

Center for Medicaid, CHIP, and Survey & Certification/Survey & Certification Group

Ref: S&C-11-21-ASC

DATE: April 8, 2011

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Clarifications to the Ambulatory Surgical Center (ASC) Interpretive Guidelines, State Operations Manual Appendix L – Obtaining consent before observing surgical procedures

Memorandum Summary

ASCs may not limit surveyor ability to observe patient care and surveyors are not required to:

- Sign documents or provide proof of vaccinations in order to observe a surgical procedure.
- Obtain the consent of the operating physician prior to observing a surgical procedure.

Surveyors will:

- Obtain patient's consent.
- Conduct themselves in a manner that protects patient safety and that does not interfere with the operating physician or procedure.

It has come to our attention that some ASCs are attempting to require surveyors satisfy certain conditions prior to entering specific areas of the facility.

An ASC may not limit surveyor access to ASC activities.

ASCs may not require surveyors to sign any type of document or provide any evidence related to the surveyor's health status or immunization history as a condition for observing surgical procedures, entering sterile areas, etc. For example, an ASC may not require surveyors to sign consent forms prior to permitting them to observe a surgical procedure, nor may the ASC develop a blanket policy prohibiting all surveyors from observing surgical procedures. We note that the survey process section of Appendix L incorrectly stated that, prior to observation of a surgical case, the operating physician must agree to the surveyor's presence in the operating/procedure room. This statement was not consistent with the survey process used in all other types of certified providers and suppliers and was not required by the ASC Conditions for Coverage (CfCs). Accordingly, in keeping with our longstanding policy that surveyors have

access to all areas of a certified facility as needed in order to assess the facility's compliance with Federal requirements, we are clarifying that a surveyor is no longer required to obtain the surgeon's consent prior to observing a surgical procedure.

A surveyor is still required to obtain the patient's consent prior to observing a surgical procedure. At the surveyor's discretion, either the ASC or the surveyor may initially approach a patient to seek the patient's consent; however, in all cases the surveyor must speak directly to the patient to obtain consent. Moreover, surveyors are expected to conduct themselves in a manner that protects patient safety and that does not interfere with the operating physician or procedure. For example, when entering a sterile area, surveyors are expected to follow appropriate protocols as to dress, etc.

If a facility denies a surveyor access to the ASC in its entirety or to parts of the ASC, or to activities which must be evaluated in order to determine compliance with the Medicare ASC CfCs, then the facility has failed to provide evidence of compliance and must be cited accordingly. Additionally, an ASC may be subject to exclusion from participation in all Federal healthcare programs by the Office of the Inspector General of the Department of Health and Human Services for failure to grant surveyor access in accordance with 42 CFR 1001.1301.

We have revised our interpretive guidelines regarding this matter. An advance copy is attached. The final version will be released at a later date and may differ slightly from this advance copy.

Effective Date: Immediately. Please ensure that all appropriate staff are fully informed within 30 days of the date of this memorandum.

Training: This policy should be shared with all survey and certification staff and their managers.

/s/
Thomas E. Hamilton

Attachment

cc: Survey and Certification Regional Office Management

CMS Manual System

Pub. 100-07 State Operations Provider Certification

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

Transmittal

(Advance Copy)

Date:

SUBJECT: Clarifications to Appendix L, Ambulatory Surgical Center Interpretive Guidelines – Obtaining Consent before Observing Surgical Procedures.

I. SUMMARY OF CHANGES: The Survey Protocol Section of the ASC Interpretive Guidelines is being revised to ensure its consistency with longstanding policy governing surveyor to access to all areas of a certified facility in order to verify the ASC is meeting the Conditions for Coverage (CfCs).

NEW/REVISED MATERIAL - EFFECTIVE DATE*: Upon Publication_____

IMPLEMENTATION DATE: _Upon Publication___

The revision date and transmittal number apply to the red italicized material only. Any other material was previously published and remains unchanged.

II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual not updated.)

(R = REVISED, N = NEW, D = DELETED) – (Only One Per Row.)

R/N/D	CHAPTER/SECTION/SUBSECTION/TITLE
R	Appendix L/Part I/Ambulatory Surgical Center Survey Protocol

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

IV. ATTACHMENTS:

	Business Requirements
X	Manual Instruction
	Confidential Requirements
	One-Time Notification
	One-Time Notification -Confidential
	Recurring Update Notification

Task 3 – Information Gathering/Investigation

(Rev)

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 to assess the status of the survey, progress 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.

- 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 to determine whether the ASC is in compliance *with the requirements*. The interpretive guidelines for each of the CfCs provide detailed guidance as to what the regulations require, as well as tips for surveyor activities to determine compliance.

Case Observation

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

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

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

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

ASC Tour

The tour may be accomplished before case observation, or surveyors who are not following a case may tour the ASC while the ASC staff is assembling the information requested during the entrance conference. The purpose of the tour is to get an overview of the whole ASC and to begin making findings about its compliance with the 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? *Is* 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?
- 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. *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. 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 to document the ASC's infection control practices.

Document Review

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

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

Photocopies

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

Medical Record Review

Closed Record Sample Size and Selection

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

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

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

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

Sampling for Complaint Surveys

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

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

It will be necessary to review several closed records. *The* selection of the sample to review will *be* dependent, *in part*, on the complaint allegations. Depending on the CfCs to be surveyed for a complaint, it may also be necessary to observe an open case. If the complaint *concerns* infection control, for example, following a case will provide a good opportunity to observe infection control practices throughout the ASC. On the other hand, if the complaint concerns a failure to assess patients preoperatively for risk, it would be more appropriate to look at a sample of closed records for the documentation of the assessments, as well as to observe portions of several open

cases, as the patients move from registration into the OR or procedure room, to observe the pre-operative assessments.

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

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

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

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

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

Interviews

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

- Prepare detailed notes of each interview conducted. Document the interview date, time, and location, the full name and title of the person interviewed, and key points made and topics discussed. To the extent possible, document quotes from the interviewee.
- Interviews with facility staff should be brief and to the point.
- Interviews should be used to determine whether staff is aware of and understand what they need to do for the ASC to comply with regulatory requirements, as well as the ASC's formal policies and procedures. It is not necessary for staff to be able to cite specific Medicare regulations, but they should be able to describe what they do in a way that *allows* surveyors *to* determine compliance with the regulations.
- Be sure to interview staff having responsibilities related to each of the CfCs being surveyed.
- Use open-ended questions whenever possible to elicit staff knowledge rather than questions that lead the staff member to certain responses. For example, to determine if a staff member is aware of building emergency procedures, and his/her role in such events, simply ask, "If you smelled smoke, what would you do?" Do not ask, "Does this ASC have policies and procedures to address emergencies?" Likewise, ask, "Can you describe what typically happens in the OR before surgery begins?" Do not ask, "Does this ASC employ a standard 'time-out' procedure before beginning surgery?"
- Surveyors must always introduce themselves and ask patients or their representatives for permission to interview them. Surveyors must be sensitive when selecting patients for interview; for example, if a patient in recovery appears to *still* be feeling the effects of the anesthesia, an interview request should not be made. The same holds if a patient appears to be experiencing significant pain or anxiety. The privacy, dignity and well-being of the patient must always be respected, along with the patient's right to refuse to allow the surveyor to conduct an interview.
- Patient interview questions should focus on factual matters *about which* the patient is likely to have information. For example, ask "Did the doctor discuss your surgery with you today? What information did the doctor discuss with you about the surgery?" "Did you notice whether people washed their hands or used a cleaning gel before providing care to you?"
- Problems or concerns identified during a patient or family interview must be addressed in the staff interviews to validate the patient's perception or to gather additional information.
- Validate as much of the information collected via interviews as possible by asking the same question of several staff or patients, or by integrating interview responses with related surveyor observations or record review findings.
- If necessary, telephone interviews may be conducted for closed cases; *however*, in-person interviews are preferred.