applicable requirements of the NFPA LSC standards adopted* for ASCs in accordance with §416.44(b).

*If an ASC occupies a separate space within a building that is also occupied by another health care facility that is subject to more stringent LSC requirements (e.g., hospital), the wall separating the ASC may require more than a one-hour fire resistance rating.*

### **Facilities with Diagnostic Imaging 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)(15) 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, *where feasible* 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.

## **B. 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](http://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 *beneficiary* ASC patients. If such recovery centers would be considered hospitals if they participated in the Medicare program (*see definition of a hospital in section 1861(e) of the Social Security Act*), 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 ASC patients are discharged to recovery centers, surveyors are to focus on whether or not the certified-ASC complies with the CfC requirements, including but not limited to: distinct entity, patient assessment, proper anesthesia recovery, and appropriate discharge (see each of the associated CfC requirements for more details).*

- 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.

### **C. 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 has reviewed the ASC's Form 855B enrollment application and made a recommendation for approval of the ASC's participation in Medicare.

### **D. 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 – 54 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 *Locations* 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 *walls having* at least a 1 hour *fire resistance rating* from any other *tenants within the building*.
- *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 *one or more* other healthcare entities, 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 hours *of operation*. 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 *Medicare-certified* ASCs utilizing the same space and there are deficiencies that are common to more than one ASC, citations must be issued to each *certified* ASC.
- 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 time frame 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.

**Q-0042**

*(Rev. 206; Issued: 06-17-22; Effective: 06-17-22; Implementation: 06-17-22)*

**§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)**

The ASC must be able to transfer a patient immediately to a local hospital when the patient experiences a medical emergency that the ASC is not capable of handling, or which requires emergency care extending well beyond the 24-hour time frame for ASC cases. (See §§416.44(*d*) and (*e*) for a discussion of the emergency care capabilities each ASC must have.)

#### **(1) Immediate Transfer Procedure**

An “effective procedure” for immediate emergency transfers includes:

- Written ASC policies and procedures that address the circumstances warranting emergency transfer, including who makes the transfer decision; the documentation that must accompany the transferred patient; and the procedure for accomplishing the transfer safely and expeditiously, including communicating with the receiving hospital. There must be evidence that staff are aware of and can implement the ASC’s policy immediately upon the development of a medical emergency.
- Provision of emergency care and initial stabilizing treatment within the ASC’s capabilities until the patient is transferred. (See §§416.44(*d*) and (*e*).)
- Arrangement for immediate emergency transport of the patient. (It is acceptable if the ASC contacts the ambulance service via 911 to arrange emergency transport, unless State licensure requires additional arrangements, but the ASC is still responsible for communicating with the receiving hospital to facilitate the transfer.)

#### **(2) Transfer to a local hospital**

The ASC is required to transfer patients who require emergency transfer to a local Medicare-participating hospital, or to a local, non-Medicare-participating hospital that meets the requirements for payment for emergency services by the Medicare program in accordance with 42 CFR 482.2. (See the interpretive guidelines for §482.2 in Appendix A of the State Operations

Manual concerning non-participating emergency hospitals.)

A “local” hospital means the ASC is to consider the most appropriate facility to which the ASC will transport its patients in the event of an emergency. If the closest hospital could not accommodate the patient population or the predominant medical emergencies associated with the type of surgeries performed by the ASC, another hospital that is able to do so and which is closer than other comparable hospitals would meet the “local” definition. For example, if there is a long term care hospital within five miles of the ASC, and a short-term acute care hospital providing emergency services within fifteen miles of the ASC, the ASC would be expected to transfer patients to the short-term acute care hospital.

Patient-specific circumstances play a role in determining the appropriate local hospital at the time of an emergency. For example, if the patient had a heart attack during surgery at the ASC and needs an interventional cardiac catheterization, and the closest hospital does not offer this service, it is expected that the ASC would transfer the patient to a farther hospital with the cardiac catheterization capability.

If there are multiple hospitals with comparable capabilities that are roughly the same distance from the ASC, i.e., there are only a few miles difference among them in their distance from the ASC, then the ASC may make the transfer to any one of these hospitals. For example, if there are three comparable, appropriate hospitals within a ten mile radius of the ASC, transfer to any one would be acceptable. Likewise, for another example, if the ASC is in a more rural area and there are two appropriate hospitals that are each about 40 miles distant from the ASC, but in opposite directions, each of those hospitals would be considered a “local” hospital for the ASC.

On the other hand, for example, if there is an appropriate hospital eight miles from the ASC, and another hospital with similar capabilities twenty miles from the ASC, the further hospital would not be considered a local hospital for ASC emergency transfer purposes, unless the closer hospital lacks capacity at the time of the transfer.

A State-specific definition of what constitutes a “local” hospital for ASC transfer purposes does not override the Medicare requirement to use the hospital nearest to the ASC with the appropriate capabilities.

CMS expects that, absent the specific types of circumstances described above, emergency transfers will ordinarily be made to a hospital with which the ASC has an arrangement(s) to meet the requirements of §416.41(b)(2). *The ASC is required to have an effective procedure to immediately transfer its emergency cases to the nearest, most appropriate local hospital, since a delay in transfer could affect the patient’s health. (See 72 FR 50472, August 31, 2007 and 73 FR 68714, November 18, 2008.)*

### **(3) *Periodic Written Notice***

The ASC is required to *periodically provide the local hospital, as specified in §416.41(b)(3), with written notice of its operations and patient population served. Communication between the ASC and a local hospital is important to assure that hospitals are aware of the potential for*

*receiving patient transfers from the ASC (See 84 FR 51732, September 30, 2019). CMS recommends the written notice be provided upon opening of the ASC and at least every 24 months to ensure the ASC keeps the local hospital informed and up-to-date on ASC information and any pertinent patient population changes.*

*The written notice must include:*

- Information concerning the ASC's operations. For example, this would include the ASC's name, address, hours of operation, administrator's name and contact information for any follow-up questions; and*
- Patient population served by the ASC. This would include, but is not limited to, surgical specialties and whether the ASC sees adult and/or pediatric patients.*

*The written notice may be provided to the local hospital electronically or through the mail. The ASC should maintain copies of their notices to demonstrate they are providing such notices periodically as required by the regulation.*

*While a transfer agreement between the local hospital and ASC is no longer required by regulation, communication between the hospital and ASC is encouraged. It should also be noted that transfer agreements may be required by state law for licensure purposes. Providing the local hospital with written notice does not preclude those ASCs and hospitals with functional working relationships to continue to have written transfer agreements as previously required by the conditions for coverage. Should an ASC have an existing transfer agreement in place with a local hospital, this could meet the requirement for the written notice so long as the agreement contains the required information regarding the ASCs operations and patient population as noted in the regulation.*

*Additionally, even if all the operating physicians within the ASC have admitting privileges at the local hospital, written notice is still required as per the regulation.*

### **Survey Procedures: §416.41(b)**

Before going on the survey, determine which hospital(s) in the vicinity of the ASC might meet the regulatory requirement of being a local hospital.

- Ask to see the ASC's policy and procedures for emergency transfer of patients. Review the document to determine whether it addresses the essential elements.
- How is this protocol communicated to the clinical staff of the ASC?
- Ask the clinical staff how they would handle a medical emergency of an ASC patient that could not be managed within the ASC. Do they know the ASC's policies and procedures for emergency transfer? Do they know how to arrange emergency transport?

- Ask if the ASC has had any emergency transfers of patients in the previous 12 months. If it has, review the medical records of patients transferred to hospitals to determine whether they were transferred to hospitals that meet the regulatory requirements for a local hospital. If the ASC transfers emergency cases to hospital(s) other than local one(s), ask for the rationale supporting these alternative transfers.
- Does the medical record give any indication that the ASC took steps to arrange the transfer, beyond calling 911?
- *Determine whether the ASC has periodically provided the local hospital with written notice of its operations and population served.*
- *If the ASC has a transfer agreement with the local hospital, it may serve as the written notice so long as it contains the information required by the regulation.*

## **Q-0061**

*(Rev. 206; Issued: 06-17-22; Effective: 06-17-22; Implementation: 06-17-22)*

### **§416.42(a) Standard: Anesthetic Risk and Evaluation**

#### ***(1) Immediately before surgery --***

- (ii) A physician or anesthesiologist as defined at §410.69(b) of this chapter must examine the patient to evaluate the risk of anesthesia.***

#### **Interpretive Guidelines: §416.42(a)(1)(ii)**

The ASC must have approved policies and procedures to assure that the assessment of anesthesia-related risks is completed just prior to every surgical procedure *by a physician or an anesthesiologist, as defined at §410.69(b). See interpretive guidelines at §416.42(b) & (c) for details on the definitions in §410.69(b).* (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<sup>1</sup> 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**

<sup>1</sup>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)(ii)**

- Verify that there is evidence for every medical record in the survey sample of an assessment by a physician *or anesthetist* of the patient’s risk for anesthesia.
- Ask the ASC to provide you with its policies and procedures for assessment of anesthesia risk.
- 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 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.

#### **Q-0065**

*(Rev. 206; Issued: 06-17-22; Effective: 06-17-22; Implementation: 06-17-22)*

#### **§416.42(a) Standard: Anesthetic Risk and Evaluation**

*[§416.42(a)(1) Immediately before surgery --]*



- (i) *A physician must examine the patient to evaluate the risk of the procedure to be performed;*

***Interpretive Guidelines: §416.42(a)(1)(i)***

The purpose of the exam immediately before surgery is to evaluate, based on the patient's current condition, whether the risks associated 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 *examination* 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 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 (*H&P*) assessment, *if required by ASC policy. If an ASC's policy requires an H&P be conducted prior to surgery, review of the H&P is considered to be a component of a pre-surgical assessment as required under* 42 CFR 416.52(a)(2) upon admission. In those cases, however, where *a* history and physical assessment is *required and* 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 *H&P*. See the interpretive guidelines for §§ *416.42(a)(1)(ii)*, 416.52(a)(1) & (2).

***Survey Procedures: §416.42(a)(1)(i)***

- 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.
- Ask the ASC to provide you with its policies and procedures for assessment of procedural risk.
- 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 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.

**Q-0101**

***(Rev. 206; Issued: 06-17-22; Effective: 06-17-22; Implementation: 06-17-22)***

**§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 *sterile* ORs and procedure rooms, this does not mean that procedure rooms must meet the same *level of* design and equipment standards as traditional operating rooms. *Whether performing surgical procedures in traditional ORs or a procedure room, each room must be designed in accordance with industry standards for the types of surgical procedures performed in the room.*

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(d) 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 *ventilation* standard for ORs is the American Society for Heating, Refrigerating, and Air Conditioning Engineers (ASHRAE) Standard 170, Ventilation of Health Care Facilities. *This ASHRAE standard is referenced by 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.* Addendum D of the ASHRAE standard requires *relative humidity* in ORs to be maintained between 20 - 60 percent. *ASCs must consider sterile supply and medical equipment manufacturer instructions for use regarding required humidity levels prior to any humidity level adjustment. Failure to maintain manufacturer required humidity levels may void sterile packaging and result in medical equipment malfunction or failure.*

Each operating room should have separate temperature control. Acceptable standards for OR temperature, such as those recommended by the Association of *periOperative Registered* 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) 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-0104**

*(Rev. 206; Issued: 06-17-22; Effective: 06-17-22; Implementation: 06-17-22)*

#### **§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)**

#### ***Life Safety Code (LSC)***

*Medicare-participating ASCs must comply with the requirements in the Ambulatory Health Care Occupancies (AHCO) chapters of the 2012 edition of the NFPA LSC (NFPA 101 and Tentative Interim Amendments 12-1 through 12-4), regardless of the number of patients served by an ASC. The LSC would permit a reduction in fire protection to another occupancy classification at facilities providing services simultaneously to less than four patients who are incapable of self-preservation. However, considering the complexity and elevated risk associated with surgical procedures in ASCs, CMS regulation requires that the minimum level of fire protection afforded by the AHCO requirements be maintained, regardless of the number of patients being served by an ASC.*

Compliance with the LSC *standard* for an ASC is assessed by a surveyor trained in the application of NFPA LSC *requirements*.

## ***Life Safety Code Waiver***

*An ASC may request LSC waivers for deficiencies that would result in unreasonable hardship to correct, but only if the waivers will not adversely affect the health and safety of patients. The ASC should request LSC waivers as part of the survey Plan of Correction. State agency (SA) or CMS-approved Accreditation Organization (AO) recommended waiver requests are sent to the CMS Location for final approval or denial.*

*An ASC is not permitted to request waivers from the provisions of 42 C.F.R. § 416.44(b)(4), (b)(5) and (b)(6), as these requirements are specifically listed in the regulation. These deficiencies must be corrected as part of the survey plan of correction within a reasonable period of time acceptable to CMS, ordinarily within 60 days of being notified of the deficiencies.*

## **State Code in Lieu of LSC**

*The provisions of the LSC do not apply to an ASC operating in a State where CMS has determined that the fire and safety code imposed by State law adequately protects patients in an ASC. Surveyors should refer to Chapter 2, section 2470E for guidance.*

## **Survey Procedures: §416.44(b)(1)-(3)**

- The Physical Environment CfC standards at 42 CFR §416.44(a), (d) and (e) are typically reviewed by one surveyor as part of the health and safety survey. However, each surveyor should assess the ASC's compliance with the Physical Environment CfC during the course of their survey. The LSC survey is typically conducted separately by surveyors trained to assess LSC requirements at 42 CFR §416.44(b)-(c). The survey results from the LSC survey are typically communicated separately to the ASC.*
- LSC waivers for survey deficiencies that would result in unreasonable hardship on an ASC to correct, and have no adverse effect on the health and safety of patients or ASC staff, may be requested by the facility as part of the survey plan of correction. Waiver requests and necessary supporting documentation received from the ASC as part of the survey plan of correction are reviewed by the SA or AO. Requests that the SA or AO recommend for approval, along with the supporting documentation, are forwarded to the CMS Location for review and final decision to approve or deny. A request for an LSC waiver must be sent to the CMS Location as part of each subsequent survey plan of correction.*
- An ASC is not permitted to request waivers from the provisions of 42 C.F.R. § 416.44(b)(4), (b)(5) and (b)(6), as these requirements are specifically listed in the regulation. These deficiencies must be corrected as part of the survey plan of correction within a reasonable period of time acceptable to CMS, ordinarily within 60 days of being notified of the deficiencies.*

## Q-0105

*(Rev. 206; Issued: 06-17-22; Effective: 06-17-22; Implementation: 06-17-22)*

### **§416.44(b) Standard: Safety From Fire**

**(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)**

*Alcohol-based hand rub (ABHR) dispensers are a common infection control method. Healthcare-acquired and surgical site infections are of increasing concern, and many such infections are transmitted because health care workers do not wash their hands or do so improperly or inadequately. An important aspect of getting health care workers to use ABHR dispensers is their accessibility. The American Hospital Association commissioned a study to determine the safest method to place ABHR dispensers in corridors. As a result of this study, the LSC was amended to permit the use of ABHRs under certain conditions in patient care areas and egress corridors.*

*In addition, CMS requires that ABHR dispensers be installed in a manner that protects against inappropriate access by persons who may not comprehend the associated risks of misusing ABHR solutions, which are both toxic and flammable (e.g., children, individual with intellectual disabilities, etc.). In order to avoid dangerous situations, ASCs must take appropriate precautions to secure ABHR dispensers from inappropriate access. This means ASCs could choose to install ABHR dispensers only in areas that can be easily and frequently monitored, such as in view of a nurse's station or areas that are continuously monitored with a security camera, or not install them at all in other areas. While an ASC has flexibility in deciding how best to secure ABHR dispensers, it must do so in a manner that protects against inappropriate access.*

*Regular maintenance of ABHR dispensers is seen as a crucial step in making sure that dispensers do not leak contents. ASCs are expected to maintain ABHR dispensers in accordance with manufacturers' guidelines. If the manufacturer does not have specific maintenance requirements, the facility is expected to develop its own policies and procedures to maintain all ABHR dispensers.*

*See the interpretive guidelines for §416.42 related to use of alcohol-based skin preparations in anesthetizing locations.*

#### **Survey Procedures: §416.44(b)(4)**

- Verify ABHR dispensers are installed in a manner that protects against inappropriate access.*
- Determine whether the ASC maintains the ABHR dispensers in accordance with the manufacturer's guidelines, or, if there are no manufacturer's guidelines, that the ASC has adopted policies and procedures to ensure that the dispensers are maintained.*

## **Q-0106**

*(Rev. 206; Issued: 06-17-22; Effective: 06-17-22; Implementation: 06-17-22)*

### ***§416.44(b) Standard: Safety From Fire***

**(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)**

*If the ASC is required to be in a sprinkler protected building, in accordance with the LSC, the sprinkler system is a significant fire protection feature. Therefore, when a sprinkler system is out of service for more than 10 hours in a 24-hour period, this regulation and the LSC requires either an evacuation of the building or portion of the building affected by the system outage, or the establishment of a fire watch until the sprinkler system has been returned to service.*

*A fire watch consists of trained personnel who continuously patrol the affected areas until the sprinkler system has been restored. The personnel must have access to fire extinguishers and the ability to quickly notify the fire department. Fire watch personnel look out for fire and other hazardous situations. They also ensure that fire protection features of the building (e.g., extinguishers, means of egress, alarm systems) are available and functioning. The fire department is to be notified any time the building sprinkler system is out of service.*

#### ***Survey Procedures: §416.44(b)(5)***

*If applicable, the LSC surveyors will assess the sprinkler system during the LSC survey, but health surveyors should also assess the status of the sprinkler system at the time of the health survey to determine if the sprinkler system has been shut down or out of service for more than 10 hours, and if so, confirm that an evacuation or a fire watch is in effect.*

## **Q-0107**

*(Rev. 206; Issued: 06-17-22; Effective: 06-17-22; Implementation: 06-17-22)*

### ***§416.44(b) Standard: Safety From Fire***

**(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)**

*Beginning July 5, 2017, existing ASCs must be in compliance with Chapter 21.3.2.1 of the LSC, which requires all doors to hazardous areas to be self-closing or automatic-closing.*



***Survey Procedures: §416.44(b)(6)***

*Typically, the LSC surveyors will assess all of the doors to hazardous areas during the LSC survey. If health surveyors find questionable door closures, this should be discussed with the LSC surveyor.*

**Q-0108**

***(Rev. 206; Issued: 06-17-22; Effective: 06-17-22; Implementation: 06-17-22)***

**§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)**

*Medicare-participating ASCs must comply with the 2012 edition of the NFPA 99 - Health Care Facilities Code (HCFC), and Tentative Interim Amendments TIA 12-2 through 12-6. Chapters 7, 8, 12, and 13 of the HCFC were not adopted by CMS and therefore do not apply to an ASC.*

*ASCs may apply for HCFC waivers for survey deficiencies that would result in unreasonable hardship to correct and will not adversely affect the health and safety of patients. HCFC waivers may be recommended by the SA or AO, but only the CMS Location may grant those waivers for Medicare-participating ASCs.*

**Survey Procedures: §416.44(c)**

*HCFC waivers for survey deficiencies that would result in unreasonable hardship on an ASC to correct, and that have no adverse effect the health and safety of patients or staff, may be requested by the ASC as part of the survey Plan of Correction. Waiver requests and necessary supporting documentation received from the ASC as part of the survey plan of correction are reviewed by the SA or CMS approved AO. Requests that the SA or AO recommend for approval are forwarded to the CMS Location for review and final decision to approve or deny.*

**Q-0109**

***(Rev. 206; Issued: 06-17-22; Effective: 06-17-22; Implementation: 06-17-22)***

**§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)**

The ASC's medical staff and governing body must adopt written policies and procedures that address the specific types of emergency equipment that must be available for use in the ASC's operating room. No specific list of emergency equipment is specified in the rule, but the ASC is expected to maintain a comprehensive, current, and appropriate set of emergency equipment, supplies and medications that meet current standards of practice and are necessary to respond to a patient emergency in the ASC.

The ASC must conduct periodic assessments of its policies and procedures in order to anticipate the emergency equipment, supplies and medications that may be needed to address any likely emergencies, taking into consideration the types of patients the ASC serves and the types of procedures performed in the ASC. *This is important as more complex surgical procedures move from the inpatient or hospital outpatient setting to the ASC setting. For example, if cardiac or spine procedures are being performed, what equipment, personnel, and training may be needed to handle specific emergencies associated with those surgical procedures (e.g., airway maintenance, emergency equipment specific to cardiology, etc.)?*

The ASC must provide the appropriate emergency equipment and supplies and qualified personnel necessary to meet the emergency needs of the ASC's entire patient population in accordance with acceptable standards of practice in the ASC industry. Acceptable standards of practice include adhering to State laws as well as standards or guidelines issued by nationally recognized professional organizations, etc. The ASC's policies and procedures must be written and ensure the emergency equipment is immediately available for use during emergency situations; be appropriate for the facility's patient population; and be maintained by appropriate personnel.

#### **Immediately available for use**

The ASC must have an adequate supply of emergency equipment and supplies immediately available to the operating room(s) (OR). The equipment and supplies must be in working condition. The ASC's policies must address whether the equipment and supplies must be present in each OR, or in what quantity and locations they will be available to all ORs as needed.

In the case of an ASC with more than one OR, the medical staff should adopt a policy, in

writing, that addresses:

- The type and quantity of emergency equipment and supplies that must be present in each OR; and
- For equipment not present in each OR, how many items must be available and in which locations so that the equipment is immediately available when needed in each OR.

The ASC must have qualified personnel capable of using all emergency equipment as necessary. Personnel must be able to utilize the emergency equipment in accordance with their scope of practice. There is no requirement for all ASC clinical personnel to be able to use all emergency equipment; however, whenever there is a patient in the OR, there must always be staff present capable of using the emergency equipment.

Although the regulation addresses availability of emergency equipment to the OR specifically, a prudent ASC should also make emergency equipment, supplies and medications available for patients in the recovery room.

### **Appropriate for the ASC's patient population**

The policies and procedures must incorporate the emergency equipment, supplies, and medications that are most suitable for the potential emergencies associated with the procedures performed in the ASC and the population the ASC serves. The ASC's policies must take into account the ASC's patient population, particularly, any risks or co-morbidities prevalent among that patient population. The ASC must consider the types of procedures performed as well as the risks and types of emergencies that the ASC may face based on those types of procedures. For example, if an ASC routinely provides care to pediatric patients, it must ensure that it has equipment and supplies that are the appropriate size for pediatric patients.

The ASC would also need to take into account the types of anesthesia used for the procedures performed. It would be expected that an ASC using general anesthesia is doing more complicated procedures that may have a higher risk of emergent complications, in addition to the risks associated with the use of general anesthesia. The ASC would be expected to have a more extensive supply of emergency equipment, supplies and medications than an ASC which only uses local anesthesia to perform low-risk procedures. For example, if an ASC uses anesthetics that carry a risk for malignant hyperthermia, then the ASC is expected to have supplies of medications required to treat this emergency condition, *based on nationally recognized guidelines*. The amount of medication that must be immediately available is to be based on available information on the frequency with which malignant hyperthermia may occur, as well as ASC patient characteristics, since the dosage for the emergency medication is weight-based. An ASC that performs bariatric procedures on obese patients would need to have more emergency medications available than would an ASC that specializes in pediatric procedures.

### **Maintained by appropriate personnel**

The ASC must ensure that mechanical and electrical equipment must be regularly inspected,

tested, and maintained to assure their availability when needed. Emergency supplies and medications must be regularly monitored and replaced when they are removed for use or expire. The ASC must use qualified personnel to maintain emergency equipment, supplies and medications. The ASC may use contracted personnel to perform these functions.

**Survey Procedures: §416.44(d)**

- Ask to see the ASC's policies and procedures on emergency equipment and supplies. Has the ASC identified supplies and equipment that are likely to be needed in emergency situations?
- Ask the ASC how it determined that the specified emergency equipment, supplies, and medications meet the emergency needs of the ASC's patients, taking into account the patient population and types of procedures performed and anesthesia used.
- For ASCs with multiple ORs, does the policy clearly identify the quantity of equipment, supplies and medications required and their location?
- Determine whether the designated emergency equipment is immediately available to the OR(s) if needed.
- Interview ASC clinical staff to determine if they know where the emergency equipment is located.
- Verify that there are sufficient clinical personnel qualified to utilize the emergency equipment, medications and supplies.
- Ask the ASC how it would handle simultaneous emergencies, e.g., an emergency in more than one OR, or an emergency in the OR and another one in the recovery room.
- Is there evidence that mechanical or electrical equipment is regularly inspected, tested, and maintained by qualified personnel?
- Are emergency supplies and medications current or expired?

**Q-0110**

**(Rev. 206; Issued: 06-17-22; Effective: 06-17-22; Implementation: 06-17-22)**

**§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)**

Whenever there is a patient who has been registered in the reception area and not yet discharged from the ASC, including patients in the waiting area, in pre-operative preparation, in surgery, or in the recovery room, the ASC must also have clinical personnel present who have appropriate training and competence in the use of the requirement emergency equipment and supplies. It is not necessary for the ASC to have one person who knows how to use all the equipment/supplies, so long as for each type of equipment/supply there is always some staff member present who is competent to use it. For example, performing a tracheostomy is outside the scope of practice of a registered nurse and must be performed by a physician. On the other hand, use of an ambu-bag is within the RN's scope of practice.

There must also be staff present in the ASC who are trained in cardiopulmonary resuscitation (CPR) techniques. Although the regulation does not require that staff must be trained in advanced cardiac life support (ACLS) techniques, an ASC would be well-advised to consider having staff trained in ACLS, depending on the types of surgery performed and the characteristics of the ASC's patient population.

For ASCs that perform multiple procedures simultaneously, or have multiple persons in the recovery room simultaneously, there must be sufficient trained personnel to deal with multiple simultaneous emergencies.

### **Survey Procedures: §416.44(e)**

- Request documentation that confirms the ASC has staff with the requisite training and competence to use all required emergency equipment and supplies, and in cardiopulmonary resuscitation.
- Ask for evidence that someone trained in the use of the emergency equipment/supplies is available whenever there is a patient in the ASC.
- Interview staff identified as having emergency responsibilities to determine if they are aware of their role in handling an emergency. Do they know where the emergency equipment/supplies are kept?
- Ask staff with emergency responsibilities what the ASC's procedures are when a staff member designated to handle emergencies is participating in a procedure on another patient? What type of back-up system is available?

### **Q-0121**

*(Rev. 206; Issued: 06-17-22; Effective: 06-17-22; Implementation: 06-17-22)*

### **§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 *a sample of files to verify* medical staff 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-0141

*(Rev. 206; Issued: 06-17-22; Effective: 06-17-22; Implementation: 06-17-22)*

### **§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 *periOperative Registered* 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(*e*), the ASC must have personnel present who are trained in the use of the required emergency equipment specified at §416.44(*d*)

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. 206; Issued: 06-17-22; Effective: 06-17-22; Implementation: 06-17-22)**

#### **§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 *ASC* 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.

*ASCs must comply with all of the standards within this CfC, but it is important to note that the ASC CfCs do not prescribe the specific details of how the ASC must set up its medical records. However, ASC staff must maintain complete, comprehensive, and accurate medical records to ensure adequate patient care, and the ASC must comply with all ASC CfCs related to medical records and patient privacy and all other relevant state and federal privacy requirements.*

## Survey Procedures: §416.47

*Since this is the condition statement, the manner and degree to which the ASC satisfies the various standards within this condition are assessed to determine compliance.*

### Q-0161

*(Rev. 206; Issued: 06-17-22; Effective: 06-17-22; Implementation: 06-17-22)*

#### **§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 *develop and maintain* a documented system that enables it to *identify each patient's medical record*. Records may exist in hard copy, electronic format, or a combination of the two media.

*The ASC must develop and maintain a system for the proper collection, storage, and use of patient records. These should be reflected in the ASC's policies and procedures and should address issues including, but not limited to, who is authorized access to the medical record system, whether they are authorized to make entries, to correct existing entries, or only to review the record's content for various clinical and administrative purposes. The ASC's medical records policy and procedures should also address, particularly in the case of electronic medical records, how staff are trained to correctly use the system.*

*The records system must permit timely access to the ASC medical record data elements required to support the delivery of care in accordance with the ASC CfCs. Surveyors acting on behalf of CMS are not to assess a health care facility's compliance with the Health Insurance Portability and Accountability Act (HIPAA) Privacy and Security Rules or State law requirements as part of the Federal survey. The main surveyor consideration when assessing whether an EHR system is in compliance with ASC requirements is whether the EHR system allows the ASC to maintain and readily use ASC medical records, as required under §416.47.*

The ASC regulations do not prescribe how long *or in what manner an ASC needs to retain "closed" medical records, i.e., records of a patient whose surgery has been completed, who has been discharged from the ASC, and for whom all medical record entries related to that surgery have been made.* Many States have laws governing retention of medical records. CMS does not interpret or enforce State law, so issues concerning how and/or how long ASC records are retained as they relate to State law are not evaluated as part of the Federal survey.

#### **Survey Procedures: §416.47(a)**

- *Ask the responsible staff to describe how the medical record system (paper or electronic) functions. Assess whether staff are able to readily identify, access, and use the ASC medical record.*



- Review a sample of medical records for completeness and accuracy in accordance with Federal and State laws and regulations and ASC policy.
- If the ASC employs a fully or partially electronic *health* record system, ask clinical personnel to demonstrate *with open records* how they use the system in order to determine whether they are able to make entries and access needed information in *a timely manner* to support the provision of care.

## **Q-0162**

*(Rev. 206; Issued: 06-17-22; Effective: 06-17-22; Implementation: 06-17-22)*

### **§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.
- As applicable, *a* medical history and physical assessment (H&P), completed and entered into the medical record in accordance with *ASC policy*, 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 *that is signed by the patient or, if applicable, the patient's representative*. 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.
- 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-0221**

*(Rev. 206; Issued: 06-17-22; Effective: 06-17-22; Implementation: 06-17-22)*

#### **§416.50(a) Standard: Notice of Rights**

**An ASC must, prior to the start of the surgical procedure, provide the patient, 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, 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 preoperative 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 States, 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-0225**

*(Rev. 206; Issued: 06-17-22; Effective: 06-17-22; Implementation: 06-17-22)*

### **§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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- (4) The grievance process must specify timeframes for review of the grievance and the provisions of a response.**

**(5) 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.**

**(6) 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-0234**

*(Rev. 206; Issued: 06-17-22; Effective: 06-17-22; Implementation: 06-17-22)*

**§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” (*PHI*) 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 *PHI* 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 *for* Civil Rights (*OCR*), 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), *OCR*, 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 *OCR*. 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.

*CMS does not interpret or enforce the HIPAA Privacy and Security Rules, which fall under the jurisdiction of OCR. Because there are a number of scenarios that allow for using or disclosing PHI in full compliance with the HIPAA Privacy and Security Rules, surveyors must defer to OCR on whether the manner in which the ASC uses, discloses, maintains or destroys PHI is consistent with these requirements. Information on how to file a HIPAA Privacy or Security complaint with OCR may be found at <http://www.hhs.gov/ocr/privacy/hipaa/complaints/index.html>.*

#### **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. 206; Issued: 06-17-22; Effective: 06-17-22; Implementation: 06-17-22)*

#### **§416.51 Conditions 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.

### **Infection Control Breaches**

*Some types of infection control breaches, including, but not limited to, medication injection practices and disinfection and sterilization of medical devices and equipment, pose a risk of blood borne pathogen transmission that may warrant engagement of public health authorities to conduct a risk assessment and, if necessary, to implement the process of patient notification.*

### **Survey Procedures: §416.51**

- One surveyor is responsible for completion of the Infection Control Surveyor Worksheet. 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-0242**

*(Rev. 206; Issued: 06-17-22; Effective: 06-17-22; Implementation: 06-17-22)*

### **§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.

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 health 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-0245**

*(Rev. 206; Issued: 06-17-22; Effective: 06-17-22; Implementation: 06-17-22)*

#### **§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.

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, 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-0261**

*(Rev. 206; Issued: 06-17-22; Effective: 06-17-22; Implementation: 06-17-22)*

### **§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)**

The purpose of a *medical* H&P is to determine whether there is anything in the patient's overall

condition that would affect the planned surgery, such as a medication allergy, or a new or existing co-morbid condition that requires additional interventions to reduce risk to the patient, or which may even indicate that an ASC setting might not be the appropriate setting for the patient's surgery.

*ASCs must develop and maintain a policy that identifies those patients who require an H&P prior to surgery. No specific list of surgical procedures or patient types is specified in the CfCs. Instead, the ASC is expected to determine which patients require an H&P, including the timeframe for completion, and develop policies to ensure those patients receive the H&P prior to surgery. Policies must address certain patient characteristics that may necessitate the need for examination and testing prior to surgery. These factors include, but are not limited to:*

- *patient age (considering the need for H&P's based on pediatric, adult, or geriatric age differences),*
- *diagnosis,*
- *the type and number of procedures scheduled to be performed on the same surgery date,*
- *known comorbidities (e.g. cardiac or pulmonary disease), and*
- *the planned anesthesia level (e.g. minimal sedation vs general anesthesia).*

*The ASC's H&P policy must include the timeframe for the examination to be completed prior to surgery. There is no "one size fits all" approach to the timeframe for H&P completion. Although no longer required by the regulation, the ASC is not precluded from retaining, in ASC policies, the previous timeframe requirement that H&Ps be completed and documented for each ASC patient no more than 30 calendar days prior to date of surgery. The current regulation allows ASCs to self-impose restrictions, and allows all affected ASC providers to retain current restrictions for some categories of surgery. It is also important to note that State law may have specific timeframe requirements for ASCs to consider.*

*Policy development must be based on nationally recognized standards of practice and guidelines, as well as any applicable State and local health and safety laws. Consideration should also be given to information on H&P recommendations from specialty societies and medical literature. For example, the American College of Surgeons, the American Society of Anesthesiologists, the American College of Cardiology, and the American Academy of Ophthalmology have best practice guidelines or recommendations for preoperative care.*

*ASCs are encouraged to review the scope of procedures performed within their ASC along with national standards, and then engage the governing body and medical staff to determine which patients require an H&P prior to surgery. Additionally, the ASC should conduct periodic assessments of its policies and procedures in order to ensure that patients receive the appropriate pre-surgical assessments taking into consideration the types of patients the ASC serves and the types of procedures performed in the ASC.*

*ASCs should also consider their policy and process for cases where the patient is referred to the ASC for surgery on the same day as the referral. The policy should state how the ASC will handle those situations that require a same day H&P per policy. The H&P may be performed on the same day as the surgical procedure, and may be performed in the ASC, as long as it is*

conducted by qualified personnel and the results of the H&P are placed in the patient's medical record prior to the surgical procedure (see §416.52(a)(4)). It is not acceptable to conduct the H&P after the patient has been prepped and brought into the operating or procedure room.

#### **Survey Procedures: §416.52(a)(1)**

- *Review the ASC's policies and procedures regarding H&Ps to determine if they are consistent with the regulatory requirement.*
- *Is there documentation that the ASC has developed the H&P policies based on nationally recognized standards of practice and guidelines, and any applicable State and local health and safety laws?*
- *Determine through a sample of medical record reviews whether the ASC is following its own policy.*
- For H&Ps performed in the ASC on the day of the surgery, *verify* that the H&P is performed *and placed in the patient's medical record* prior to the *surgical procedure*.

#### **Q-0262**

**(Rev. 206; Issued: 06-17-22; Effective: 06-17-22; Implementation: 06-17-22)**

#### **§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)**

Each ASC patient upon admission to the ASC must have a pre-surgical assessment. *The assessment documents any pre-existing medical conditions and appropriate test results in the medical record, which would need to be considered before, during, and after surgery (84 FR 51732, 51733, 9/30/19). The focus is on identifying any health conditions that can have an impact on the patient's ability to tolerate the surgery or anesthesia, and to provide an opportunity for appropriate action, up to and including postponing or cancellation of the surgery. In addition, the pre-surgical assessment must identify and document any allergies the patient may have to drugs and biologicals, or indicate that the patient has no known allergies to drugs and biologicals.*

*The pre-surgical assessment must be completed upon admission for each patient, and is separate from any H&P assessment that may also be required by ASC policy. The operating physician or other qualified practitioner in accordance with applicable State health and safety laws, standards of practice, and ASC policy must complete the pre-surgical assessment. The*

requirement at §416.42(a)(1)(i) for a physician to examine the patient immediately before surgery to evaluate the risk of the procedure for that patient is one component of the requirement at 42 CFR 416.52(a)(2). This component must be conducted by a physician, immediately prior to surgery. (See the interpretive guidelines for §416.42(a)(1)(i).

If *ASC policy requires an* H&P under §416.52(a)(1) *and such H&P* is performed on the day of the surgical procedure in the ASC, some, but not all, elements of the pre-surgical assessment may be incorporated into the H&P. However, the assessment of the patient's risk for the procedure and anesthesia required under §416.42(a)(1) must still be conducted separately.

The patient's medical record must include documentation that the patient was examined prior to the commencement of surgery. The physician or qualified *practitioner* uses *their* clinical judgment, based upon *their* assessment of the patient's condition and co-morbidities, if any, in relation to the patient's planned surgery to decide the extent of the assessment needed.

#### **Survey Procedures: §416.52(a)(2) & (3)**

- In the sample of medical records selected for review, verify that *a pre-surgical assessment of the patient's condition was completed prior to the surgery by a physician who will be performing the surgery or other qualified practitioner as required by the regulation.*
- Verify that the pre-surgical assessment includes documentation in the medical record of the patient's allergies or lack of known allergies to drugs and biologicals.

#### **Q-0263**

*(Rev. 206; Issued: 06-17-22; Effective: 06-17-22; Implementation: 06-17-22)*

#### **§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)**

The H&P, *if one was required*, must be placed in the patient's medical record prior to the pre-surgical assessment required under §416.52(a)(2), since that assessment *should* consider the findings of the H&P before examining the patient *prior to surgery*. Both the H&P, *if any*, and the pre-surgical assessment must be placed in the patient's medical record before the surgery.

#### **Survey Procedures: §416.52(a)(4)**

In the sample of medical records selected for review, verify that, *for each patient requiring an H&P per ASC policy*, the record contains both the H&P and pre-surgical assessment. Focus in particular on open records of patients scheduled for surgery during the on-site survey, to determine whether these documents are in the patients' records before the start of their surgical procedures.

***REFER TO E-TAGS (Appendix Z)***  
***(New)***

***§ 416.54 Condition for coverage: Emergency preparedness.***

***Interpretive Guidelines: § 416.54***

*ASCs must comply with the applicable emergency preparedness requirements referenced in Appendix Z of the State Operations Manual. Please refer to Appendix Z for all applicable requirements and guidance for Emergency Preparedness. Compliance with the emergency preparedness requirements is assessed in conjunction with either the ASC health safety or life safety code survey in accordance with the survey protocol outlined within Appendix Z.*

**Exhibit 351**

**AMBULATORY SURGICAL CENTER (ASC) INFECTION CONTROL SURVEYOR WORKSHEET**

*(Rev. 206, 06-17-22)*

**Name of State Agency or AO (please specify)** \_\_\_\_\_

**Instructions:** The following is a list of items that must be assessed during the on-site survey, in order to determine compliance with the infection control Condition for Coverage. Items are to be assessed primarily by surveyor observation, with interviews used to provide additional confirming evidence of observations. In some cases information gained from interviews may provide sufficient evidence to support a deficiency citation.

The interviews and observations should be performed with the most appropriate staff person(s) for the items of interest (*e.g.*, the staff person responsible for sterilization should answer the sterilization questions). A minimum of one surgical procedure must be observed during the site visit. The surveyor(s) must identify at least one patient and follow that case from registration to discharge to observe pertinent practices. For facilities that perform brief procedures, *e.g.*, colonoscopies, it is preferable to follow at least two cases. When performing interviews and observations, any single instance of a breach in infection control would constitute a breach for that practice.

***Citation instructions are provided throughout this instrument, indicating the applicable regulatory provision to be cited on the Form CMS-2567 when deficient practices are observed.***

**PART 1 – ASC CHARACTERISTICS**

1. ASC Name

\_\_\_\_\_

2. Address, State and Zip Code

\_\_\_\_\_ Address

\_\_\_\_\_ City State Zip

3. 10-digit CMS Certification Number

--	--	--	--	--	--	--	--	--	--

4. What year did the ASC open for operation?

--	--	--	--

y y y y

5. Please list date(s) of site visit:

--	--

m m

--	--

d d

--	--	--	--

y y y y

--	--

m m

--	--

d d

--	--	--	--

y y y y

6. What was the date of the most recent previous federal (CMS) survey:

--	--

m m

--	--

d d

--	--	--	--

y y y y

7. Does the ASC participate in Medicare via accredited "deemed" status? ☐ YES  
☐ NO

7a. If YES, by which CMS-recognized accreditation organization(s)?

- ☐ Accreditation Association for Ambulatory Health Care (AAAHC)
- ☐ American Associate for Accred. of Ambulatory Surgery Facilities (AAAASF)
- ☐ *Accreditation Commission for Health Care (ACHC)*
- ☐ The Joint Commission (TJC)

7b. If YES, according to the ASC, what was the date of the most recent accreditation survey?

		/			/				
m	m		d	d		y	y	y	y

8. What is the ownership of the facility?  
(SELECT only ONE bubble)

- ☐ Physician-owned  
☐ Hospital-owned  
☐ National corporation (including joint ventures with physicians)  
☐ Other (please print):

--

9. What is the primary procedure performed at the ASC (i.e., what procedure type reflects the majority of procedures performed at the ASC)?  
(Select only ONE bubble)

- ☐ Dental  
☐ Endoscopy  
☐ Ear/Nose/Throat  
☐ OB/Gyn  
☐ Ophthalmologic  
☐ Orthopedic  
☐ Pain  
☐ Plastic/reconstructive  
☐ Podiatry  
☐ Other (please specify):

--

10. What additional procedures are performed at the ASC? (Select all that apply)

Do not include the procedure type indicated in question 9.

- ☐ Dental  
☐ Endoscopy  
☐ Ear/Nose/Throat  
☐ OB/Gyn  
☐ Ophthalmologic  
☐ Orthopedic  
☐ Pain  
☐ Plastic/reconstructive  
☐ Podiatry  
☐ Other (please specify):  
☐ N/A

--

11. Who does the ASC perform procedures on?  
(Select only ONE bubble)

- ☐ Pediatric patients only  
☐ Adult patients only  
☐ Both pediatric and adult patients

12. What is the average number of procedures performed at the ASC per month?

--	--	--	--	--	--

 per month

13. How many Operating Rooms (including procedure rooms) does the ASC have?

- |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |
|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|
| <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 1                     | 2                     | 3                     | 4                     | 5                     | 6                     | 7                     | 8                     | 9+                    |                       |

Number actively maintained:

- |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |
|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|
| <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 1                     | 2                     | 3                     | 4                     | 5                     | 6                     | 7                     | 8                     | 9+                    |                       |



---

14. Please indicate how the following services are provided: **(fill in all that apply)**

	Contract	Employee	Other	If Other, Please print:
Anesthesia/Analgesia	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Environmental Cleaning	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Linen	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Nursing	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Pharmacy	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Sterilization/Reprocessing	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Waste Management	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	

#### INFECTION CONTROL PROGRAM

15. Does the ASC have an explicit infection control program?

- ☐ YES  
☐ NO

NOTE! If the ASC does not have an explicit infection control program, a condition-level deficiency related to 42 CFR 416.51 **must** be cited.

---

16. Does the ASC's infection control program follow nationally recognized infection control guidelines? ☐ YES  
☐ NO

NOTE! If the ASC does not follow nationally recognized infection control guidelines, a deficiency related to 42 CFR 416.51(b) **must** be cited. Depending on the scope of the lack of compliance with national guidelines, a condition-level citation may also be appropriate.

---

16a. Is there documentation that the ASC considered and selected nationally-recognized infection control guidelines for its program?

- ☐ YES  
☐ NO

NOTE! If the ASC cannot document that it considered and selected specific guidelines for use in its infection control program, a deficiency related to 42 CFR 416.51(b) **must** be cited. This is the case even if the ASC's infection control practices comply with generally accepted standards of practice/national guidelines. If the ASC neither selected any nationally recognized guidelines nor complies with generally accepted infection control standards of practice, then the ASC should be cited for a condition-level deficiency related to 42 CFR 416.51.

16b. If YES to (a), which nationally-recognized infection control guidelines has the ASC selected for its program?

(Select all that apply)

- ☐ CDC/HICPAC Guidelines:
- ☐ Guideline for Isolation Precautions (CDC/HICPAC)
  - ☐ Hand hygiene (CDC/HICPAC)
  - ☐ Disinfection and Sterilization in Healthcare Facilities (CDC/HICPAC)
  - ☐ Environmental Infection Control in Healthcare Facilities (CDC/HICPAC)

- ☐ Perioperative Standards and Recommended Practices (AORN)

- ☐ Guidelines issued by a specialty surgical society / organization (List)

Please specify (please limit to the space provided):

--

- ☐ Others

Please specify (please limit to the space provided):

--

17. Does the ASC have a licensed health care professional qualified through training in infection control and designated to direct the ASC's infection control program? ☐ YES ☐ NO

NOTE! If the ASC cannot document that it has designated a qualified professional with training (not necessarily certification) in infection control to direct its infection control program, a deficiency related to 42 CFR 416.51(b)(1) **must** be cited. Lack of a designated professional responsible for infection control should be considered for citation of a condition-level deficiency related to 42 CFR 416.51.

17a. If YES, Is this person an:  
(Select only ONE bubble)

- ☐ ASC employee  
☐ ASC contractor

17b. Is this person certified in infection control (i.e., CIC)  
(Note: §416.50(b)(1) does **not** require that the individual be certified in infection control.)

- ☐ YES  
☐ NO

17c. If this person is **NOT** certified in infection control, what type of infection control training has this person received?

--

17d. On average, how many hours per week does this person spend in the ASC directing the infection control program?

--	--

hours per week

(Note: §416.51(b)(1) does **not** specify the amount of time the person must spend in the ASC directing the infection control program, but it is expected that the designated individual spends sufficient time on-site directing the program, taking into consideration the size of the ASC and the volume of its surgical activity.)

---

18. Does the ASC have a system to actively identify infections that may have been related to procedures performed at the ASC? ☐ YES

NOTE! If the ASC does not have a documented identification system, a deficiency related to 42 CFR 416.51(b)(3) must be cited. ☐ NO

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18a. If YES, how does the ASC obtain this information?

(Select ALL that apply)

- ☐ The ASC sends e-mails to patients after discharge
- ☐ The ASC follows-up with their patients' primary care providers after discharge
- ☐ The ASC relies on the physician performing the procedure to obtain this information at a follow-up visit after discharge, and report it to the ASC
- ☐ Other (please specify):

---

18b. Is there supporting documentation confirming this tracking activity?

☐ YES

☐ NO

NOTE! If the ASC does not have supporting documentation, a deficiency related to 42 CFR 416.51(b)(3) **must** be cited.

---

18c. Does the ASC have a policy/procedure in place to comply with State notifiable disease reporting requirements?

☐ YES

☐ NO

NOTE! If the ASC does not have a reporting system, a deficiency **must** be cited related to 42 CFR 416.51(b)(3). CMS does not specify the means for reporting; generally this would be done by the State health agency.

---

19. Do staff members receive infection control training?

☐ YES

If training is completely absent, then consideration should be given to condition-level citation in relation to 42 CFR 416.51, particularly when the ASC's practices fail to comply with infection control standards of practice.

☐ NO

---

19a. If YES, how do they receive infection control training?  
(Select all that apply)

- ☐ In-service
- ☐ Computer-based training
- ☐ Other (please specify):

---

19b. Which staff members receive infection control training?  
(Select all that apply)

- ☐ Medical staff
- ☐ Nursing staff
- ☐ Other staff providing direct patient care
- ☐ Staff responsible for on-site sterilization/high-level disinfection
- ☐ Cleaning staff
- ☐ Other (please specify):

---

19c. Is training:

- ☐ the same for all categories of staff  
☐ different for different categories of staff
- 

19d. Indicate frequency of staff  
infection control training  
(Select all that apply)

- ☐ Upon hire  
☐ Annually  
☐ Periodically / as needed  
☐ Other (please specify):

--

---

19e. Is there documentation confirming that training is provided to all  
categories of staff listed above?

- ☐ YES  
☐ NO

NOTE! If training is not provided to appropriate staff upon hire/granting of privileges, with some refresher training thereafter, a deficiency **must** be cited in relation to 42 CFR 416.51(b) and (b)(3).

---

20. How many procedures were  
observed during the site visit?

- ☐ 1                      ☐ 2                      ☐ 3                      ☐ 4                      ☐ Other
- 

If other, please specify the number:

--	--

procedures

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## PART 2 – INFECTION CONTROL & RELATED PRACTICES

### INSTRUCTIONS:

- Please **select ONE bubble** for each “Was Practice Performed?” question, unless otherwise noted.
- If N/A or unable to observe is selected as the response, please explain why there is no associated observation, or why the question is not applicable, in the surveyor notes box. Surveyors should attempt to assess the practice by interview or document review if unable to observe the actual practice during survey.
- During the survey, observations or concerns may prompt the surveyor to request and review specific policies and procedures. Surveyors are expected to use their judgment and review only those documents necessary to investigate their concern(s) or to validate their observations.

### I. Hand Hygiene

**Observations are to focus on staff directly involved in patient care (e.g., physicians, nurses, CRNAs, etc.).**

Hand hygiene should be observed not only during the case being followed, but also while making other observations in the ASC throughout the survey.

Unless otherwise indicated, a “No” response to any question below **must** be cited as a deficient practice in relation to 42 CFR 416.51(a).

Practices to be Assessed	Was Practice Performed?	Surveyor Notes:
A. All patient care areas have readily accessible, in appropriate locations:		
a. Soap and water	<input type="radio"/> Yes <input type="radio"/> No	
b. Alcohol-based hand rubs	<input type="radio"/> Yes <input type="radio"/> No	
I. If alcohol-based hand rub is available in patient care areas, it is installed as required. <b>(There are LSC requirements at 42 CFR 416.44(b)(4) for installation of alcohol-based hand rubs)</b>	<input type="radio"/> Yes <input type="radio"/> No	
B. Staff perform hand hygiene:		
a. After removing gloves	<input type="radio"/> Yes <input type="radio"/> No	
b. Before direct patient contact	<input type="radio"/> Yes <input type="radio"/> No	
c. After direct patient contact	<input type="radio"/> Yes <input type="radio"/> No	
d. Before performing invasive procedures (e.g. placing an IV)	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unable to observe	

- e. After contact with blood, body fluids, or contaminated surfaces (even if gloves are worn)
- ☐ Yes  
☐ No  
☐ Unable to observe

C. Regarding gloves, staff:

- a. Wear gloves for procedures that might involve contact with blood or body fluids
- ☐ Yes  
☐ No  
☐ Unable to observe

- b. Wear gloves when handling potentially contaminated patient equipment
- ☐ Yes  
☐ No  
☐ Unable to observe

- c. Remove gloves before moving to the next tasks and/or patient
- ☐ Yes  
☐ No  
☐ Unable to observe

- D. Personnel providing direct patient care do not wear artificial fingernails and/ or extenders when having direct contact with patients.
- ☐ Yes  
☐ No

**II. Injection Practices (injectable medications, saline, other infusates)**

**Observations are to be made of staff preparing and administering medications and performing injections (e.g., anesthesiologists, certified registered nurse anesthetists, nurses).**

Unless otherwise indicated, a “No” response to any question below **must** be cited as a deficient practice in relation to 42 CFR 416.51(a).

If unable to observe is selected, please clarify in the surveyor notes box why it was not observed and attempt to assess by means of interview or documentation review.

NOTE: Some types of infection control breaches, including some specific to medication administration practices, pose a risk of bloodborne pathogen transmission that warrant engagement of public health authorities. When management review confirms that a survey has identified evidence of one or more of the breaches described in S&C: 14-36-All, in addition to taking appropriate enforcement action to ensure the deficient Medicare practices are corrected, the SA should also make the responsible State public health authority aware of the identified breach.

Practices to be Assessed	Was Practice Performed?	Surveyor Notes
A. Needles are used for only one patient.	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unable to observe	

Practices to be Assessed	Was Practice Performed?	Surveyor Notes
B. Syringes are used for only one patient (this includes manufactured prefilled syringes).	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unable to observe	
C. The rubber septum on a medication, whether unopened or previously accessed, vial is disinfected with alcohol prior to piercing.	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unable to observe	
D. Medication vials are always entered with a new needle.	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unable to observe	
E. Medication vials are always entered with a new syringe	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unable to observe	
F. Medications that are pre-drawn are labeled with the date and time of draw, initials of the person drawing, medication name, strength and beyond-use date and time	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unable to observe	
NOTE: A "No" answer should result in citation as a deficient practice in relation to 42 CFR 416.48(a), Administration of Drugs		
G. a. Single dose (single-use) medication vials are used for only one patient	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unable to observe	
b. Bags of IV solutions are used for only one patient (and not as a source of flush solution for multiple patients).	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unable to observe	
c. Medication administration tubing and connectors are used for only one patient	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unable to observe	

Practices to be Assessed	Was Practice Performed?	Surveyor Notes
H. The ASC has voluntarily adopted a policy that medications labeled for multi-dose use for multiple patients are nevertheless only used for one patient.	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> N/A	
(Fill in N/A if no multi-dose medications/infusates are used).		
<b>Questions “H, I and J” relate to injection practices and not to multi-dose eye drop bottles</b>		
(NOTE: a “No” answer to question H. does not indicate a breach in infection control practices and does not result in a citation. <b>However</b> , a “No” response to either or both of the related questions I and J should be cited).		
<b>If YES, please skip to “K”</b>		
<b>If NO, you must also assess the practices at questions “I and J”:</b>		
I. Multi-dose vials are dated when they are first opened and discarded within 28 days unless the manufacturer specifies a different (shorter or longer) date for that opened vial. Note: This is different from the expiration date for the vial. The multi-dose vial can be dated with either the date opened or the beyond-use date as per ASC policies and procedures, so long as it is clear what the date represents and the same policy is used consistently throughout the ASC.	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unable to observe	
J. Multi-dose medication vials used for more than one patient are stored appropriately and do not enter the immediate patient care area (e.g., operating room, anesthesia carts).	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unable to observe	
NOTE: If multi-dose vials enter the immediate patient care area, they must be dedicated for single patient use and discarded immediately after use.		
K. All sharps are disposed of in a puncture-resistant sharps container	<input type="radio"/> Yes <input type="radio"/> No	
L. Sharps containers are replaced when the fill line is reached	<input type="radio"/> Yes <input type="radio"/> No	



### III. Single Use Devices, Sterilization, and High Level Disinfection

**Pre-cleaning** must always be performed prior to sterilization and high-level disinfection

**Sterilization** must be performed for critical equipment (i.e., instruments and equipment that enter normally sterile tissue or the vascular system, such as surgical instruments)

**High-level disinfection** must be performed for semi-critical equipment (i.e., items that come into contact with non-intact skin or mucous membranes such as reusable flexible endoscopes, laryngoscope blades)

**Observations are to be made of staff performing equipment reprocessing (e.g., surgical techs), unless these activities are performed under contract or arrangement off-site from the ASC.**

Unless otherwise indicated, a “No” response to any question below **must** be cited as a deficient practice in relation to 42 CFR 416.51(a).

#### SINGLE-USE DEVICES

*(Choose N/A if single-use devices are never reprocessed and used again) (Surveyor to confirm there is a contract or other documentation of an arrangement with a reprocessing facility by viewing it)*

Practices to be Assessed	Was Practice Performed?	Surveyor Notes
A. a. If single-use devices are reprocessed, they are devices that are approved by the FDA for reprocessing	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> N/A	
b. If single-use devices are reprocessed, they are reprocessed by an FDA-approved reprocessor.	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> N/A	

#### STERILIZATION

A. Critical equipment is sterilized	<input type="radio"/> Yes <input type="radio"/> No
B. Are sterilization procedures performed on-site? (If NO, skip to “F”)	<input type="radio"/> Yes <input type="radio"/> No

(A “No” answer does not result in a citation, since ASCs are permitted to provide for sterilization off-site, under a contractual arrangement.)

(Surveyor to confirm there is a contract or other documentation of an arrangement for off-site sterilization by viewing it)

- a. If **YES to B**, please indicate method of sterilization:
- ☐ Steam autoclave  
☐ Peracetic acid  
☐ Other (please specify):

--

Practices to be Assessed	Was Practice Performed?	Surveyor Notes
C. Items are pre-cleaned according to manufacturer's instructions or, if the manufacturer does not provide instructions, evidence-based guidelines prior to sterilization	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unable to observe	
D.	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unable to observe	
a. Medical devices and instruments are visually inspected for residual soil and re-cleaned as needed before packaging and sterilization	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unable to observe	
b. A chemical indicator (process indicator) is placed correctly, as described in manufacturer's instructions for use, in the instrument packs in every load.	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unable to observe	
c. A biological indicator is used at least weekly for each sterilizer and with every load containing implantable items, as evidenced by ASC documentation (i.e., log).	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unable to observe	
d. Each load is monitored with mechanical indicators (e.g. time, temperature, pressure)	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unable to observe	
e. Documentation for each piece of sterilization equipment is maintained and up to date and includes results from each load	<input type="radio"/> Yes <input type="radio"/> No	
E. Items are appropriately contained and handled during the sterilization process to assure that sterility is not compromised prior to use	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unable to observe	
F. After sterilization, medical devices and instruments are stored in a designated clean area so that sterility is not compromised	<input type="radio"/> Yes <input type="radio"/> No	
G. Sterile packages are inspected for integrity and compromised packages are reprocessed	<input type="radio"/> Yes <input type="radio"/> No	

Practices to be Assessed	Was Practice Performed?	Surveyor Notes
H. Is immediate-use steam sterilization (IUSS) performed on-site?	<input type="radio"/> Yes <input type="radio"/> No	
<b>If NO, skip to “High Level Disinfection Section”</b>		
<b>If YES, you must also assess the practices at questions “I - K”:</b>		
(A “No” answer does not result in a citation)		
I. If IUSS is performed, all of the following criteria are met:		
<ul style="list-style-type: none"> <li>• Work practices ensure proper cleaning and decontamination, inspection, and arrangement of the instruments into the recommended sterilizing trays or other containment devices before sterilization.</li> <li>• Once clean, the item is placed within a container intended for immediate use. The sterilizer cycle and parameters used are selected according to the manufacturers’ instructions for use for the device, container, and sterilizer.</li> <li>• The sterilizer function is monitored with monitors (e.g., mechanical, chemical and biologic) that are approved for the cycle being used.</li> <li>• The processed item must be transferred immediately, using aseptic technique, from the sterilizer to the actual point of use, the sterile field in an ongoing surgical procedure.</li> </ul>	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unable to observe <input type="radio"/> N/A	
<p>Note: “Immediate use” is defined as the shortest possible time between a sterilized item’s removal from the sterilizer and its aseptic transfer to the sterile field. A sterilized item intended for immediate use is not stored for future use, nor held from one case to another. IUSS is <u>not</u> equivalent to “short cycle” sterilization performed in accordance with manufacturers’ IFUs. IUSS must not be a routine or frequent practice in the ASC.</p>		

Practices to be Assessed	Was Practice Performed?	Surveyor Notes
J. Immediate-use steam sterilization is NOT performed on the following devices: <ul style="list-style-type: none"> <li>• Implants.</li> <li>• Post-procedure decontamination of instruments used on patients who may have Creutzfeldt-Jakob disease or similar disorders.</li> <li>• Devices that have not been validated with the specific cycle employed.</li> <li>• Single-use devices that are sold sterile.</li> </ul>	<input type="radio"/> Yes <input type="radio"/> No	
K. Is IUSS performed on a routine basis?	<input type="radio"/> Yes <input type="radio"/> No	

(A "Yes" answer **must** be cited as a deficient practice in relation to 42 CFR 416.51(a).

#### HIGH-LEVEL DISINFECTION

Practices to be Assessed	Was Practice Performed?	Surveyor Notes
A. Semi-critical equipment is high-level disinfected or sterilized	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> N/A	
B. Is high-level disinfection performed on site? (If NO, Skip to "F")	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> N/A	
(A "No" answer does not result in a citation, since ASCs are permitted to provide for high-level disinfection off-site, under a contractual arrangement.)		
(Surveyor to confirm there is a contract or other documentation of an arrangement for off-site sterilization by viewing it)		
a. If answer to B was YES, please indicate method of high-level disinfection:	<input type="radio"/> Manual <input type="radio"/> Automated <input type="radio"/> Other (please specify):	<div style="border: 1px solid black; height: 40px; width: 100%;"></div>
C. Items are pre-cleaned according to manufacturer's instructions or, if the manufacturer does not provide instructions, evidence-based guidelines prior to high-level disinfection	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unable to observe	

Practices to be Assessed	Was Practice Performed?	Surveyor Notes
D. a. Medical devices and instruments are visually inspected for residual soil and re-cleaned as needed before high-level disinfection	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unable to observe	
b. High-level disinfection equipment is maintained according to manufacturer instructions	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unable to observe	
c. Chemicals used for high-level disinfection are:		
I. Prepared according to manufacturer instructions	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unable to observe	
II. Tested for appropriate concentration according to manufacturer's instructions	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unable to observe	
III. Replaced according to manufacturer's instructions	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unable to observe	
IV. Documented to have been prepared and replaced according to manufacturer's instructions	<input type="radio"/> Yes <input type="radio"/> No	
d. Instruments requiring high-level disinfection are:		
I. Disinfected for the appropriate length of time as specified by manufacturer's instructions or, if the manufacturer does not provide instructions, evidence-based guidelines	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unable to observe	
II. Disinfected at the appropriate temperature as specified by manufacturer's instructions or, if the manufacturer does not provide instructions, evidence-based guidelines	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unable to observe	
E. Items that undergo high-level disinfection are allowed to dry before use	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unable to observe	
F. Following high-level disinfection, items are placed in a designated clean area in a manner to prevent contamination	<input type="radio"/> Yes <input type="radio"/> No	

#### IV. Environmental Infection Control

**Observations are to be made of staff performing environmental cleaning (e.g., surgical technicians, cleaning staff, etc.)**

If unable to observe is selected, please clarify in the surveyor notes box why it was not observed and attempt to assess by means of interview or documentation review.

Unless otherwise indicated, a “No” response to any question below **must** be cited as a deficient practice in relation to 42 CFR 416.51(a).

Practices to be Assessed	Was Practice Performed?	Surveyor Notes
A. Operating rooms are cleaned and disinfected after each surgical or invasive procedure with an EPA-registered disinfectant	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unable to observe	
B. Operating rooms are terminally cleaned daily	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unable to observe	
C. Environmental surfaces in patient care areas are cleaned and disinfected, using an EPA-registered disinfectant on a regular basis (e.g., daily), when spills occur and when surfaces are visibly contaminated.	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unable to observe	
D. The ASC has a procedure in place to decontaminate gross spills of blood.	<input type="radio"/> Yes <input type="radio"/> No	

#### V. Point of Care Devices (e.g., blood glucose meter)

**Observations are to be made of staff performing fingerstick testing (e.g., nurses)**

If unable to observe or N/A is selected, please clarify in the surveyor notes box why it was not observed or applicable and attempt to assess by means of interview or documentation review.

Unless otherwise indicated, a “No” response to any question below **must** be cited as a deficient practice in relation to 42 CFR 416.51(a).

Practices to be Assessed	Was Practice Performed?	Surveyor Notes
1. Does the ASC use a point-of-care testing device, such as a blood glucose meter? <b>If NO, STOP HERE.</b>	<input type="radio"/> Yes <input type="radio"/> No	

Practices to be Assessed	Was Practice Performed?	Surveyor Notes
A. Hand hygiene is performed before and after performing a finger stick procedure to obtain a sample of blood and using the point-of-care testing device.	<input type="radio"/> Yes <input type="radio"/> No	
B. Gloves are worn by health care personnel when performing a finger stick procedure to obtain a sample of blood, and are removed after the procedure (followed by hand hygiene).	<input type="radio"/> Yes <input type="radio"/> No	
C. Finger stick devices are not used for more than one patient.	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unable to observe	
NOTE: This includes both the lancet and the lancet holding device.		
D. If used for more than one patient, the point-of-care testing device (e.g., blood glucose meter, INR monitor) is cleaned and disinfected after every use according to the manufacturer's instructions.	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> N/A	
NOTE: if the manufacturer does not provide instructions for cleaning and disinfection, then the device should not be used for >1 patient.		