Washington Ambulatory Surgery Center Association

Our Patients Come First

Ambulatory Surgical Center Medicare Conditions for Coverage

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Emily R. Studebaker practices exclusively in the area of health law, advising ambulatory surgery centers and physician practices on regulatory compliance and transactional matters. In the area of regulatory compliance, Ms. Studebaker counsels physicians on fraud and abuse laws, including the Anti-Kickback Statute, the Stark Law, and state anti-rebate and self-referral laws, and general healthcare compliance matters. She also assists clients on licensure as well as accreditation and certification issues.

Ms. Studebaker represents clients in acquisitions, divestitures and joint ventures and drafts and negotiates operating agreements, asset-purchase agreements, and healthcare management agreements. She also assists clients to structure transactions to properly avoid or comply with certificate of need laws and represents clients in certificate of need review and related litigation.

In 2009, Ms. Studebaker prepared a brief *amicus curiae* to the Washington Supreme Court on behalf of the Washington Ambulatory Surgery Center Association in Columbia Physical Therapy, Inc., P.S. v. Benton Franklin Orthopedic Associates, P.L.L.C., et al., 168 Wash.2d 421 (2010). In 2006, she prepared a brief amicus curiae to the Washington Supreme Court on behalf of the Washington Academy of Eye Physicians and Surgeons and the American Academy of Ophthalmology in Wright v. Jeckle, 158 Wash.2d 375 (2006). These cases involved claims asserted under Washington's Anti-Rebate Statute and Washington's corporate practice of medicine doctrine and Professional Services Corporation Act.

Ms. Studebaker has served as legal counsel to the Washington Ambulatory Surgery Center Association (WASCA) since 2005. WASCA is a nonprofit association representing the interests of those who own, operate and seek the services of the nearly 250 ambulatory surgery centers in the State of Washington. In 2009, Ms. Studebaker received the Clutch Player Award from WASCA for service to the ambulatory surgery industry in Washington State.

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Governing Body and Management Condition for Coverage

In order to receive Medicare payment for surgical services furnished to program beneficiaries, an ambulatory surgical center ("ASC") must meet certain specific requirements referred to as Conditions for Coverage and set forth at 42 C.F.R. 416, Subpart C. This section discusses the Governing Body and Management Condition for Coverage and provides a checklist based on the survey protocol outlined in the Medicare State Operations Manual to assist an ASC in evaluating whether it meets the condition's requirements.

The Governing Body and Management Condition for Coverage requires that an ASC have a designated governing body that exercises oversight for all ASC activities. The governing body is responsible for establishing the ASC's policies, making sure that the policies are implemented, monitoring internal compliance with the policies, and assessing the policies periodically to determine whether revision is needed.[1] The Condition for Coverage states:

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

It emphasizes the responsibility of the governing body for (1) direct oversight of the ASC's quality assessment and performance improvement ("QAPI") program; (2) the quality of the ASC's healthcare services; (3) the safety of the ASC's environment; and (4) the development and maintenance of the ASC's disaster preparedness plan. The regulation sets forth standards for contract services, hospitalization and disaster preparedness, described in detail below.

It is important to note that, where a condition-level deficiency is cited related to another Condition for Coverage based on a determination that an ASC does not provide quality healthcare or a safe environment, it is likely that the ASC will also be cited for non-compliance with the Governing Body and Management Condition for Coverage.

Contract Services

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

Although the governing body may delegate day-to-day operational responsibilities to administrative, medical or other personnel, the ASC's governing body retains the ultimate responsibility for the overall operations of the ASC and the quality and safety of its services and environment. Examples of common contract services include the following:

[1] 42 C.F.R. § 416.41; Appendix L to the Medicare State Operations Manual sets forth the "Guidance for Surveyors: Ambulatory Surgical Centers."

- *Anesthesia services:* If an ASC contracts for provision of anesthesia services, it remains responsible for reviewing the credentials of all anesthesiologists and anesthetists providing anesthesia services and granting them privileges to do so in a manner that complies with the Medical Staff Condition for Coverage.

- *Administrative services:* If an ASC contracts (*e.g.*, with an associated adjacent physician practice) for provision of receptionist services, it is responsible for assuring that such services are provided in a manner that complies with the Patient Rights Condition for Coverage requirements.

- *Medical records services:* If an ASC contracts for medical records services, it must ensure that the contractor meets all requirements of the Medical Records Condition for Coverage.

Delegation of governing body authority should be documented in writing. However, as indicated above, such a contract does not relieve the ASC's governing body from its responsibility to oversee the delivery of the contract services. The ASC must assure that the contract services are provided safely and effectively and that the services are included in the ASC's QAPI program.

Hospitalization

> *(b) Standard: Hospitalization.*
> *(1) The ASC must have an effective procedure for the immediate transfer, to a hospital, of patients requiring emergency medical care beyond the capabilities of the ASC.*
> *(2) This hospital must be a local, Medicare-participating hospital or a local, nonparticipating hospital that meets the requirements for payment for emergency services under § 482.2 of this chapter.*
> *(3) The ASC must--*
> *(i) Have a written transfer agreement with a hospital that meets the requirements of paragraph (b)(2) of this section; or*
> *(ii) Ensure that all physicians performing surgery in the ASC have admitting privileges at a hospital that meets the requirements of paragraph (b)(2) of this section.*

An 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 that requires emergency care extending beyond the 24-hour time frame for ASC cases.

An "effective procedure" for immediate emergency transfers includes the following: (1) written 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; (2) provision of emergency care and initial stabilizing treatment within the ASC's capabilities until the patient is transferred; and (3) arrangement for immediate emergency transport of the patient.

The ASC is required to transfer patients to the nearest 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. If the closest hospital could not accommodate the patient population or the predominant medical emergencies associated with the type of surgeries performed at the ASC, a more distant hospital might meet the "local" definition.

A transfer agreement is a written agreement, signed by authorized representatives of the ASC and the hospital, in which the hospital agrees to accept the transfer of the ASC's patients who need inpatient hospital care, including emergency care. An ASC's transfer agreement must be in force at the time of the survey. If the ASC does not have a transfer agreement, then it must maintain documentation of the current admitting privileges at local hospitals of all physicians who perform surgery at the ASC.[2]

The existence of a transfer agreement or the possession of hospital admitting privileges by the ASC's operating physicians is not necessarily a guarantee that a hospital will accept a specific transfer, since the hospital may lack the capacity to provide the required service at the time an emergency transfer request is made. The ASC should have alternative plans to address such contingencies.

Disaster Preparedness Plan

> *(c) Standard: Disaster preparedness plan.*
> *(1) The ASC must maintain a written disaster preparedness plan that provides for the emergency care of patients, staff and others in the facility in the event of fire, natural disaster, functional failure of equipment, or other unexpected events or circumstances that are likely to threaten the health and safety of those in the ASC.*
> *(2) The ASC coordinates the plan with State and local authorities, as appropriate.*
> *(3) The ASC conducts drills, at least annually, to test the plan's effectiveness. The ASC must complete a written evaluation of each drill and promptly implement any corrections to the plan.*

An ASC's governing body is responsible for the development of a disaster preparedness plan to care for patients, staff and other individuals who are on the ASC's premises when a major disruptive event occurs. The ASC must take an all-hazards approach when developing its plan, identifying hazards that are specific to the operating environment of the ASC as well as hazards that may affect the community in which the ASC operates, including the ASC.

An ASC should consider the following when developing its disaster preparedness plan:

- *Hazard Identification:* The plan should address any potential hazards that could affect the facility directly and indirectly for the particular area in which it is located.

- *Hazard Mitigation:* The plan should include hazard mitigation[3] processes for patients, staff and others present in the facility at the time of the disaster. Mitigation details should address provision of needed care for the ASC's patients being prepared for procedures, undergoing procedures, or recovering from procedures, as well as how the ASC will educate staff in protecting themselves and others present in the ASC in the event of a disaster.

- *Preparedness:* The plan should address how the ASC will meet the needs of patients, staff and others present in the ASC if essential services break down as a result of a disaster.

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[2] If there is more than one local hospital that meets the regulatory requirement for an appropriate local transfer destination, the ASC may satisfy the requirement if its operating physicians each have admitting privileges at one of the eligible hospitals. It is not necessary that they all have privileges in the same hospital.

[3] Hazard mitigation consists of those activities taken to eliminate or reduce the probability of the event, or reduce the event's severity or consequences, either prior to or following a disaster or emergency.

- *Response:* The plan should address activities taken immediately before, during and after a disaster to address the immediate and short-term effects of the disaster.

- *Recovery:* The plan should address activities and programs that are implemented during and after the ASC's response that are designed to return the ASC to its usual state or a "new normal."

At least once per year, an ASC must conduct a drill to test the plan's effectiveness. While the drill does not have to test the response to every identified hazard, it is expected to test a significant portion of the plan. The ASC must prepare a written evaluation of each annual drill, identifying problems that arose as well as methods to address those problems. The disaster preparedness plan must be promptly updated to reflect the lessons learned from the drill and the needed changes identified in the evaluation.

An ASC must coordinate its disaster preparedness plan with state and local authorities. At a minimum, the ASC should document that it has made efforts to communicate with its state and local emergency preparedness officials to inquire about potential coordination.

Governing Body and Management Checklist

General

- □ Can your ASC's leadership articulate how frequently the governing body meets? Can it articulate the typical items on its meeting agendas? Can it provide documentation showing that the meetings occurred and the agenda items were addressed?

- □ Can your ASC provide an organizational chart of the ASC management reflecting who performs the following functions: (1) human resources; (2) medical staff credentialing and granting of privileges; (3) management of surgical services; (4) management of nursing services; (5) management of pharmaceutical services; (6) management of laboratory and radiologic services; (7) management of the ASC's physical plant; (8) medical records maintenance; (9) infection control; and (10) QAPI activity?

- □ Can your ASC provide meeting minutes or other evidence that the ASC's policies and procedures have been formally adopted by the governing body?

- □ Can your ASC provide meeting minutes or other evidence of how the governing body assures that the policies are implemented and how the governing body monitors internal compliance with and reassesses the ASC's policies?

- □ Can your ASC provide meeting minutes or other evidence of how the governing body exercises ongoing oversight of and accountability for the ASC's QAPI program?

Contracted Services

- □ Can your ASC provide a complete list of its currently contracted services?

- □ Does your ASC maintain personnel files for contract personnel that establish their credentials, privileges, training and periodic evaluation?

- □ If your ASC shares space with any other entity and the entity provides services when the ASC is in operation, can your ASC provide a contract or other formalized arrangement with that entity?

- □ Can your ASC demonstrate how it assesses the safety and effectiveness of the services provided by each contractor, including how contractor services are incorporated into its QAPI program?

- □ Can your ASC management demonstrate the process it uses to correct deficiencies in contracted services?

Hospitalization

- □ Can your ASC provide its policy and procedures for emergency transfer of patients?

- □ Can your ASC demonstrate how its emergency transfer policies and procedures are communicated to the clinical staff?

- □ Can the clinical staff articulate how they would handle a medical emergency that could not be managed within the ASC?

- □ Can your ASC identify which local hospitals meet the regulatory requirements for transfer?

- □ Can your ASC identify where it transfers patients needing emergency care that is beyond the capabilities of the ASC? If patients are transferred to hospitals that are located farther away from the ASC than other hospitals, can your ASC articulate why it does not transfer its patients to a closer hospital?

- □ Does your ASC have a current transfer agreement with an eligible local hospital?

- □ If your ASC does not have a transfer agreement, can your ASC provide documentation that each physician who has privileges to perform surgery in the ASC has admitting privileges in an eligible local hospital? Can your ASC articulate how it ensures that its information is up-to-date?

Disaster Preparedness Plan

- □ Can your ASC's leadership provide the ASC's disaster preparedness plan? Can the ASC's leadership summarize the plan, explaining how it addresses protecting patients, staff and others present in the ASC at the time of a disaster?

- □ Can your ASC's leadership articulate how the staff is informed of the plan, including their roles and responsibilities?

- □ Can your ASC provide evidence of coordination with state or local emergency management agencies, including at a minimum the ASC documentation that it made appropriate state and local agencies aware of the ASC's interest in coordination?

- □ Can your ASC provide documentation of the annual drill? Can your ASC's leadership describe how the drill was conducted and what features of the plan it is designed to test?

- □ Can your ASC provide a written evaluation of the drill that reviews the drill in detail, makes assessments of whether the plan features that were tested performed as expected, indicates what changes are needed to address any problems, and verifies that the plan was revised accordingly and that the changes were implemented?

Surgical Services
Condition for Coverage

In order to receive Medicare payment for surgical services furnished to program beneficiaries, an ambulatory surgical center ("ASC") must meet certain specific requirements referred to as Conditions for Coverage and set forth at 42 C.F.R. 416, Subpart C. This section discusses the Surgical Services Condition for Coverage and provides a checklist based on the survey protocol outlined in the Medicare State Operations Manual to assist an ASC in evaluating whether it meets the condition's requirements.

The Surgical Services Condition for Coverage requires that surgical procedures be performed in a safe manner by qualified physicians who have been granted clinical privileges by the governing body of the ASC.[4] The Condition for Coverage states:

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

Surgery in an ASC may only be performed by a qualified physician. In all cases, the physician must be licensed in the state in which the ASC is located and must be practicing within the scope of his or her license.

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

The ASC must have written policies and procedures that address the criteria for clinical staff privileges in the ASC and the process that the governing body uses when reviewing physician credentials and determining whether to grant privileges and the scope of the privileges for each physician.

The surgical procedures that take place in the ASC must be performed in a "safe manner." This means primarily that physicians and other clinical staff follow acceptable surgical standards of practice in all phases of a surgical procedure, beginning with the pre-operative preparation of the patient, through to the post-operative recovery and discharge. Acceptable standards of practice include maintaining compliance with applicable federal and state laws, regulations and guidelines governing surgical services as well as any standards and recommendations promoted by or established by nationally recognized professional organizations.[5]

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[4] 42 C.F.R. § 416.42; Appendix L to the Medicare State Operations Manual sets forth the "Guidance for Surveyors: Ambulatory Surgical Centers."

[5] Condition-level deficiencies in certain other areas may also constitute condition-level noncompliance with the Surgical Services Condition, including the following: 42 C.F.R. § 416.44(a)(1) concerning operating room design and equipment; 42 C.F.R. § 416.44(a)(2) concerning a separate recovery room; 42 C.F.R. § 416.44(a)(3) and § 416.51 concerning infection control; and 42 C.F.R. § 416.44(c) and (d) concerning emergency equipment and personnel.

In addition, acceptable standards of practice include the use of standard procedures to ensure proper identification of a patient and surgical site, in order to avoid wrong site, wrong person or wrong procedure errors. Generally accepted procedures to avoid such surgical errors require the following: (1) pre-procedure verification process to make sure all relevant documents and related information are available, correctly identified, match the patient, and are consistent with the procedure the patient and the ASC's clinical staff expect to be performed; (2) marking of the intended procedure site by the physician who will perform the procedure or another member of the surgical team so that it is unambiguously clear; and (3) a "time out" before starting the procedure to confirm that the correct patient, site and procedure have been identified, and that all required documents and equipment are available and ready for use.

In order for surgery to be performed in a safe manner in the ASC, there must be evidence that the ASC is complying with the requirements concerning quality assessment and performance improvement.[6]

Anesthetic Risk and Evaluation

> *(a) Standard: Anesthetic risk and evaluation.*
> *(1) A physician must examine the patient immediately before surgery to evaluate the risk of anesthesia and of the procedure to be performed.*
> *(2) Before discharge from the ASC, each patient must be evaluated by a physician or by an anesthetist as defined at §410.69(b) of this chapter, in accordance with applicable State health and safety laws, standards of practice, and ASC policy, for proper anesthesia recovery.*

The purpose of the exam immediately before surgery is to evaluate, based on the patient's current condition, whether the risks associated with the anesthesia that will be administered and with the surgical procedure that will be performed fall within an acceptable range for a patient having that procedure in an ASC, given that the ASC does not provide services to patients requiring hospitalization. The assessment must be specific to each patient. It is not acceptable for an ASC to assume that coverage of a specific procedure by Medicare or an insurance company in an ASC setting is a sufficient basis to conclude that the risks of the anesthesia and surgery are acceptable generically for every ASC patient.[7] The ASC must have approved policies and procedures to assure that the assessment of anesthesia-related and procedural risks is completed just prior to every surgical procedure. 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.

An evaluation of the patient's recovery from anesthesia, to determine whether the patient is recovering appropriately, must be completed and documented before the patient is discharged from the ASC. The evaluation must be completed and documented by a physician or anesthetist, a certified registered nurse anesthetist or an anesthesiologist's assistant.

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[6] Therefore, condition-level noncompliance with 42 C.F.R. § 416.43 may also constitute condition-level noncompliance with the Surgical Services Condition for Coverage.

[7] The requirement for a physician to examine the patient immediately before surgery is not to be confused with the separate requirement at 42 C.F.R. § 416.52(a)(1) for a history and physical assessment performed by a physician, although it is expected that the physician will review the materials from such pre-admission examination as part of the evaluation.

Administration of Anesthesia

> *(b) Standard: Administration of anesthesia.*
> *Anesthetics must be administered by only*
> *(1) A qualified anesthesiologist, or*
> *(2) A physician qualified to administer anesthesia, a certified registered nurse anesthetist (CRNA) or an anesthesiologist's assistant as defined in §410.69(b) of this chapter, or a supervised trainee in an approved educational program. In those cases in which a non-physician administers the anesthesia, unless exempted in accordance with paragraph (c) of this section, the anesthetist must be under the supervision of the operating physician, and in the case of an anesthesiologist's assistant, under the supervision of an anesthesiologist.*
>
> *(c) Standard: State exemption.*
> *(1) An ASC may be exempted from the requirement for physician supervision of CRNAs as described in paragraph (b)(2) of this section, if the State in which the ASC is located submits a letter to CMS signed by the Governor, following consultation with the State's Boards of Medicine and Nursing, requesting exemption from physician supervision of CRNAs. The letter from the Governor must attest that he or she has consulted with State Boards of Medicine and Nursing about issues related to access to and the quality of anesthesia services in the State and has concluded that it is in the best interests of the State's citizens to opt-out of the current physician supervision requirement, and that the opt-out is consistent with State law.*
> *(2) The request for exemption and recognition of State laws, and the withdrawal of the request may be submitted at any time, and is effective upon submission.*

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

When granting anesthesia privileges to a physician who is not an anesthesiologist, the ASC's governing body must consider (1) the practitioner's scope of practice, (2) state law, (3) the individual competencies, education, and training of the practitioner, and (4) the practitioner's compliance with the ASC's other criteria for granting physician privileges.

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

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

An "anesthesiologist's assistant" is defined as a person who (1) works under the direction of an anesthesiologist; (2) is in compliance with all applicable requirements of state law, including any licensure requirements the state imposes on non-physician anesthetists; and (3) is a graduate of a medical school-based anesthesiologist's assistant education program that is accredited by the Committee on Allied Health Education and Accreditation and includes approximately two years of specialized basic science and clinical education in anesthesia at a level that builds on a premedical undergraduate science background. An anesthesiologist's assistant may administer anesthesia when under the direct supervision of an anesthesiologist. The anesthesiologist must be immediately available if needed, meaning the anesthesiologist is physically present in the ASC and prepared to immediately conduct hands-on intervention if needed.

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

Surgical Services Checklist

General

- □ Does your ASC have policies and procedures that establish the criteria and process the governing body uses when granting surgical privileges to a physician? Has the governing body approved these policies and procedures?
- □ For each physician who currently has surgical privileges or has had surgical privileges within the previous six months, can your ASC provide documentation of the governing body's action to grant privileges?
- □ Can your ASC verify that the individuals who have performed surgeries in the ASC were physicians who had been granted privileges by the ASC's governing body?
- □ Does your ASC employ standard procedures to avoid wrong site/procedure/patient surgical errors?
- □ Does your ASC employ appropriate measures to reduce the risk of surgical fires?
- □ If your ASC has ever had a surgical fire, can it document what follow-up actions it took to prevent the recurrence of surgical fires?

Anesthetic Risk and Evaluation

- □ Can your ASC provide evidence for every medical record of an assessment by a physician of the patient's risk for the planned surgery and anesthesia?
- □ Can your ASC provide policies and procedures for assessment of anesthesia and procedural risk? Do the policies include the criteria the ASC's physicians are to use in making the assessments?
- □ Can your ASC's leadership demonstrate how it assures consistency in the assessments?
- □ Can your ASC's leadership identify any cases where an assessment resulted in a decision not to proceed with the surgery? If there are no such cases, can your ASC explain how its patient selection criteria assure that there is an acceptable level of anesthesia and procedural risk for every patient scheduled for surgery in your ASC?
- □ If your ASC has cases where a patient died or needed to be transferred to a hospital, can your ASC address the pre-surgical assessment of the patient in those cases, including the basis on which the patient was found to be suitable for the surgery and anesthesia?
- □ Are your ASC's policies and procedures regarding post-anesthesia recovery and evaluation consistent with the regulatory requirement? Is your ASC following its own policy?
- □ Do your ASC's medical records for patients who had surgery or a procedure requiring anesthesia document that a post-anesthesia evaluation was conducted for each patient?
- □ Are post-anesthesia evaluations conducted by practitioners who are qualified to administer anesthesia?
- □ Does your ASC conduct post-anesthesia evaluations prior to discharging all patients who have surgeries or procedures requiring anesthesia?.

Administration of Anesthesia

- □ Are the qualifications of individuals authorized to deliver anesthesia in your ASC consistent with the regulatory requirements?
- □ Can your ASC provide documentation of current licensure or current certification status for all persons administering anesthesia?
- □ If your ASC uses CRNAs, anesthesiologist's assistants or trainees, do the medical records indicate that required physician supervision is provided?

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Quality Assessment and Performance Improvement Condition for Coverage

In order to receive Medicare payment for surgical services furnished to program beneficiaries, an ambulatory surgical center ("ASC") must meet certain specific requirements referred to as Conditions for Coverage and set forth at 42 C.F.R. 416, Subpart C. This section discusses the Quality Assessment and Performance Improvement ("QAPI") Condition for Coverage and provides a checklist based on the survey protocol outlined in the Medicare State Operations Manual to assist an ASC in evaluating whether it meets the condition's requirements.

The QAPI Condition for Coverage requires an ASC to take a proactive and comprehensive approach to improving the quality and safety of the surgical services it delivers. It states that the ASC "must develop, implement and maintain an on-going, data-driven quality assessment and performance improvement … program."[8]

The QAPI Condition for Coverage presumes that an ASC employs a systems approach to evaluating its processes, identifying problems that have occurred or that potentially could occur from the ASC's practices and determining the root causes of the problems. CMS instructs surveyors to focus not on whether an ASC has any deficient practices, but rather on whether it has an effective system in place for identifying problematic practices, taking remedial action, and following up to determine whether the remedial action was effective in improving quality and safety.

Program Scope

> *(a) Standard: Program scope.*
> *(1) The program must include, but not be limited to, an ongoing program that demonstrates measurable improvement in patient health outcomes, and improves patient safety by using quality indicators or performance measures associated with improved health outcomes and by the identification and reduction of medical errors.*
> *(2) The ASC must measure, analyze, and track quality indicators, adverse patient events, infection control and other aspects of performance that includes care and services furnished in the ASC.*

CMS does not prescribe a particular QAPI program. However, each program must be ongoing, *i.e.*, the program must be a continuing one, not just a one-time effort. Evidence of an ongoing program includes collection of quality data at regular intervals, analysis of the updated data at regular intervals, updated records of actions taken to address quality problems identified in the analyses, and new data collection to determine if the corrective actions were effective. In addition, each program must be data-driven, *i.e.*, the program must identify in a systematic manner the data it will collect to measure various aspects of quality of care, the frequency of data collection, how the data will be collected and analyzed, and evidence that the program uses the data collected to assess quality and stimulate performance improvement.

[8] 42 C.F.R. § 416.43; Appendix L to the Medicare State Operations Manual sets forth the "Guidance for Surveyors: Ambulatory Surgical Centers."

An ASC's QAPI program must improve both patient health outcomes and patient safety in the ASC. In order to achieve these goals, the ASC's QAPI program must be on-going, use quality indicators or performance measures associated with improved health outcomes in a surgical setting, and identify and reduce adverse patient events and medical errors.

Program Data

> *(b) Standard: Program data.*
> *(1) The program must incorporate quality indicator data, including patient care and other relevant data regarding services furnished in the ASC.*
> *(2) The ASC must use the data collected to--*
> *(i) Monitor the effectiveness and safety of its services, and quality of its care.*
> *(ii) Identify opportunities that could lead to improvements and changes in its patient care.*

An ASC must not only identify quality indicators or performance measures, but also actively collect data related to those indicators and measures at the intervals called for by its QAPI program. The staff responsible for collection of the data must be trained in appropriate techniques to collect and maintain that data.

CMS does not prescribe a certain set of indicators for an ASC to use.[9] However, the ASC must be able to demonstrate that the indicators it is using will enable it to improve health outcomes for its patients. The ASC is required to focus on high risk, high volume, and problem-prone areas. When selecting the indicators or measures, it is required to consider the incidence, prevalence and severity of problems.[10]

In addition, an ASC must track all patient adverse events and identify errors that result in near misses.[11]

Program Activities

> *(c) Standard: Program activities.*
> *(1) The ASC must set priorities for its performance improvement activities that--*
> *(i) Focus on high risk, high volume, and problem-prone areas.*
> *(ii) Consider incidence, prevalence, and severity of problems in those areas.*
> *(iii) Affect health outcomes, patient safety, and quality of care.*
> *(2) Performance improvement activities must track adverse patient events, examine their causes, implement improvements, and ensure that improvements are sustained over time.*
> *(3) The ASC must implement preventive strategies throughout the facility targeting adverse patient events and ensure that all staff are familiar with these strategies.*

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[9] Indicators can be broken down into several types. "Outcomes indicators" measure results of care. "Process of care" indicators measure how often the standard of care was met for patients with a diagnosis related to that standard. "Patient perception indicators" measure a patient's experience of the care he or she received in the ASC.

[10] "Incidence" refers to the rate or frequency at which problems occur in the ASC related to the area measured by the indicator. "Prevalence" refers to how widespread something is in an ASC at a given point in time.

[11] An "adverse event" is defined as "an injury caused by medical management rather than the underlying condition of the patient." An "error" is defined as "the failure of a planned action to be completed as intended (*i.e.*, error of execution) or the use of a wrong plan to achieve an aim (*i.e.*, error of planning)."

Once having collected the data, an ASC must analyze it to monitor ASC performance, *i.e.*, to determine what the data suggests about the ASC's quality of care and the effectiveness and safety of its services. Analysis must take place at regular intervals. In the case of data related to adverse events, the ASC must use the data to analyze the causes of the adverse events.

The staff responsible for this analysis must be qualified to interpret quantitative data. While CMS does not expect an ASC to engage in sophisticated statistical modeling of data, it does expect the ASC to conduct thorough analyses that focus on systemic issues. An ASC may elect to use contractors for technical aspects of the QAPI program, including analysis of data. However, the ASC is expected to actively involve its staff in the program, and the ASC's leadership is expected to retain responsibility for the ongoing management of the program.

Analysis of the data must be used to identify areas where there is room for improvement in the ASC's performance. Once an ASC's analysis has identified opportunities for improvement, the ASC must develop specific changes to make improvements and also have a method to ensure that the improvements it makes are sustained over time.

The ASC also must implement preventive strategies designed to reduce the likelihood of adverse events throughout the ASC and must make all staff aware of the strategies it has adopted for prevention of adverse events.

Performance Improvement Projects

> *(d) Standard: Performance improvement projects.*
> *(1) The number and scope of distinct improvement projects conducted annually must reflect the scope and complexity of the ASC's services and operations.*
> *(2) The ASC must document the projects that are being conducted. The documentation, at a minimum, must include the reason(s) for implementing the project, and a description of the project's results.*

Every ASC must undertake one or more specific quality improvement projects per year. Large, complex or high volume ASCs are expected to undertake more or more complex projects.

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

Governing Body Responsibilities

> *(e) Standard: Governing body responsibilities.*
> *The governing body must ensure that the QAPI program--*
> *(1) Is defined, implemented, and maintained by the ASC.*
> *(2) Addresses the ASC's priorities and that all improvements are evaluated for effectiveness.*
> *(3) Specifies data collection methods, frequency, and details.*
> *(4) Clearly establishes its expectations for safety.*
> *(5) Adequately allocates sufficient staff, time, information systems and training to implement the QAPI program.*

A successful QAPI program requires the direction and support of an ASC's leadership. CMS expects the ASC's governing body to assume responsibility for all aspects of the design and implementation of each phase of the QAPI program. The governing body must ensure that the ASC's QAPI program: (1) is defined in writing (*e.g.*, in the minutes of a meeting where the governing body established the program); (2) is actually implemented; (3) is implemented on an ongoing basis; (4) employs quality and safety indicators; (5) describes in detail the indicator data to be collected, how it will be collected, and how frequently it will be collected; (6) uses the data collected and analyzed to improve the ASC's performance; (7) evaluates changes designed to improve the ASC's performance to determine whether they are effective; and (8) takes appropriate actions to make further changes as needed.

Quality Assessment and Performance Improvement Checklist

Program Scope

- □ Can your ASC's leadership describe the QAPI program, including staff responsibilities for QAPI and the indicators your ASC tracks?
- □ Is there a rationale for the particular indicators that your ASC has chosen to track? Are the indicators based on nationally-recognized recommendations? If not, does your ASC have evidence that the indicators are associated with improvement in patient health outcomes and safety? Do the indicators include measures appropriate for surgery? Do the indicators include infection control measures?
- □ Does your ASC have a system for tracking adverse events?
- □ Can the staff responsible for QAPI articulate the method for data collection for each QAPI program indicator? Can the staff articulate the frequency for data collection for each QAPI program indicator?

Program Data and Program Activities

- □ Is your ASC collecting data on all of the indicators it identified for its QAPI program? Is it collecting the data at the frequency specified in its QAPI program?
- □ Can your ASC identify who is responsible for the data collection and analysis and articulate what their qualifications are? In particular, can your ASC explain who determines the causes of adverse events, including the immediate cause and the underlying root causes?
- □ Does the ASC staff that handles data collection and analysis have appropriate education or training?
- □ Can your ASC provide examples of instances where it used QAPI data to identify opportunities for improving processes for providing care? Can your ASC demonstrate that it evaluated whether the improvements were effective and sustained?
- □ Can the ASC staff explain how it trains staff on ways to prevent adverse events from occurring?
- □ Can the ASC staff explain what they know about the ASC's QAPI program?

Performance Improvement Projects

- □ Can your ASC provide documentation for performance improvement projects currently underway and for projects completed in the prior year? If a large, complex, or high volume ASC with only one project underway, is the scope of that project such that it is likely to have a significant impact on your ASC's quality of care or patient safety?
- □ Does your ASC's documentation indicate the rationale for undertaking each project? Does your ASC have data indicating it had a problem in the area targeted for improvement, or could your ASC point to recommendations from a nationally recognized expert organization suggesting the activities?
- □ Does the documentation for the completed projects include the project's results? If a project was unsuccessful, can your ASC explain what actions it took as a result of that information? If the project was successful, can your ASC explain how it is sustaining the improvement?

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Governing Body Responsibilities

- □ Can your ASC's leadership explain how the governing body is involved in the QAPI program?
- □ Can your ASC's leadership display ready knowledge of the program's structure and activities? If a contractor is used for some portions of the program, can your ASC's leadership demonstrate that it monitors closely the contractor's activities?
- □ Is there evidence of a governing body review of all elements of the QAPI program, *e.g.*, meeting minutes?
- □ Can your ASC's leadership articulate how it uses the program to improve performance? Can your ASC's leadership provide evidence of changes made as a result of QAPI program activities?
- □ Can your ASC's leadership provide documentation of the details of the resources that are dedicated to the QAPI program? Is there evidence that these resources were actually made available as planned?

Medical Staff
Condition for Coverage

In order to receive Medicare payment for surgical services furnished to program beneficiaries, an ambulatory surgical center ("ASC") must meet certain specific requirements referred to as Conditions for Coverage and set forth at 42 C.F.R. 416, Subpart C. This section discusses the Medical Staff Condition for Coverage and provides a checklist based on the survey protocol outlined in the Medicare State Operations Manual to assist an ASC in evaluating whether it meets the condition's requirements.

The Medical Staff Condition for Coverage states, "The medical staff of the ASC must be accountable to the governing body."[12]

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

It is possible for an ASC to be owned and operated by one physician, who could be both the sole member of the governing body and also the sole member of the ASC's medical staff. In such cases the physician owner must nevertheless implement a formal process for complying with all medical staff regulatory requirements.

Membership and Clinical Privileges

> *(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.*

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. 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.

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[12] 42 C.F.R. § 416.45; Appendix L to the Medicare State Operations Manual sets forth the "Guidance for Surveyors: Ambulatory Surgical Centers."

"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.

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. The ASC should consider seeking the recommendations of qualified outside physicians when it does not have appropriate expertise in-house to evaluate the competency of an applicant for privileges.

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 following: (1) the documentation it reviews for each candidate; (2) the criteria it uses in evaluating the candidate; (3) how it selects the qualified medical personnel who make recommendations on the practitioner's qualifications; and (4) whether and under what circumstances the governing body may make a privileging decision contrary to the recommendation of the qualified medical staff.

Reappraisals

> *(b) Standard: Reappraisals.*
> *Medical staff privileges must be periodically reappraised by the ASC. The scope of procedures performed in the ASC must be periodically reviewed and amended as appropriate.*

The ASC's governing body must have a process reappraising the medical staff privileges granted to each practitioner at least every 24 months. The reappraisal must include a review of the practitioner's current credentials and the practitioner's ASC-specific case record.

The ASC's governing body should use a similar process, including the recommendation of qualified medical personnel, for the periodic reappraisal as it used when initially granting privileges. Based on the evidence, the ASC's governing body must decide whether to continue the practitioner's current privileges without change, or to amend those privileges by contracting or expanding them, or by withdrawal of the practitioner's privileges entirely. The ASC must also reappraise a practitioner any time the practitioner seeks to perform procedures outside the scope of previously granted procedures.

The ASC should also develop triggers for reappraisal of privileges outside the periodic reappraisal schedule, *e.g.*, any instance of gross misconduct by the practitioner.

Other Practitioners

> *(c) Standard: Other practitioners.*
> *If the ASC assigns patient care responsibilities to practitioners other than physicians, it must have established policies and procedures, approved by the governing body, for overseeing and evaluating their clinical activities.*

Patient care responsibilities may be assigned to licensed practitioners not meeting the definition of physician.

When an ASC uses licensed practitioners to provide patient care, other than nursing care, the ASC's governing body must approve written policies and procedures that establish a system for overseeing and evaluating the quality of the clinical services provided by other practitioners. The policies must address the following: (1) the specific types of clinical activities that each class of practitioner will be eligible to perform; (2) the process by which the ASC exercises oversight over each class of practitioner[13]; (3) the process and criteria for reviewing the qualifications of each individual practitioner before he or she is permitted to provide patient care; and (4) the process, criteria and frequency for evaluating the performance in providing clinical services by practitioners other than physicians.[14]

[13] Depending on the practitioner's scope of practice, physician supervision of the practitioner may be required. In other cases oversight through collaborative practice with a physician or some other means may suffice.

[14] Evaluations must take place at regular intervals specified in the ASC's policy.

Medical Staff Checklist

Membership and Clinical Privileges

- □ Can your ASC's leadership provide its policy detailing how the governing body holds the medical staff accountable?
- □ Can your ASC's leadership explain its process for granting clinical privileges?
- □ Do your ASC's personnel records for all medical staff that have been granted clinical privileges contain, at a minimum, the following:
  - □ 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 he or she is legally and professionally qualified to exercise the privileges granted by the ASC?

Reappraisals

- □ Does the ASC periodically reappraise all practitioners granted clinical privileges?
- □ Can your ASC's leadership explain how it re-evaluates the professional qualifications of practitioners with privileges to practice in the ASC?
- □ Have all practitioners with privileges to practice in the ASC been reappraised within the timeframe specific in the medical staff policy?
- □ Do the reappraisals include evidence that data on the practitioner's practice within the ASC is considered along with the practitioner's credentials?

Other Practitioners

- □ If your ASC uses licensed practitioners other than physicians to provide care, other than nursing care, within the ASC:
  - □ Does your ASC have a policy governing the oversight and evaluation of practitioners other than physicians? Does the policy address all required issues?
  - □ For each licensed practitioner who is not a physician providing patient care in the ASC, do the ASC's personnel files contain evidence of the practitioner's qualifications, consistent with the ASC's policy? Does each file contain evidence of periodic evaluation of the practitioner's performance?

Nursing Services
Condition for Coverage

In order to receive Medicare payment for surgical services furnished to program beneficiaries, an ambulatory surgical center ("ASC") must meet certain specific requirements referred to as Conditions for Coverage and set forth at 42 C.F.R. 416, Subpart C. This section discusses the Nursing Services Condition for Coverage and provides a checklist based on the survey protocol outlined in the Medicare State Operations Manual to assist an ASC in evaluating whether it meets the condition's requirements.

The Nursing Services Condition for Coverage states:

> The nursing services of the ASC must be directed and staffed to assure that the nursing needs of all patients are met.[15]

An ASC must ensure that nursing services are directed under the leadership of a registered nurse ("RN"). The ASC must have documentation that it has designated an RN to direct nursing services.

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

> *(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.*

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. This 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.

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. The ASC must have personnel present who are trained in the use of the required emergency equipment and in cardiopulmonary resuscitation whenever there is a patient in the ASC. The RN 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.

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[15] 42 C.F.R. § 416.46; Appendix L to the Medicare State Operations Manual sets forth the "Guidance for Surveyors: Ambulatory Surgical Centers."

Nursing Service Checklist

- □ Can your ASC's leadership identify the person responsible for the direction of nursing services within your ASC? Is that person an RN?
- □ Does your ASC have sufficient staff to address each patient's nursing needs?
- □ Do nursing staff have the appropriate qualifications for the tasks they are asked to perform?
- □ Are the general responsibilities for each ASC nurse for providing patient care clearly documented?
- □ Can the nursing staff explain what their duties are and can they articulate clearly what their patient care responsibilities are?
- □ Can you explain to the surveyor how your ASC evaluates the nursing care provided for conformance to acceptable standards of practice?
- □ Can you identify the RNs who are available for emergency treatment? Can you provide documentation of their qualifications to provide emergency treatment? Do staff in your ASC know which RNs to call when a patient develops an emergency?
- □ Can you provide evidence that one or more RNs are readily available to provide emergency treatment? Can you explain how they assure that an RN can leave his or her current task to respond to the emergency without putting another patient at risk of harm?

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Medical Records
Condition for Coverage

In order to receive Medicare payment for surgical services furnished to program beneficiaries, an ambulatory surgical center ("ASC") must meet certain specific requirements referred to as Conditions for Coverage and set forth at 42 C.F.R. 416, Subpart C. This section discusses the Medical Records Condition for Coverage and provides a checklist based on the survey protocol outlined in the Medicare State Operations Manual to assist an ASC in evaluating whether it meets the condition's requirements.

The Medical Records Condition for Coverage states:

> The ASC must maintain complete, comprehensive, and accurate medical records to ensure adequate patient care.[16]

An ASC must have a complete, comprehensive and accurate medical record for each patient. Material required under other Conditions for Coverage must be incorporated into the medical record in a timely fashion. The ASC must use the information contained in each medical record in order to assure that adequate care is delivered to each ASC patient. The ASC must ensure the confidentiality of each patient's medical record in accordance with the provisions of the Patients' Rights Condition.

Organization

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

The ASC must have a documented system that enables it to systematically develop a unique medical record for each patient, permit timely access to the medical record to support the delivery of care, and to store records. Records may exist in hard copy, electronic format, or a combination of the two media.

Form and Content of Record

> *(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;*
> *(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;*

[16] 42 C.F.R. § 416.47; Appendix L to the Medicare State Operations Manual sets forth the "Guidance for Surveyors: Ambulatory Surgical Centers."

(7) Documentation of properly executed informed patient consent; and
(8) Discharge diagnosis.

The medical record must contain all of the required elements listed in the regulation, including the following: (1) the identity of the patient; (2) a comprehensive medical history and physical assessment as well as the results of the pre-surgical assessments; (3) pre-operative diagnostic studies, if any; (4) an operative report that describes the surgical techniques and findings; (5) 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[17]; (6) 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; (7) information related to the administration of anesthesia during the procedure and the patient's recovery from anesthesia after the procedure; and (8) documentation of a properly executed informed patient consent.

A well-designed informed consent process would most likely include a discussion of the following elements: (1) a description of the proposed surgery, including the anesthesia to be used; (2) the indications for the proposed surgery; (3) 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; (4) treatment alternatives, including the attendant material risks and benefits; (5) who will conduct the surgical intervention and administer the anesthesia; (6) whether physicians other than the operating practitioner will be performing important tasks related to the surgery[18]; and (7) 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 (8) 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 or transferred to another healthcare facility.

[17] 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.

[18] Important surgical tasks include opening and closing, dissecting tissue, removing tissue, harvesting grafts, transplanting tissue, administering anesthesia, implanting devices and placing invasive lines.

Medical Records Checklist

General

- □ Does your ASC maintain complete and accurate medical records in accordance with federal and state laws and regulations and ASC policy? Are patient records collected in a systematic manner for easy access?

Organization

- □ Can the person responsible for your ASC's medical records describe the medical record policy and explain why the system is structured appropriately?
- □ If your ASC employs a fully or partially electronic medical record system, can clinical personnel demonstrate how they use the system, including demonstrating how to make entries and access needed information to support the provision of care?
- □ Does your ASC retain closed records in accordance with applicable state law?

Form and Content of Record

- □ Will records selected for review contain all of the required elements?
- □ If your ASC removes tissue during surgery, does it have a policy to exempt any or all classes of tissue removed from the requirement for analysis by a pathologist? If yes, was the policy adopted by the governing body and can your ASC's leadership explain the policy's rationale?

Pharmaceutical Services Condition for Coverage

In order to receive Medicare payment for surgical services furnished to program beneficiaries, an ambulatory surgical center ("ASC") must meet certain specific requirements referred to as Conditions for Coverage and set forth at 42 C.F.R. 416, Subpart C. This section discusses the Pharmaceutical Services Condition for Coverage and provides a checklist based on the survey protocol outlined in the Medicare State Operations Manual to assist an ASC in evaluating whether it meets the condition's requirements.

The Pharmaceutical Services Condition for Coverage states:

> The ASC must provide drugs and biologicals in a safe and effective manner, in accordance with accepted professional practice, and under the direction of an individual designated responsible for pharmaceutical services.[19]

The ASC must provide drugs and biologicals in a safe and effective manner in accordance with accepted professional practice and under the direction of an individual designated responsible for pharmaceutical services. The ASC must designate a specific licensed healthcare professional to provide direction to the ASC's pharmaceutical service. That individual must be routinely present when the ASC is open for business, but continuous presence is not required, particularly when the ASC is open for longer periods of time to accommodate the recovery of patients for up to 24 hours.

> *(a) Standard: Administration of drugs.*
> *Drugs must be prepared and administered according to established policies and acceptable standards of practice*
> *(1) Adverse reactions must be reported to the physician responsible for the patient and must be documented in the record.*
> *(2) Blood and blood products must be administered only by physicians or registered nurses.*
> *(3) Orders given orally for drugs and biologicals must be followed by a written order and signed by the prescribing physician.*

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

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

The ASC must have policies and procedures designed to promote medication administration consistent with acceptable standards of practice. The policies and procedures should address the following: (1) a physician

[19] 42 C.F.R. § 416.48; Appendix L to the Medicare State Operations Manual sets forth the "Guidance for Surveyors: Ambulatory Surgical Centers."

or other qualified member of the medical staff acting within his or her scope of practice issuing an order for all drugs or biologicals administered in the ASC[20]; (2) following the manufacturer's label; (3) avoiding preparation of medications too far in advance of their use; (4) initialing pre-filled syringes by the person who draws it, dated and timed to indicate when they were drawn, and labeled as to both content and expiration date; and (5) employing standard infection control practices when using injectable medications.

There must be records of receipt and disposition of all drugs listed in Schedules II, III, IV, and V of the Comprehensive Drug Abuse Prevention and Control Act of 1970, if the ASC uses any such scheduled drugs. The ASC's policies and procedures should also address the following: (1) accountability procedures to ensure control of the distribution, use, and disposition of all scheduled drugs; (2) records of the receipt and disposition of all scheduled drugs must be current and must be accurate; (3) records to trace the movement of scheduled drugs throughout the ASC; (4) the licensed health care professional who has been designated responsible for the ASC's pharmaceutical services is responsible for determining that all drug records are in order and that an account of all scheduled drugs is maintained and reconciled; (5) the record system, delineated in policies and procedures, tracks movement of all scheduled drugs from the point of entry into the ASC to the point of departure, either through administration to the patient, destruction, or return to the manufacturer; (6) all drug records are in order and an account of all scheduled drugs is maintained and any discrepancies in count are reconciled promptly; and (7) the ASC's system is capable of readily identifying loss or diversion of all controlled substances in such a manner as to minimize the time frame between the actual loss or diversion to the time of detection and determination of the extent of loss or diversion.

Every adverse reaction to a drug or biological that a patient experiences while in the ASC must be reported promptly to the physician on the ASC's medical staff who is responsible for that patient. All adverse drug reactions experienced by patients while in the ASC must be documented in the patient's medical record. The ASC's policies and procedures must incorporate these requirements and ASC staff must be aware of and comply with them.

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

Orders for drugs and biologicals that are transmitted as oral, spoken communications between the prescribing physician and the ASC's nursing staff, delivered either face-to-face or via telephone, commonly called "verbal orders," must be followed by a written order that is signed by the prescribing physician. ASC policies and procedures for verbal orders must include a read-back and verification process whereby the nurse receiving the order repeats it back to the prescribing physician, who verifies that it is correct. When administering a drug or biological per a verbal order, the nurse should include in the medical record entry covering the administration of the drug or biological a note that it was prescribed orally, indicating the name of the prescribing physician. The prescribing physician must sign, date, and time the written order in the patient's medical record confirming the verbal order. This should be done as soon as possible after the verbal order is issued.

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[20] The administration of the drugs or biologicals must be by, or under the supervision of, nursing or other personnel in accordance with applicable laws, standards of practice and the ASC's policies.

Pharmaceutical Services Checklist

- □ Can your ASC's leadership provide evidence that a qualified individual has been designated to direct pharmaceutical services?
- □ Can your ASC document that the individual is providing active direction and oversight to the program?
- □ For every drug or biological administered to a patient, is there evidence in the medical records that there is an order, signed by a physician or other qualified practitioner?
- □ Are drugs or biologicals administered only by nurses or other qualified individuals, or under the supervision of nurses or other qualified individuals, as permitted under federal or state law and your ASC's policy?
- □ Are medications properly labeled, stored, and unexpired?
- □ Does your ASC employs safe injection practices?
- □ If your ASC uses scheduled drugs:
  - □ Does your ASC have a record system in place that provides information on controlled substances in a readily retrievable manner?
  - □ Do your ASC's records trace the movement of scheduled drugs throughout the ASC?
  - □ Does your ASC have a system, delineated in policies and procedures, that tracks the movement of all scheduled drugs from the point of entry into the ASC to the point of departure, either through administration to the patient, destruction or return to the manufacturer? Does this system provide documentation on scheduled drugs in a readily retrievable manner to facilitate reconciliation of the receipt and disposition of all scheduled drugs?
  - □ Is the licensed health care professional who is in charge of the ASC's pharmaceutical services responsible for determining that all drug records are in order and that an account of all scheduled drugs is maintained and periodically reconciled?
  - □ Is the ASC's system capable of readily identifying loss or diversion of all controlled substances in such a manner as to minimize the time between the actual losses or diversion to the time of detection and determination of the extent of loss or diversion?
- □ Can your ASC's clinical staff explain steps they would take if a patient experiences an adverse reaction to a drug? Are staff aware of the requirement to promptly report this information to the physician on your ASC's medical staff who is responsible for the patient?
- □ Are your ASC's policies and procedures that address adverse drug reactions consistent with the regulatory requirements?
- □ Does your ASC administer blood or blood products to patients? If yes:
  - □ Do your medical records indicate that anyone other than a physician on your ASC's medical staff or an RN administered the blood or blood product?
  - □ Do your ASC's policies specifically restrict administration of blood and blood products to a physician or an RN?
  - □ Do your ASC's policy and procedures minimize scheduled drug diversion?

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- □ Does your ASC have policies and procedures addressing verbal orders? Does your ASC require the prescribing practitioner to sign, date, and time a written order as soon as possible after issuing the verbal order?
- □ Do the ASC's policies and procedures for verbal orders include a "read back and verify" process where the nurse who receives the order repeats it back to the prescribing physician to verify that the order was understood accurately?
- □ Does your nursing staff's practice of handling verbal orders conform to the regulatory requirements? Do they use a read-back and verify process?
- □ Is there evidence in the medical records reviewed that each verbal order was followed by a written order signed by the prescribing physician?

Laboratory and Radiologic Services Condition for Coverage

In order to receive Medicare payment for surgical services furnished to program beneficiaries, an ambulatory surgical center ("ASC") must meet certain specific requirements referred to as Conditions for Coverage and set forth at 42 C.F.R. 416, Subpart C. This section discusses the Laboratory and Radiologic Services Condition for Coverage and includes a discussion of the hospital Conditions of Participation for radiologic services, which is incorporated into this condition.

The Laboratory and Radiologic Services Condition for Coverage sets forth separate standards for laboratory and radiologic services.[21] Lack of substantial compliance with either standard is a basis for citing an ASC for a condition-level deficiency. Each standard is discussed in detail below.

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

An ASC performing laboratory services must meet the requirements of 42 C.F.R. § 493, the regulations implementing the Clinical Laboratory Improvement Amendments of 1988 ("CLIA"). If the ASC does not provide its own laboratory services, it must have procedures for obtaining laboratory services from a laboratory certified in accordance with 42 C.F.R. § 493.

An ASC should adopt and maintain policies and procedures that list the kinds of laboratory services that are provided directly by the ASC as well as services that are provided through a contractual agreement with a third party. These policies and procedures should address the following: (1) laboratory services that are provided by the ASC; (2) well-defined arrangements with outside laboratory service providers; (3) routine procedures for requesting laboratory tests; and (4) language that requires the incorporation of laboratory reports into patient records.

> *(b) Standard: Radiologic services.*
> *(1) The ASC must have procedures for obtaining radiological services from a Medicare approved facility to meet the needs of patients.*
> *(2) Radiologic services must meet the hospital conditions of participation for radiologic services specified in §482.26 of this chapter.*

If an ASC uses radiologic services as an integral part of the surgical procedures it performs, the radiologic services must be provided in a manner that complies with the requirements for radiologic services in the

[21] 42 C.F.R. § 416.49. *See also* Appendix L to the Medicare State Operations Manual which sets forth the "Guidance for Surveyors: Ambulatory Surgical Centers."

hospital Conditions of Participation.[22] If the ASC does not provide these radiologic services directly, *i.e.*, utilizing its own staff, then it must obtain the services through a contractual agreement from a Medicare-participating facility. Radiologic services considered integral to the procedure itself are those imaging services performed immediately before, during or after the procedure that are medically necessary to the completion of the procedure.[23]

The following is a discussion of the requirements for radiologic services set forth in the hospital Conditions of Participation. Radiologic services provided by or on behalf of an ASC must meet these requirements.

> *The hospital must maintain, or have available, diagnostic radiologic services. If therapeutic services are also provided, they, as well as the diagnostic services, must meet professionally approved standards for safety and personnel qualifications.*

The hospital must maintain or have available diagnostic radiological services according to the needs of its patients.

The services must be provided in accordance with acceptable standards of practice and must meet professionally approved standards for safety and personnel qualifications.[24] The scope and complexity of services offered should be specified in writing and approved by the medical staff and governing body. In addition, the hospital's radiologic services, including any contracted services, must be integrated into its hospital-wide QAPI program.

> *(a) Standard: Radiologic services.*
> *The hospital must maintain, or have available, radiologic services according to the needs of the patients.*

The scope and complexity of radiologic services provided must meet the needs of the patients. Radiologic services may be provided by the hospital directly or through a contractual arrangement. The same standards apply whether the service is provided by the hospital directly or under contract. Diagnostic radiological services provided under contract may be provided either on the hospital premises or in an adjacent or other nearby, readily accessible facility.

> *(b) Standard: Safety for patients and personnel.*
> *The radiologic services, particularly ionizing radiology procedures, must be free from hazards for patients and personnel.*
> *(1) Proper safety precautions must be maintained against radiation hazards. This includes adequate shielding for patients, personnel, and facilities, as well as appropriate storage, use, and disposal of radioactive materials.*
> *(2) Periodic inspection of equipment must be made and hazards identified must be promptly corrected.*

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[22] 42 C.F.R. § 482.26. *See also* Appendix A to the Medicare State Operations Manual which sets forth the "Survey Protocol, Regulations and Interpretive Guidelines for Hospitals."

[23] If an ASC does not perform any procedures where radiological services are integral to the procedure, then the ASC is not required to have arrangements for obtaining radiological services.

[24] Acceptable standards of practice include maintaining compliance with applicable federal and state laws, regulations and guidelines governing radiological services as well as any standards and recommendations promoted by nationally recognized professional organizations.

(3) Radiation workers must be checked periodically, by the use of exposure meters or badge tests, for amount of radiation exposure.
(4) Radiologic services must be provided only on the order of practitioners with clinical privileges or, consistent with State law, of other practitioners authorized by the medical staff and the governing body to order the services.

The hospital must adopt and implement policies and procedures that provide safety for patients and personnel. The hospital policies must contain safety standards for at least: (1) adequate shielding for patients, personnel and facilities; (2) labeling of radioactive materials, waste, and hazardous areas; (3) transportation of radioactive materials between locations within the hospital; (4) security of radioactive materials, including determining who may have access to radioactive materials and controlling access to radioactive materials; (5) testing of equipment for radiation hazards; (6) maintenance of personal radiation monitoring devices; (7) proper storage of radiation monitoring badges when not in use; (8) storage of radio nuclides and radio pharmaceuticals as well as radioactive waste; (9) disposal of radio nuclides, unused radio pharmaceuticals, and radioactive waste; and (10) methods of identifying pregnant patients. The hospital must implement and ensure compliance with its established safety standards. In addition, the hospital must have policies and procedures in place to ensure that periodic inspections of radiology equipment are conducted and that problems identified are corrected in a timely manner. The hospital must ensure that equipment is inspected in accordance with manufacturer's instructions, federal and state laws, regulations, and guidelines, and hospital policy. The hospital must have a system in place to correct hazards. The requirement that "radiation workers must be checked periodically, by use of exposure meters or badge tests, for amount of radiation exposure" would include radiologic services personnel as well as other hospital employees who may be regularly exposed to radiation due to working near radiation sources.

(c) Standard: Personnel.
(1) A qualified full-time, part-time, or consulting radiologist must supervise the ionizing radiology services and must interpret only those radiologic tests that are determined by the medical staff to require a radiologist's specialized knowledge. For purposes of this section, a radiologist is a doctor of medicine or osteopathy who is qualified by education and experience in radiology.
(2) Only personnel designated as qualified by the medical staff may use the radiologic equipment and administer procedures.

The medical staff must establish the qualifications necessary for radiologist appointment to the medical staff.

There must be written policies developed and approved by the medical staff to designate which radiological tests require interpretation by a radiologist. When telemedicine is used, and the radiologist who interprets radiological tests and the patient are located in different states, the radiologist interpreting the radiological test must be licensed and/or meet the other applicable standards that are required by state or local laws in both the state where the practitioner is located and the state where the patient is located.

Supervision of the radiology services may only be performed by a radiologist who is a member of the medical staff. Supervision should include at least the following: (1) ensuring that radiology reports are signed by the practitioner who interpreted them; (2) assigning duties to radiology personnel appropriate to their level of training, experience, and licensure, if applicable; (3) enforcing infection control standards; (4) ensuring that emergency care is provided to patients who experience an adverse reaction to diagnostic agents in the radiology service; (5) ensuring that files, scans, and other image records are kept in a secure area and are readily retrievable; and (6) training radiology staff on how to operate the equipment safely, how to perform tests offered by the facility and on the management of emergency radiation hazards and

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

> *(d) Standard: Records of radiologic services must be maintained.*
> *(1) The radiologist or other practitioner who performs radiology services must sign reports of his or her interpretations.*
> *(2) The hospital must maintain the following for at least 5 years:*
> *(i) Copies of reports and printouts.*
> *(ii) Films, scans, and other image records, as appropriate.*

The hospital must maintain records for all radiology procedures performed. At a minimum, the records should include copies of reports and printouts, and any films, scans or other image records, as appropriate. The hospital should have written policies and procedures that protect the privacy of radiology records. Patient radiology records are considered patient medical records and the hospital must comply with 42 C.F.R. § 482.24. It requires that medical records for any care, procedure, treatment, or test provided or conducted within the past five years must be secure, properly stored, accessible and promptly retrievable.

Laboratory and Radiologic Services Checklist

- □ Are radiological services integrated into your ASC-wide QAPI program?
- □ Does your ASC maintain, or have available, organized radiology services that meet the needs of the patients and are provided in accordance with accepted standards of practice?
- □ Are locations in your ASC where radiological services are provided safe for patients and personnel?
- □ Does your ASC properly maintain and routinely inspect patient shielding?
- □ Does your ASC properly store hazardous materials in a safe manner?
- □ Does your ASC have inspection records showing periodic inspections are conducted in accordance with manufacturer's instructions, federal and state laws, regulations, and guidelines and ASC policy?
- □ Can your ASC show that any problems identified are properly corrected in a timely manner?
- □ Does your ASC require periodic checks on all radiology personnel and any other ASC staff exposed to radiation? Are ASC personnel knowledgeable about radiation exposure that may occur in a month, a year, and an entire working life?
- □ Do your ASC personnel have radiation-detecting devices and appropriately wear them?
- □ Does your ASC's records verify that periodic tests of radiology personnel by exposure meters or test badges are performed?
- □ Do your ASC's medical records demonstrate that radiological services are provided only on the orders of practitioners with clinical privileges and practitioners outside the ASC who have been authorized by the medical staff and the governing body to order radiological services, consistent with state law?
- □ Does your ASC's radiologist's credentialing file demonstrate that he or she meets the qualifications established by the medical staff for appointment?
- □ Do your ASC's medical records demonstrate that a radiologist interprets those tests that have been designated by the medical staff to require interpretation by a qualified radiologist?
- □ Is supervision of the radiology services restricted to a radiologist who is a member of your ASC's medical staff?
- □ Does your ASC maintain records for at least 5 years and in the manner required by federal and state laws, regulations, and guidelines and ASC policy?

Patient Rights
Condition for Coverage

In order to receive Medicare payment for surgical services furnished to program beneficiaries, an ambulatory surgical center ("ASC") must meet certain specific requirements referred to as Conditions for Coverage and set forth at 42 C.F.R. 416, Subpart C. This section discusses the Patient Rights Condition for Coverage and provides a checklist based on the survey protocol outlined in the Medicare State Operations Manual to assist an ASC in evaluating whether it meets the condition's requirements.

The Patient Rights Condition for Coverage states:

> The ASC must inform the patient or the patient's representative or surrogate of the patient's rights and must protect and promote the exercise of these rights, as set forth in this section. The ASC must also post the written notice of patient rights in a place or places within the ASC likely to be noticed by patients waiting for treatment or by the patient's representative or surrogate, if applicable.[25]

An ASC must inform each of its patients, or the patient's representative or surrogate in the case of minor patients or other situations where there is a designated representative for the patient, of their rights as an ASC patient.[26] All of the ASC's policies and procedures must be consistent with the protection of patient rights set forth in this Condition for Coverage.

In addition, the ASC must ensure that the written notice of patient rights is posted in one or more places where it is likely to be seen by patients waiting for treatment. Notices must be posted in at least one area.[27]

> *(a) Standard: Notice of rights.*
> *An ASC must, prior to the start of the surgical procedure, provide the patient, or the patient's representative, or the patient's surrogate with verbal and written notice of the patient's rights in a language and manner that ensures the patient, the representative, or the surrogate understand all of the patient's rights as set forth in this section. The ASC's notice of rights must include the address and telephone number of the State agency to which patients may report complaints, as well as the Web site for the Office of the Medicare Beneficiary Ombudsman.*

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[25] 42 C.F.R. § 416.50; Appendix L to the Medicare State Operations Manual sets forth the "Guidance for Surveyors: Ambulatory Surgical Centers."

[26] References below to a "patient" include the patient's representative or surrogate. The patient's representative or surrogate is an individual designated by the patient, in accordance with applicable state law, to make health care decisions on behalf of the individual or to otherwise assist the patient during his or her stay in the ASC. Designation may be in writing, as in an advance directive or medical power of attorney, or may be verbal. Written designation may occur before the patient presents to the ASC or during the ASC registration process. Verbal designation may take place at any time during the patient's visit in the ASC.

[27] Whether the ASC must post more than one notice depends on the size and physical layout of the areas where notices are posted. The determining factor is whether the notice or notices are posted in a manner that all patients are likely to see the notice.

The ASC must inform each patient of the patient's rights. This notice must be provided both verbally and in writing prior to the start of the surgical procedure, *i.e.*, prior to the patient's movement out of the pre-operative area, and, if applicable, before the patient is medicated with a drugs that suppresses the patient's consciousness.

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 website for the Office of the Medicare Beneficiary Ombudsman: www.medicare.gov/ombudsman/resources.asp. Patients who are Medicare beneficiaries 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.

The notice must address all of the patient's rights under this condition and be provided and explained in a language and manner that the patient 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.[28] 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.

Notice of Rights

> *(a) Standard: Notice of rights.*
> *(1)[…] In addition, the ASC must--*
> *(i) Post written notice of patient rights in a place or places within the ASC likely to be noticed by patients (or their representatives, if applicable) waiting for treatment. The ASC's notice of rights must include the name, address, and telephone number of a representative in the State agency to whom patients can report complaints, as well as the Web site for the Office of the Medicare Beneficiary Ombudsman.*

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

[28] A professional interpreter is not considered to be a patient's representative or surrogate.

Disclosure of Physician Financial Interest or Ownership

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

An ASC that has physician owners or investors must provide written notice to the patient prior to the start of the surgical procedure, that the ASC has physician-owners or physicians with a financial interest in the ASC.

Advance Directives

> *(c) Standard: Advance directives.*
> *The ASC must comply with the following requirements:*
> *(1) Provide the patient or, as appropriate, the patient's representative with written information concerning its policies on advance directives, including a description of applicable State health and safety laws and, if requested, official State advance directive forms.*
> *(2) Inform the patient or, as appropriate, the patient's representative of the patient's rights to make informed decisions regarding the patient's care.*
> *(3) Document in a prominent part of the patient's current medical record, whether or not the individual has executed an advance directive.*

An advance directive is a written instruction, such as a living will or durable power of attorney for healthcare, recognized under state law, relating to the provision of healthcare when the individual who has issued the directive is incapacitated.

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

The ASC must provide the patient the following information in writing, prior to the start of the surgical procedure: (1) information on the ASC's policies on advance directives; (2) a description of the applicable state health and safety laws; and (3) if requested, official state advance directive forms, if such exist.

The ASC must include in the information concerning its advance directive policies a clear and precise statement of limitation if the ASC cannot implement an advance directive on the basis of conscience or any other specific reason that is permitted under state law. A blanket statement of refusal by the ASC to comply with any patient advance directives is not permissible. However, if and to the extent permitted under state law, the ASC may decline to implement elements of an advance directive on the basis of conscience or any other reason permitted under state law if it includes in the information concerning its advance directive policies a clear and precise statement of limitation. A statement of limitation must: (1) clarify any differences between ASC-wide conscience objections and those that may be raised by individual ASC staff; (2) identify the state legal authority permitting such objection; and (3) describe the range of medical conditions and procedures affected by the objection.

A patient may wish to delegate his or her right to make informed decisions to another person, even though the patient is not incapacitated. To the extent permitted by state law, the ASC must respect such delegation.

In some cases, the patient may be unconscious or otherwise incapacitated. If the patient is unable to make a decision, the ASC must consult the patient's advance directives, medical power of attorney, or patient representative or surrogate, if any of these are available. In the advance directive or the medical power of attorney, the patient may provide guidance as to his or her wishes in certain situations, or may delegate decision-making to another individual as permitted by state law. If such an individual has been selected by the patient, or if a person willing and able under applicable state law is available to make treatment decisions, relevant information should be provided to the representative or surrogate, so that informed healthcare decisions can be made for the patient. However, as soon as the patient is able to be informed of his or her rights, the ASC should also provide that information to the patient.

The right to make informed decisions presumes that the patient' has been provided information about the patient's health status, diagnosis and prognosis. It includes providing consent to the surgical procedure(s) to be performed in the ASC. The patient must receive adequate information, provided in a manner that the patient or the patient's representative or surrogate can understand, to assure that the patient can effectively exercise the right to make informed decisions about care in the ASC.

The ASC must document in the patient's current medical record whether or not the patient has executed an advance directive. This documentation must be placed in a prominent part of the medical record where it will be readily noticeable by any ASC staff providing clinical services to the patient.

If the patient with an advance directive is transferred from the ASC to another healthcare facility, the ASC must ensure that a copy of the patient's advance directive is provided with the medical record when the patient is transferred.

Submission and Investigation of Grievances

> *(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.*

A "patient grievance" is a formal or informal written or verbal complaint that is made to the ASC by a patient 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 written complaint is always considered a grievance. An email or fax is considered written.

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 in the ASC who has authority to respond to grievances. All grievances must be investigated. 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. The ASC's grievance process must include a reasonable 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 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 in writing of the ASC's decision regarding each grievance. 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. 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.

Grievances making allegations related to mistreatment, neglect, or verbal, mental, sexual or physical abuse must be fully documented. This means that all pertinent details of the allegation must be recorded and retained in the ASC's files. Documentation of the allegation should include, at a minimum, the date and time of the alleged occurrence, the location, the names of all individuals involved, and a description of the behavior that is alleged to have occurred within the ASC and to have constituted mistreatment, neglect or abuse or other serious harm.

If there is applicable state law defining the terms "mistreatment," "neglect" or "abuse" in a healthcare facility, including ASCs, those definitions will apply.

All grievances alleging mistreatment, neglect or abuse that are submitted to any ASC staff member, whether verbally or in writing, must be reported immediately, *i.e.*, as soon as possible, and at least on the same day, by the staff member to an ASC official who has authority to address grievances. The ASC's grievance policies and procedures must identify the persons in the ASC who has the authority to respond to grievances. The ASC is expected to educate staff on their obligation to immediately report all grievances alleging mistreatment, neglect or abuse, including to whom they should report the grievance.

Grievances alleging mistreatment, neglect, abuse or other behavior that endangers a patient should be investigated as soon as possible, given the seriousness of the allegations and the potential for harm to patients. The ASC must conduct a careful investigation, balancing the need for speedy resolution with the need to ascertain all pertinent facts. If the ASC confirms that the alleged mistreatment, abuse, neglect or other serious harm took place, then the ASC is obligated to report the event to the appropriate local or state authority, or even both. The ASC should contact the appropriate authority promptly after it concludes its investigation of the grievance.

Exercise of Rights and Respect for Property and Person

> *(e) Standard: Exercise of rights and respect for property and person.*
> *(1) The patient has the right to the following:*
> *(i) Be free from any act of discrimination or reprisal.*
> *(ii) Voice grievances regarding treatment or care that is (or fails to be) provided.*
> *(iii) Be fully informed about a treatment or procedure and the expected outcome before it is performed.*
> *(2) If a patient is adjudged incompetent under applicable State laws by a court of proper jurisdiction, the rights of the patient are exercised by the person appointed under State law to act on the patient's behalf.*
> *(3) If a State court has not adjudged a patient incompetent, any legal representative or surrogate designated by the patient in accordance with State law may exercise the patient's rights to the extent allowed by State law.*

The ASC must utilize an informed consent process that assures patients are given the information and disclosures needed to make an informed decision about whether to consent to a surgical procedure in the ASC. The primary purpose of the informed consent process in the ASC is to ensure that the patient is provided information necessary to enable him or her to evaluate a proposed surgery before agreeing to the surgery. Typically, this information would include potential short- and longer-term risks and benefits to the patient of the proposed intervention, including the likelihood of each, based on the available clinical evidence, as informed by the responsible physician's professional judgment. Informed consent must be obtained, and the informed consent form must be placed in the patient's medical record, prior to surgery. It would be acceptable if the ASC required the physician who performs procedures in the ASC to obtain the patient's informed consent outside of the ASC, prior to the date of the surgery, since this might allow more time for discussion between the patient and physician than would be feasible on the date of the surgery. In such cases, the physician must follow the ASC's informed consent process. In all cases, the ASC must ensure that the patient's informed consent is secured prior to the start of the surgical procedure, and that this consent is documented in the patient's medical record.

Given that ASC surgical procedures generally entail use of some form of anesthesia, and that there are risks as well as benefits associated with the use of anesthesia, ASCs should assure that their informed consent process provides the patient with information on anesthesia risks and benefits as well as the risks and benefits of the surgical procedure.

The ASC's surgical informed consent policy should describe the following: (1) who may obtain the patient's informed consent; (2) the circumstances when a patient's representative, rather than the patient, may give informed consent for a surgery; (3) the content of the informed consent form and instructions for completing it; (4) the process used to obtain informed consent, including how informed consent is to be documented in the medical record; (5) mechanisms that ensure that the informed consent form is properly executed and is in the patient's medical record prior to the surgery; and (6) if the informed consent process and informed consent form are obtained outside the ASC, how the properly executed informed consent form is incorporated into the patient's medical record prior to the surgery. If there are additional requirements under state law for informed consent, the ASC must comply with those requirements.

A patient who has been determined to be incompetent under a state legal process is not capable of exercising his or her rights independently. For such patients, the person appointed under state law to act on the patient's behalf may exercise any and all of the rights afforded to the ASC patient.

In addition, a competent patient may wish to delegate his or her right to make informed decisions to another person. To the degree permitted by state law, and to the maximum extent practicable, the ASC must respect the patient's wishes and follow that process. In some cases, the patient may be unconscious or otherwise incapacitated, for example, if a complication requiring a treatment decision arises during a procedure. If the patient is unable to make a decision, the ASC must consult the patient's advance directives, medical power of attorney or patient representative or surrogate, if any of these are available. In the advance directive or the medical power of attorney, the patient may provide guidance as to his or her wishes in certain situations, or may delegate decision-making to another individual as permitted by state law. If such an individual has been selected by the patient, or if a person willing and able under applicable state law is available to make treatment decisions, relevant information should be provided to the representative or surrogate so that informed healthcare decisions can be made for the patient.

Privacy and Safety

> *(f) Standard: Privacy and safety.*
> *The patient has the right to –*
> *(1) Personal privacy.*
> *(2) Receive care in a safe setting.*
> *(3) Be free from all forms of abuse or harassment.*

The underlying principle of this requirement is the patient's basic right to respect, dignity, and comfort. "The right to personal privacy" includes at a minimum, that patients have privacy during personal hygiene activities during surgical treatments, and when requested as appropriate.

People not involved in the care of the patient should not be present without the patient's consent while the patient is being examined or treated. Video or other electronic monitoring or recording methods should not be used when the patient is being examined without the patient's consent. If a patient requires assistance during toileting and other personal hygiene activities, staff should assist, giving the utmost attention to the patient's need for privacy. Privacy should also be afforded when staff visits the patient to discuss clinical care issues or conduct any examination.

A patient's right to privacy may be limited in situations where a person must be continuously observed, such as when there is an emergency and transfer to a hospital is pending.

Each patient should receive care in an environment that a reasonable person would consider to be safe. The ASC staff should follow current standards of practice for patient environmental safety, infection control, and security. The ASC staff should also provide protection for the patient's emotional health and safety as well as the patient's physical safety.

An ASC must prohibit all forms of abuse, neglect and harassment from staff, other patients, or visitors. The ASC must have mechanisms in place ensure that patients are free from all forms of abuse, neglect or harassment.

Confidentiality of Clinical Records

> *(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.*

Section 45 C.F.R. Parts 160 and 164, generally known as the Health Insurance Portability and Accountability Act 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).

Patient Rights Checklist

Notice of Patient Rights

- □ Does your ASC provide patients (or their representatives or surrogates, as applicable), with notice of their rights, consistent with the standards under this condition?
- □ Does your ASC promote the patients' exercise of their rights (or their representatives or surrogates, as applicable), consistent with the standards under this condition?
- □ Do your ASC's posted notices contain the same information as the individual written notice provided to patients?
- □ Are the notices posted in conspicuous locations in the waiting rooms, pre-operative preparation areas, recovery rooms, or other common areas?
- □ Can you provide your ASC's policy and procedures for providing all patients notice of their rights prior to the start of the surgical procedure? Are the policies and procedures consistent with the regulatory requirements?
- □ Is the information your ASC provides in the written notice to the patients complete and accurate:
  - □ Does the notice address all of the patients' rights listed in this condition?
  - □ 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?
- □ Can your ASC demonstrate how it 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?

Notice of Physician Ownership

- □ Has your ASC reported in accordance with 42 CFR Part 420 to the Medicare program whether the ASC has any physicians with financial interests or ownership in the ASC?
- □ Does your ASC have policies and procedures in place to make the required disclosures to patients? Are the policies and procedures consistent with the regulatory requirements?
- □ Does your ASC provide a written notice of disclosure to all patients prior to the start of the surgical procedure, including a list of physicians with financial interests or ownership in the ASC?
- □ Do your ASC staff know and understand the physician ownership notice requirements, including the ASC's process for delivering the notice?

Advance Directives

- □ Do your ASC's policies and procedures related to the advance directives conform to the regulatory requirements?

- □ Can you provide a copy of the written notice of the ASC's advance directive policies and applicable state law? Does it contain all required information? If there is a statement of limitations based on conscience or state law, does it include all required information?

- □ If the State has an official advance directive form, can you demonstrate how your ASC provides these forms upon request to patients?

- □ Can you demonstrate how your ASC documents that required advance directive information is provided to patients prior to the start of surgical procedures?

- □ Does your ASC advise patients, or the patients' representatives or surrogates, of their rights to make informed decisions about their care in the ASC?

- □ Do your medical records prominently display information as to whether or not there is an advance directive in effect for the patient? Is the information displayed in a manner such that patients with advance directives can be readily distinguished from patients without an advance directive?

- □ Does your ASC have a training class or any educational materials available for the staff regarding advance directives and informed patient decision-making?

Submission and Investigation of Grievances

- □ Does your ASC have 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?

- □ Can your ASC provide documentation on how many grievances it received during the past year, how it documents the existence of grievances, what the disposition is of grievances?

- □ Is your ASC's staff aware of grievance policies? Do staff know the difference between a complaint handled on the spot and a grievance?

- □ Do your ASC's grievance policies and procedures separately address the process for investigating grievances alleging mistreatment, abuse, neglect or other serious harm? Do the policies and procedures conform to the regulatory requirement?

- □ Does your ASC staff know how to handle a grievance alleging mistreatment, abuse, neglect or other serious harm? Do they know to whom to report the grievance? Do they know that it should be reported immediately?

- □ Can you identify who is the person authorized to handle such grievances? Does the person authorized to handle such grievances understand the requirements to fully document the allegation, conduct a prompt investigation, and to report substantiated grievances to the proper authority?

Exercise of Rights and Respect for Property and Person

- □ Does your ASC staff understand that it may not discriminate against patients, or take punitive actions against any patient as a reprisal for some act on the patient's part?

- □ Do your ASC's policies and procedures make it clear that patients, or their representatives, or surrogates may exercise their rights without fear of reprisal?

- □ Does your ASC staff know how a patient who has filed a grievance or has otherwise exercised his or her rights is to be treated? Is staff aware that they should not treat a patient differently if the patient files a grievance?
- □ Are your ASC staff aware of the patient's right to file a grievance?
- □ Does your ASC have an informed consent policy that meets the regulatory requirements?
- □ Do your ASC patients' medical records document that informed consent was given prior to the surgical procedure?
- □ Are ASC patients informed of the risks and benefits of their procedures at that time they are asked to consent to their procedures?
- □ Does your ASC have a policy addressing the exercise of rights on behalf of a patient judged legally incompetent?
- □ Does your ASC have a policy addressing the delegation by a patient of the exercise of rights to a representative?

Privacy and Safety

- □ Does your ASC provide patients privacy during examinations, activities concerning personal hygiene, and discussions regarding the patient's health status or healthcare, and any other appropriate situations?
- □ Is your ASC identifying safety, infection control, and security problems, evaluating those problems, and taking steps to ensure a safe patient environment?
- □ Does your ASC have policies and procedures to curtail unwanted visitors and/or contaminated materials?
- □ Does your ASC have a system in place to protect patients from abuse, neglect, and harassment of all forms, whether from staff, other patients, visitors, or other persons?
- □ Does your ASC have policies and procedures for investigating allegations of abuse and neglect in addition to the grievance process that applies to allegations from patients or their representatives?
- □ Does your ASC use the same process as for grievances alleging abuse and neglect? If not, what is your ASC's policy and process, including the process for training staff?
- □ Do ASC staff members know what to do if they witness abuse and neglect?
- □ Do your ASC's records indicate whether appropriate agencies were notified in accordance with state and federal laws regarding incidents of substantiated abuse and neglect?

Confidentiality of Clinical Records

- □ What policies and procedures does your ASC have in place to prevent the release or disclosure of individually identifiable patient information?
- □ Is 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?

Infection Control
Condition for Coverage

In order to receive Medicare payment for surgical services furnished to program beneficiaries, an ambulatory surgical center ("ASC") must meet certain specific requirements referred to as Conditions for Coverage and set forth at 42 C.F.R. 416, Subpart C. This section discusses the Infection Control Condition for Coverage and the interpretive guidance related to infection control set forth in the Medicare State Operations Manual.

The Infection Control Condition for Coverage requires an ASC to maintain an active program for the minimization of infections and communicable diseases. It provides:

> The ASC must maintain an infection control program that seeks to minimize infections and communicable diseases.[29]

An ASC's infection control program must (1) provide a functional and sanitary environment for surgical services; (2) be based on nationally recognized infection control guidelines; (3) be directed by a designated health care professional with training in infection control; (4) be integrated into the ASC's QAPI program; (5) be ongoing; (6) include actions to prevent, identify and manage infections and communicable diseases; and (7) include a mechanism to immediately implement corrective actions and preventive measures that improve the control of infection within the ASC.

During a Medicare certification survey, one surveyor is responsible for completion of the Infection Control Surveyor Worksheet (Exhibit 351 to the Medicare State Operations Manual), which is used by the surveyor in order to determine compliance with the Infection Control Condition for Coverage.[30]

Sanitary Environment

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

The ASC must maintain a functional and sanitary environment for surgical services. This includes all areas of the ASC, including waiting areas, pre-surgical prep areas, recovery rooms, and operating and procedure rooms. The ASC must monitor housekeeping, maintenance and other activities such as repair, renovation, and construction to ensure a functional and sanitary environment. The ASC should develop and maintain policies and procedures for a functional and sanitary environment addressing the following: (1) ventilation and water quality control; (2) safe air handling systems in areas of special ventilation; (3) techniques for food sanitation (if employee food storage and eating areas are provided); (4) techniques for cleaning

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[29] 42 C.F.R. § 416.51. Appendix L to the Medicare State Operations Manual sets forth the "Guidance for Surveyors: Ambulatory Surgical Centers."

[30] The Infection Control Surveyor Worksheet is available at www.cms.gov/manuals/downloads/som107_exhibit_351.pdf.

and disinfecting environmental surfaces, carpeting, and furniture; (5) techniques for disposal of regulated and non- regulated waste; and (6) techniques for pest control.

The ASC's infection control activities must be conducted in accordance with professionally recognized standards of infection control practice.[31]

Infection Control Program

> *(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. …*

The ASC's infection control program must have an active surveillance component that covers ASC patients and personnel working in the facility. Surveillance must include infection detection through ongoing data collection and analysis.

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: (1) 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); (2) mitigation of risks associated with healthcare-associated infections; (3) identifying infections; (4) monitoring compliance with policies, procedures, protocols and other infection control program requirements; and (5) program evaluation and revision of the program, when indicated.

The ASC should evaluate the immunization status of each member of its staff for designated infectious diseases. In addition, it should develop and maintain 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 an exposed individual, and for reportable diseases, as required under local, state, or federal public health authority as well as policies articulating when infected ASC staff are restricted from providing direct patient care or are required to remain away from the facility entirely. The ASC should also require new employee and regular update training in preventing and controlling healthcare-associated infections ("HAI") and methods to prevent exposure to and transmission of infections and communicable diseases.

The ASC should take the following surgery-related infection risk mitigation measures:

- Implementing appropriate prophylaxis to prevent surgical site infection, 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

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[31] 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").

- Addressing aseptic technique practices used in surgery, including sterilization or high-level disinfection of instruments, as appropriate.

In addition, the ASC should take other HAI risk mitigation measures such as the following:

- 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; and
- Educating patients, visitors, and staff, as appropriate, about infections and communicable diseases and methods to reduce transmission in the ASC and in the community.

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 activities. Monitoring includes follow-up of patients after discharge, in order to gather evidence of whether the patients develop an infection associated with their stay in the ASC. The ASC must also 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.

The ASC must take steps to determine whether its staff adheres to its infection control policies and procedures.

An ASC's infection control program must be an integral part of the ASC's QAPI program.

Infection Control Program

> *(b) Standard: Infection control program.*
> *… The program is--*
> *(1) Under the direction of a designated and qualified professional who has training in infection control;*
> *(2) An integral part of the ASC's quality assessment and performance improvement program; and*
> *(3) Responsible for providing a plan of action for preventing, identifying, and managing infections and communicable diseases and for immediately implementing corrective and preventive measures that result in improvement.*

The ASC must designate in writing, a qualified licensed health care professional who will lead the facility's infection control program.[32] The individual must have training in the principles and methods of infection control. The individual selected to lead the ASC's infection control program must maintain his or her qualifications through ongoing education and training.

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 must include mechanisms that result in immediate action to implement preventive or corrective measures that improve the ASC's infection control outcomes. It also must be specific to each particular area of the ASC, including the waiting rooms, the recovery rooms, and the surgical areas.

The infection control professional must assure that the program's plan addresses the following activities: (1) maintenance of a sanitary environment; (2) development and implementation of infection control measures related to ASC personnel; (3) mitigation of risks associated with patient infections present upon admission; (4) mitigation of risks contributing to HAI; (5) active surveillance; (6) monitoring compliance with all policies, procedures, protocols, and other infection control program requirements; (7) plan evaluation and revision of the plan, when indicated; (8) 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 (9) compliance with reportable disease requirements of the local health authority.

[32] Certification in infection control, such as that offered by the Certification Board of Infection Control and Epidemiology Inc. ("CIBC"), while highly desirable, is not required. However, the ASC must be able to provide documentation that the individual has training that qualifies the individual to lead an infection control program.

Infection Control Checklist

Sanitary Environment

- □ Has your ASC reviewed the Infection Control Surveyor Worksheet, Exhibit 351?
- □ Can your staff identify where cleaning and disinfection takes place and at what frequencies? Does your ASC have supporting documentation of cleaning and disinfection schedules?
- □ Does your ASC have a procedure for decontamination after gross spills of blood or other bodily fluids?
- □ Does your ASC properly dispose of used sharps?
- □ Does your ASC re-use devices marketed for single use, and if so, does it send them to an FDA-approved vendor for reprocessing?

Infection Control Program

- □ Does your ASC have an ongoing program for the prevention, control, and investigation of infections and communicable diseases among patients and ASC personnel, including contract workers and volunteers?
- □ Does your ASC correctly implement the policies and procedures of the program of the infection control program?
- □ Does your ASC mitigate risks contributing to healthcare-associated infections?
- □ Does your ASC perform monitoring activities to identify infections?
- □ Does your ASC monitor compliance with all infection control program requirements?
- □ Does your ASC review the parameters of the program to determine whether it is consistent with nationally recognized infection control guidelines?
- □ Is there documentation that your ASC has developed the procedures and policies of the program based on nationally recognized infection control guidelines?
- □ Has your ASC designated a qualified individual with the responsibility for leading the infection control program? Does his or her personnel file demonstrate that he or she is qualified through ongoing education, training, or certification to oversee the infection control program?
- □ Does your ASC's QAPI program include measures and activities related to infection control on an ongoing basis?
- □ Have your ASC's QAPI infection control activities resulted in specific actions designed to improve infection control within the ASC?
- □ Can your ASC's designated infection control professional describe actual examples of how, as a result of the action plan, infection control issues were identified and corrective or preventive actions were taken?
- □ Does your ASC have documentation of how those actions were evaluated to assure that they resulted in improvement?
- □ Does your ASC's infection control plan address all the basic elements of infection control?
- □ Can your ASC's leadership address how it tracks infections among patients and staff?
- □ Can your ASC provide documentation of tracking of all patients?
- □ Can your ASC's leadership identify what diseases are reportable to the state to verify the ASC's awareness of applicable reporting requirements?

Patient Admission, Assessment and Discharge Condition for Coverage

In order to receive Medicare payment for surgical services furnished to program beneficiaries, an ambulatory surgical center ("ASC") must meet certain specific requirements referred to as Conditions for Coverage and set forth at 42 C.F.R. 416, Subpart C. This section discusses the Patient Admission, Assessment and Discharge Condition for Coverage and provides a checklist based on the survey protocol outlined in the Medicare State Operations Manual to assist an ASC in evaluating whether it meets the condition's requirements.

The Patient Admission, Assessment and Discharge Condition for Coverage provides:

> The ASC must ensure each patient has the appropriate pre-surgical and post-surgical assessments completed and that all elements of the discharge requirements are completed.[33]

This condition seeks to ensure that: (1) a patient can tolerate a surgical experience; (2) a patient's anesthesia risk and recovery are properly evaluated; (3) a patient's post-operative recovery is adequately evaluated; and (4) a patient receives effective discharge planning and is successfully discharged from an ASC. The condition establishes requirements for admission and pre-surgical assessments, post-surgical assessments, and discharge. These requirements are discussed in detail below.

It is important to note that a surveyor will consider deficiencies related to 42 C.F.R. § 416.42(a) (the anesthetic risk and evaluation requirements of the Surgical Services Condition for Coverage) when determining whether requirements for the Patient Admission, Assessment and Discharge Condition for Coverage have been met.[34]

Admission and Pre-surgical Assessment

> *(a) Standard: Admission and pre-surgical assessment.*
> *(1) Not more than 30 days before the date of the scheduled surgery, each patient must have a comprehensive medical history and physical assessment completed by a physician (as defined in section 1861(r) of the Act) or other qualified practitioner in accordance with applicable State health and safety laws, standards of practice, and ASC policy.*
> *(2) Upon admission, each patient must have a pre-surgical assessment completed by a physician or other qualified practitioner in accordance with applicable State health and safety laws, standards of practice, and ASC policy that includes, at a minimum, an updated medical record entry documenting an examination for any changes in the*

[33] 42 C.F.R. § 416.52; Appendix L to the Medicare State Operations Manual sets forth the "Guidance for Surveyors: Ambulatory Surgical Centers."

[34] 42 C.F.R. § 416.42(a) requires that a physician examine a patient immediately before surgery to evaluate the risk of anesthesia and of the procedure to be performed. It also requires that, before discharge from the ASC, the patient be evaluated by a physician or by an anesthetist for proper anesthesia recovery.

patient's condition since completion of the most recently documented medical history and physical assessment, including documentation of any allergies to drugs and biologicals.
(3) The patient's medical history and physical assessment must be placed in the patient's medical record prior to the surgical procedure.

A medical history and physical assessment ("H&P") must be completed and documented for a patient of an ASC *no more than 30 calendar days prior to the date the patient is scheduled for surgery* in the ASC.[35] The purpose of this requirement is to ensure the ASC determines whether there is anything in the patient's overall condition that would affect the surgery or that indicates an ASC is not be an appropriate setting for the patient's surgery.

The H&P must be completed and documented by a physician or other qualified licensed practitioner. For purposes of this condition, the term "physician" includes a doctor of medicine or osteopathy, a doctor of dental surgery or of dental medicine, a doctor of podiatric medicine, a doctor of optometry or a chiropractor. Other qualified licensed practitioners are those who are authorized to perform an H&P under applicable state scope of practice laws, generally accepted standards of practice, and ASC policy.[36] The H&P is typically completed by the patient's primary care practitioner rather than a member of the ASC's medical staff. The ASC's policy on H&Ps should address submission of an H&P prior to the patient's scheduled surgery date by a physician or other qualified licensed practitioner who is not a member of the ASC's medical staff.

In those cases where the patient is referred to the ASC for surgery on the same day as the referral, an H&P is still required. It may be performed by the referring physician (if the ASC's policies permit it) or a qualified licensed practitioner in the ASC.

Upon admission to the ASC, each patient must also have a pre-surgical assessment.[37] The patient must be assessed for any changes in his or her condition since the patient's H&P was performed. The patient's medical record must include documentation that the patient was examined prior to the commencement of surgery for changes since the H&P. If, upon examination, the licensed practitioner finds no change in the patient's condition since the H&P was completed, he or she may indicate in the patient's medical record that the H&P was reviewed, the patient was examined, and that "no change" has occurred in the patient's condition since the H&P was completed. Likewise, any changes in the patient's condition must be documented by the practitioner in the update note prior to the start of surgery.

Ideally, the H&P should be submitted to the ASC prior to the patient's scheduled surgery date, in order to allow sufficient time for review of the H&P by the ASC's medical staff and adjustments if necessary, including postponement or cancellation of the surgery. At a minimum, the H&P must be placed in the patient's medical record prior to the pre-surgical assessment required by this condition, since that assessment must first consider the findings of the H&P before examining the patient for changes. Both the H&P and the pre-surgical assessment must be placed in the patient's medical record before the surgery.

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[35] In cases where a patient is scheduled for two surgeries in an ASC within a short period of time, the same H&P may be used so long is it is completed no more than 30 calendar days before each surgery.

[36] More than one qualified practitioner can participate in performing, documenting and authenticating an H&P for a patient. When performance, documentation and authentication are split among qualified practitioners, the practitioner who authenticates the H&P will be held responsible for its contents.

[37] *See also* 42 C.F.R. § 416.42(a)(1).

Post-surgical Assessment

> *(b) Standard: Post-surgical assessment.*
> *(1) The patient's post-surgical condition must be assessed and documented in the medical record by a physician, other qualified practitioner, or a registered nurse with, at a minimum, post-operative care experience in accordance with applicable State health and safety laws, standards of practice, and ASC policy.*
> *(2) Post-surgical needs must be addressed and included in the discharge notes.*

Each patient must be assessed after the surgery is completed. In addition, each post-surgical patient's overall condition must be assessed and documented in the medical record, in order to determine how the patient's recovery is proceeding, what needs to be done to facilitate the patient's recovery, and whether the patient is ready for discharge or in need of further treatment or monitoring.

Except for the assessment of the patient's recovery from anesthesia, the assessment may be performed by a physician, another qualified licensed practitioner, or a registered nurse with post-operative care experience who is authorized under applicable state scope of practice laws, generally accepted standards of practice, and ASC policy to assess patients post-operatively.[38]

If the assessment identifies post-surgical patient needs that must be addressed in order for the patient to be safely discharged (or, in the case of patients who develop needs that exceed the capabilities of the ASC, to be appropriately and timely transferred to a hospital for further care), the ASC must address those patient needs. This must be documented in the discharge notes in the patient's medical record.

Discharge

> *(c) Standard: Discharge.*
> *The ASC must--*
> *(1) Provide each patient with written discharge instructions and overnight supplies. When appropriate, make a follow-up appointment with the physician, and ensure that all patients are informed, either in advance of their surgical procedure or prior to leaving the ASC, of their prescriptions, post-operative instructions and physician contact information for follow-up care.*
> *(2) Ensure each patient has a discharge order, signed by the physician who performed the surgery or procedure in accordance with applicable State health and safety laws, standards of practice, and ASC policy.*
> *(3) Ensure all patients are discharged in the company of a responsible adult, except those patients exempted by the attending physician.*

Each patient, or the adult who accompanies the patient upon discharge, must be provided with written discharge instructions. Each patient must be provided with: (1) prescriptions the patient will need to fill associated with recovery from surgery; (2) written instructions that specify actions the patient should take in the immediate post-discharge period to promote recovery from surgery; and (3) information concerning how to contact the physician who will provide follow-up care to the patient. When appropriate, the ASC

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[38] *See also* 42 C.F.R. § 416.42(a)(2).

must make an appointment with the physician for follow-up care. In addition, the ASC must provide supplies sufficient for the patient's needs through the first night after surgery.

No patient may be discharged from the ASC unless the physician who performed the surgery signs a discharge order. It is expected that a patient will leave the ASC within 15 to 30 minutes of the time when the physician signs the discharge order.

Finally, unless the physician who is responsible for the patient's care in the ASC has exempted the patient, the ASC may not discharge any patient who is not accompanied by a responsible adult who will go with the patient after discharge. Exemptions must be specific to individual patients, not blanket exemptions to a whole class of patients.

Patient Admission, Assessment and Discharge Checklist

Admission and Pre-surgical Assessment

- □ Does your ASC have a policy requiring that an H&P be performed for each patient no more than 30 days before each patient's scheduled surgery by a physician or other qualified licensed individual?
- □ Does your ASC's policy address who may perform the H&P? If it permits H&Ps performed by qualified licensed individuals who are not physicians, is it consistent with state scope of practice laws?
- □ Do your ASC's medical records demonstrate that: (1) an H&P was completed no more than 30 days before the patient's surgery date; and (2) the H&P was performed by a physician or other qualified licensed individual?
- □ Does your ASC have a policy requiring a pre-surgical assessment for all patients to update the findings of the H&P performed prior to the date of surgery?
- □ Do your ASC's medical records demonstrate that a pre-surgical assessment was performed?
- □ Does a physician perform those components of the pre-surgical assessment related to evaluation of anesthetic risk and procedural risk?
- □ Does the pre-surgical assessment include documentation in the medical record of the patient's allergies or lack of known allergies to drugs and biologicals?

Post-surgical Assessments

- □ Do your ASC's medical records demonstrate that your ASC evaluates each patient after surgery, both for recovery from anesthesia and for his or her overall recovery from the surgery and suitability for discharge?
- □ Are the post-surgical assessments at your ASC performed by appropriate personnel?
- □ Does your ASC identify patient needs related to safe discharge or identify patients who require transfer to a hospital for further treatment that exceeds the ASC's capabilities? Do your ASC's medical records reflect actions by the ASC to address the needs it has identified?

Discharge

- □ Do your ASC's medical records include discharge instructions?
- □ Do your ASC's discharge instructions include post-operative care instructions for the patient? Do they indicate whether the patient was provided prescriptions, if applicable? Do they provide physician contact information?
- □ Can your ASC explain when and how it schedules follow-up appointments with the physician for patients?
- □ Can your ASC explain what types of supplies it typically provides to patients upon discharge?
- □ Do your ASC's medical records include a discharge order, signed by the physician who performed the surgery?
- □ Do your ASC's medical records identify for each patient the responsible adult who will accompany the patient after discharge or the specific exemption from this requirement?

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