Washington Ambulatory Surgery Center Association
Our Patients Come First

Medicare Conditions for Coverage Alert: Governing Body and Management

Emily R. Studebaker
WASCA General Counsel
Garvey Schubert Barer
1191 Second Avenue, Suite 1800
Seattle, WA 98101
Direct 206.816.1417
Mobile 206.406.2729
estudebaker@gsblaw.com

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 alert 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.

Background

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 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" and is available at www.cms.gov/GuidanceforLawsandRegulations/02_ASCs.asp.

- *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 Patients' 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 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*

[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.

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.

- *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.[4]

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

- □ 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 (if applicable) and radiologic services; 7) management of the ASC's physical plant; 8) medical records maintenance; 9) infection control; and 10) quality assurance and performance improvement?
- □ 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?

[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.

[4] Resources for providers and suppliers on effective healthcare emergency preparedness may be found on CMS' Web site at www.cms.hhs.gov/SurveyCertEmergPrep/03_HealthCareProviderGuidance.asp#TopOfPage.

- □ 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 the other 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?
