Northwest ASC Update

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Emily R. Studebaker, Esq.
Garvey Schubert Barer
1191 Second Avenue,
Suite 1800
Seattle, WA 98101
(206) 816-1417
estudebaker@gsblaw.com

CMS Revises Interpretive Guidelines for Ambulatory Surgical Centers Conditions for Coverage

In order to receive Medicare payment for surgical services furnished to program beneficiaries, an ambulatory surgical center (ASC) is required to comply with federal requirements set forth in the Conditions for Coverage at 42 C.F.R. 416, Subpart C. On May 12, 2014, the Centers for Medicare & Medicaid Services (CMS) adopted a final rule, entitled "Medicare and Medicaid Programs; Regulatory Provisions To Promote Program Efficiency, Transparency, and Burden Reduction; Part II," which included new and revised regulations effective July 11, 2014 that apply to a number of provider types, including ASCs. Specifically, the final rule changed certain requirements set forth in the Conditions for Coverage.

Initial certification, recertification, and representative sample validation surveys require assessment of the ASC's compliance with all Conditions for Coverage conducted by surveyors in accordance with the State Operations Manual, Appendix L: Guidance for Surveyors – Ambulatory Surgical Centers (commonly referred to as the "Interpretive Guidelines"). CMS released a surveyor memorandum on January 30, 2015, announcing updates to the Interpretative Guidelines that reflect the new and revised regulations applicable to ASCs. The updates to the Interpreted Guidelines are summarized below.

Surgical Services

The Condition for Coverage concerning surgical services requires that surgical procedures are performed in a safe manner by qualified physicians who have been granted clinical privileges by the governing body of an ASC in accordance with approved policies and procedures of the ASC.[1] In the final rule, CMS introduced a standard-level tag for the regulatory language found in the condition related to a requirement to perform surgery in a safe manner, to allow citation at either the standard or condition level, as appropriate. The Interpretive Guidelines have been revised to reflect the standard-level tag.

Laboratory and Radiologic Services

The Condition for Coverage concerning laboratory and radiologic services requires that an ASC have procedures for obtaining radiological services from a Medicare-approved facility to meet the needs of patients.[2]

[1] *See* 42 C.F.R. § 416.42.

[2] *Id*. at § 416.49(b).

The Interpretive Guidelines have been revised to make explicit that radiologic services may *only* be provided in the ASC when integral to surgical procedures offered by the ASC.

The prior regulation required the ASC to comply with the *entire* hospital Conditions of Participation (CoPs) for radiologic services specified in 42 C.F.R. § 482.26. The Interpretive Guidelines have been revised to reflect that an ASC providing radiologic services must comply with only the following provisions of the hospital CoPs for radiologic services: (i) 42 C.F.R. § 482.26(b) regarding safety for patients and personnel; (ii) 42 C.F.R. § 482.26(c)(2) regarding qualified personnel who may use radiologic equipment and administer procedures; and (iii) 42 C.F.R. § 482.26(d)(2) regarding maintenance for at least five years of certain records of radiologic services. As revised, hospital radiologic requirements not expressly listed in §416.49(b), including those related to mandatory provision of radiologic services, supervision of such services by a radiologist, and practitioner signing of radiologic reports, no longer apply to ASCs.

The Interpretive Guidelines have been revised to reflect that the ASC's governing body is required to appoint an individual qualified in accordance with state law and ASC policies who is responsible for assuring that all radiologic services are provided in accordance with the cross-referenced hospital CoPs requirements. In order to assure compliance with this requirement, the individual is expected to be qualified, through training and/or experience, to oversee areas including the following: (i) use of safety precautions against radiation hazards; (ii) regular equipment inspection and hazard correction; (iii) regular review of radiation worker radiation exposure; (iv) assuring use of radiologic equipment only by qualified personnel; and (v) maintenance of imaging results or records. The person appointed to oversee radiologic services could be someone already working in the ASC who is qualified in accordance with state law and ASC policies. Under the medical staff credentialing and privileging requirements at 42 C.F.R. § 416.45, the ASC's governing body continues to be required to ensure that the operating surgeon is competent both to perform the surgical procedures for which privileges have been issued by the ASC and to appropriately and safely use the imaging modalities that are integral to the procedures he or she performs.

Hospitalization

The Condition for Coverage concerning governing body and management requires that an ASC have an effective procedure for the immediate transfer to a hospital of patients requiring emergency medical care beyond the capabilities of the ASC.[3] The hospital must be a local, Medicare participating hospital or a local, nonparticipating hospital that meets the requirements for payment for emergency services.[4] The ASC must have a written transfer agreement with a hospital that meets these requirements or ensure that all physicians performing surgery in the ASC have admitting privileges at a hospital that meets these requirements.[5]

The Interpretive Guidelines have been revised to clarify that an "effective procedure" for immediate emergency transfers includes written ASC policies and procedures that address the following: (i) the circumstances warranting emergency transfer, including who makes the transfer decision; (ii) the documentation that must accompany the transferred patient; and (iii) the procedure for accomplishing the transfer safely and expeditiously, *including communicating with the receiving hospital*. It is acceptable if

[3] *See* 42 C.F.R. § 416.41(b).

[4] *Id.*

[5] *Id.*

the ASC contacts the ambulance service via 911 to arrange emergency transport, unless state licensure requires additional arrangements, *but the ASC is still responsible for communicating with the receiving hospital to facilitate the transfer*.

The ASC is required to transfer patients who require emergency transfer to a local Medicare-participating hospital, or to a local, non-Medicare-participating hospital that meets the requirements for payment for emergency services by the Medicare program. A "local" hospital means the ASC is to consider the most appropriate facility to which the ASC will transport its patients in the event of an emergency. If the closest hospital could not accommodate the patient population or the predominant medical emergencies associated with the type of surgeries performed by the ASC, *another hospital that is able to do so and which is closer than other comparable hospitals would* meet the "local" definition.[6]

Physical Environment

The Condition for Coverage concerning an ASC's physical environment requires that the ASC provide a functional and sanitary environment for the provision of surgical services.[7] Each operating room (OR) must be designed and equipped so that the types of surgery conducted can be performed in a manner that protects the lives and assures the physical safety of all individuals in the area.[8]

The Interpretive Guidelines have been revised to clarify that an OR in an ASC includes not only traditional ORs, but also procedure rooms, including those where surgical procedures that do not require a sterile environment are performed. ORs must be designed in accordance with industry standards for the types of surgical procedures performed in the room, including whether the OR is used for sterile and/or non-sterile procedures. Existing ORs must meet the standards in force at the time they were constructed, while new or reconstructed ORs must meet current standards. Although the term "operating room" includes both traditional ORs and procedure rooms, this does not mean that procedure rooms must meet the same design and equipment standards as traditional ORs. In all cases, the OR design and equipment must be appropriate to the types of surgical procedures performed in it.

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[6] For example, if there is a long term care hospital within five miles of the ASC, and a short-term acute care hospital providing emergency services within 15 miles of the ASC, the ASC would be expected to transfer patients to the short-term acute care hospital.

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

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

On the other hand, for example, if there is an appropriate hospital eight miles from the ASC, and another hospital with similar capabilities 20 miles from the ASC, the farther hospital would not be considered a local hospital for ASC emergency transfer purposes, unless the closer hospital lacks capacity at the time of the transfer.

[7] *See* 42 C.F.R. § 416.44(a).

[8] *Id.*

The OR must also be appropriately equipped for the types of surgery performed in the ASC. Equipment includes both facility equipment and medical equipment. Medical equipment for the OR includes the appropriate type and volume of surgical and anesthesia equipment, including surgical instruments. Surgical instruments must be available in a quantity that is commensurate with the ASC's expected daily procedure volume, taking into consideration the time required for appropriate cleaning and, if applicable, sterilization. In addition, emergency equipment determined to be necessary must be either in or immediately available to the OR.

ASCs must also ensure that the OR humidity level is appropriate for all of their surgical and anesthesia equipment and that supplies requiring a different level of humidity than that in the OR are appropriately stored until used.

Patient Rights

The Condition for Coverage concerning patient rights requires that an ASC inform each patient, or the patient's representative or surrogate, of the patient's rights.[9] The notice must include, with respect to ASC patients who are Medicare beneficiaries, a website for the Office of the Medicare Beneficiary Ombudsman. The Interpretive Guidelines have been revised to include the following updated website address: http://www.medicare.gov/claims-and-appeals/medicare-rights/get-help/ombudsman.html.

The Condition also requires that an ASC utilize an informed consent process that assures each patient or the patient's representative or surrogate is given the information and disclosures needed to make an informed decision about whether to consent to a surgical procedure in the ASC.[10] The Interpretive Guidelines have been revised to clarify that the informed consent form must be signed by the patient, or as appropriate, the patient's representative or surrogate, and placed in the patient's medical record, prior to surgery.

Discharge

The Condition for Coverage concerning patient admission, assessment and discharge requires that an ASC 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.[11]

The ASC must ensure that physicians follow applicable state laws as well as generally accepted standards of practice and ASC policy when determining that a patient has recovered sufficiently from surgery and may be discharged from the ASC, or, as applicable, that the patient must be transferred to another healthcare facility that can provide the ongoing treatment that the patient requires and that the ASC is unable to provide. The Interpretive Guidelines have been revised to clarify that it is permissible for the operating physician to write a discharge order indicating "the patient may be discharged when stable." In such cases there must be documentation of when patient was stable. It is expected that a patient will actually leave the ASC within 15 to 30 minutes of the time when the physician signs the discharge order or when he or she was found to be stable, whichever happens later.

The new and revised regulations and their associated guidance were effective July 11, 2014. CMS has instructed that all survey staff be advised of the revised Interpretive

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[9] *See* 42 C.F.R. § 416.50(a).

[10] *Id*. at § 416.50(e).

[11] *Id*. at § 416.52(c)(2).

Guidelines by March 1, 2015. ASCs should be prepared to demonstrate compliance with the new and revised requirements during their surveys.