

HEALTH LAW

Update

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Medicare Rules for Ambulatory Surgery Centers: What a Difference a Year Makes

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The past year has seen several significant changes to Medicare regulations for ambulatory surgery centers (ASCs), including changes to the ASC payment system. So significant are these changes that earlier this month the Centers for Medicare & Medicaid Services (CMS) posted on its website a series of over forty frequently asked questions (FAQs) regarding the ASC payment system.¹ In this Health Law Update, we will review the recent revisions to the ASC payment system as well as proposed changes to the current requirements that ASCs must meet in order to participate in the Medicare program. We will also briefly mention guidance issued by CMS within the last week regarding the processing of CMS Form 855B filings submitted by ASCs.²

CMS Revised Payment System Policies for Services Furnished in ASCs – Effective January 1, 2008

On August 2, 2007, CMS published a final rule for Medicare payments to ASCs (the "Final Rule").³ The Final Rule, effective January 1, 2008, represents one of the most significant changes to Medicare ASC payments in decades.

Final Rule – Overview

Under the previous payment system, procedures performed at ASCs were reimbursed by Medicare at one of nine payment rates (or "groupers") ranging from \$333 to \$1,339. Surgical procedures were added to the list of ASC procedures reimbursable by Medicare (the "ASC List") if they met various criteria, and, once added, the procedures were assigned to one of the nine groupers.

In the Final Rule, CMS abandons the approach of incrementally adding procedures to the ASC List and instead adopts the "exclusionary" approach (i.e. procedures should be part of the ASC List unless there is a good reason to exclude them). As a result, 793 new procedures now appear on the ASC List (in

¹ To access the FAQs, visit <http://questions.cms.hhs.gov> and click "Medicare," then "Medicare Fee-for-Service Payment," then "ASC Payment" on the pull-down menus, and then click the "Search" button (new FAQs were last updated on January 7, 2008)

² Pub. 100-08 – Medicare Program Integrity Manual; Transmittal 233 (January 18, 2008) To access the transmittal, visit <http://www.cms.hhs.gov/transmittals/downloads/R233PI.pdf>

³ 72 Fed. Reg. 42470 (Aug. 2, 2007).

addition to the approximately 2,500 existing procedures). The payment rate for each procedure is now determined by using the payment categories for reimbursing procedures performed at hospital outpatient departments (HOPDs). Accordingly, procedures performed at ASCs are not assigned to one of the nine groupers, but instead are set at one of the hospital outpatient payment system (OPPS) ambulatory payment categories (APCs) – of which there are over 200 – and then adjusted downward using an "ASC conversion factor." CMS noted that ASC costs are generally lower than hospital costs, and as a result, Medicare will pay an ASC about 65% of what it would pay a hospital for the same surgical service (based on 2008 HOPD rates).

While these payment changes are significant, the system is designed to be budget neutral. Therefore, by necessity, some procedures will begin receiving higher payments and other procedures lower payments than under the prior system. CMS noted in its preamble commentary accompanying the Final Rule that, in particular, many gastrointestinal, pain management, and ophthalmology procedures would face payment cuts. For this and other reasons, CMS is incorporating a four-year blended phase-in of the new payment system thus allowing ASCs an opportunity to balance their Medicare case mix between procedures whose rates decrease and procedures whose rates increase. However, new procedures that are being added to the ASC List in 2008 will be paid 100% of the new rates immediately.

Covered Procedures Under the Final Rule

Under the Final Rule, Medicare will now pay for most procedures performed at an ASC that do not involve significant safety risk to beneficiaries, and do not require an overnight stay (proposed changes to the definition of "overnight stay" are discussed in the last section of this update). The criteria used to identify procedures that could pose a *significant safety risk* at an ASC include, among other things, whether the procedure: generally results in extensive blood loss, requires major or prolonged invasion of body cavities, directly involves major blood vessels, or is emergent or life-threatening. Procedures deemed to require an *overnight stay* are those procedures for which standard medical practice dictates that the beneficiary would typically be expected to require active medical monitoring and care at midnight following the procedure. This does not mean that an ASC is prohibited from ever keeping a patient overnight if the circumstances of that particular patient unexpectedly require extra monitoring; it simply means that Medicare will not provide reimbursement for procedures that typically require that level of care.

New Policies for Specific Items and Services

The Final Rule contains a number of changes to specific categories of payment. A general summary of some of the more significant changes follows:

- *Office-based Procedures.* In the past, procedures that are commonly performed in physicians' offices have generally been excluded from the ASC List. However, as of January 2008, ASCs *can* be reimbursed for these procedures. The Final Rule lists those procedures that will be considered "office based," and provides that these procedures be reimbursed at *the lower of*: (i) the amount that would be received under the new ASC payment system, or (ii) the physician-office rate for such procedure.
- *Radiology.* For the first time Medicare will provide separate ASC payment for certain covered ancillary services, including certain radiology services, when they are integral to the performance of a covered surgical procedure (i.e. when the ancillary services are required for the successful performance of the surgery and are performed in the ASC immediately preceding, during, or immediately following the covered surgical procedure). Those services include some fluoroscopy and ultrasound services. However, ASCs will still be prohibited from billing Medicare for more

extensive comprehensive radiology services that are not integral to the performance of a surgical procedure. The addition of ancillary radiology services to the ASC List creates a potential issue for physician-owned ASCs under the Federal physician self-referral prohibition (the "Stark" law). Some radiology procedures are "designated health services" under the Stark law, and thus generally cannot be billed separately by non-rural physician-owned ASCs outside the ASC composite rate. To address this issue, CMS has, in the final 2008 hospital outpatient prospective payment system (OPPS) rule,⁴ modified the Stark regulations such that radiology and other imaging services that are "covered ancillary services" under the Final Rule will not be considered as "designated health services" subject to the Stark law.⁵

- *Drugs and Biologicals.* As of January 2008, Medicare will pay separately for all OPPS pass-through and nonpass-through drugs and biologicals that are separately paid under the OPPS, when they are provided in association with a covered surgical procedure at an ASC (i.e. if the drugs or biologicals are integral to the performance of the covered surgical procedure, and are required for the successful performance of the surgery, and are provided in the ASC immediately preceding, during, or immediately following the procedure). The Final Rule provides a list of the drugs and biologicals that may be reimbursed separately. As with radiology services, CMS separately addressed any potential Stark law issues in the final 2008 OPPS rule by defining "outpatient prescription drugs" (which are Stark "designated health services") as excluding those drugs that are "covered ancillary services" under the Final Rule.⁶ In contrast, Stark would continue to prohibit non-rural physician-owned ASCs from furnishing outpatient prescription drugs for use in a patient's home.
- *Brachytherapy Sources.* Under the Final Rule, ASCs may be paid separately for brachytherapy sources when they are provided in association with a surgical procedure not excluded from ASC payment and billed by the ASC on the same day. **Note** that, unlike the definitions of "radiology and other imaging services" and "outpatient prescription drugs," as discussed above, CMS has **not** yet adopted a modification of the definition of "radiation therapy services and supplies" (which are Stark "designated health services") that would exclude separately paid brachytherapy sources from this definition.⁷ However, even though brachytherapy sources *are* designated health services under the Stark law, CMS has indicated on its website that brachytherapy sources may potentially meet the Stark *exception* for implants furnished by an ASC. CMS posted this guidance on the "frequently asked questions" section of its website on December 19, 2007.⁸ Because CMS "frequently asked questions" do not constitute part of the official regulation, it is advisable that interested parties confirm this conclusion with CMS.
- *Implantable Devices With Pass-Through Status Under the OPPS.* Separate payment will be provided to ASCs for implantable devices that are included in device categories with "pass-through" status⁹ under the OPPS. This subset of implantable devices will receive separate payment under the new ASC payment system as "covered ancillary services."
- *Implantable Devices Without Pass-Through Status Under the OPPS.* Separate payment will generally not be made for implantable devices that do not have pass-through status under the

⁴ 72 Fed. Reg. 66579 (Nov. 27, 2007).

⁵ *Id.* at 66851.

⁶ *Id.* See 42 C.F.R. § 411.351.

⁷ 72 Fed. Reg. 66852 (Nov. 27, 2007).

⁸ See http://questions.cms.hhs.gov/cgi-bin/cmshhs.cfg/php/enduser/std_adp.php?p_faqid=8807.

⁹ Devices with "pass-through" status are reimbursed separately to HOPDs based on the hospital's estimated cost in obtaining the device.

OPPS. Payment for these devices is generally *built in* to the OPPS payment for the *procedure* involving the implant; therefore, CMS determined that an additional separate payment for the *device itself* is not necessary. However CMS acknowledged that this could lead to unintended consequences for device-intensive procedures because of the ASC conversion factor. To address this situation, CMS structured the Final Rule so that the ASC conversion factor only applies to the non-device portion of such procedures.

CMS Proposed Regulations Revising ASC Conditions for Coverage

On August 31, 2007, CMS issued a proposed rule to revise and add to the current ASC conditions for coverage (the "Proposed Rule").¹⁰ Originally published in August 1982, these conditions for coverage ("CfCs") have remained largely unchanged since that time. Although CMS stated in the press release accompanying the Proposed Rule that a final rule would be issued toward the end of 2007,¹¹ so far no final rule has appeared.

Revised Conditions for Coverage

The Proposed Rule revises three of the existing conditions for coverage for ASCs: Governing Body and Management; Evaluation of Quality (renamed Quality Assessment and Performance Improvement ("QAPI")); and Laboratory and Radiology Services.¹²

- *Condition for Coverage – Governing Body and Management.* The Proposed Rule, if implemented, will require the ASC governing body to assume direct oversight and accountability for the QAPI program (focusing on identifying areas that need improvement), and to create and maintain a disaster preparedness plan. CMS is proposing to require that ASCs coordinate their plan with State and local agencies, conduct drills at least annually, evaluate the drill in a written report, and immediately implement any corrections to the plan.
- *Condition for Coverage – Quality Assessment and Performance Improvement.* As proposed, this condition will require ASCs to develop a QAPI program that measures, analyzes, and tracks quality indicators, including adverse patient events, infection control and other aspects of performance. The ASC must use quality indicator data to monitor the effectiveness and safety of its services and the quality of its care, and to identify opportunities for improving patient care. An ASC will be free to develop programs that meet its individual needs as long as such program is approved by its governing body.
- *Condition for Coverage – Laboratory and Radiology Services.* Under the Proposed Rule, if an ASC performs laboratory or radiology services, the ASC must meet the Medicare conditions applicable to laboratories¹³ or radiological services providers, respectively. With respect to laboratory services, the condition remains substantively unchanged from the earlier version, whereas, with respect to radiological services, the condition actually represents an expansion of the ability of an ASC to provide radiological services by allowing an ASC to directly perform such services where they are "medically necessary and integral to the performance of surgical

¹⁰ 72 Fed. Reg. 50469 (August 31, 2007).

¹¹ See August 24, 2007 CMS press release, available at <http://www.cms.hhs.gov/apps/media/>.

¹² 72 Fed. Reg. 50485 – 50486 (Aug. 31, 2007).

¹³ The laboratory requirements allow for differing levels of Clinical Laboratory Improvement Amendment (CLIA) certification based on the complexity of tests being performed. *See* 42 C.F.R. § 493

procedures." If the ASC does so, however, it must meet the conditions for coverage requirements applicable to portable X-ray services.¹⁴

New Conditions for Coverage

Finally, the Proposed Rule also adds three new conditions: Patients' Rights (which includes a physician-ownership disclosure requirement); Infection Control; and Patient Admission, Assessment, and Discharge.

- *Condition for Coverage – Patients' Rights.* Under this requirement, ASCs must "notify patients of their rights, provide for the exercise of rights, establish the right of privacy and safety, and maintain the confidentiality of clinical records." The proposed condition specifies that patients have the right to: (i) exercise their rights without discrimination or reprisal; (ii) voice grievances; (iii) be fully informed about a treatment or procedure and the expected outcome prior to undergoing such treatment or procedures; (iv) personal privacy; (v) receive care in a safe setting; (vi) be free from all forms of abuse or harassment; and (vii) confidentiality of their clinical records maintained by the ASC.

ASCs will have to provide patients (or their representatives) with written and verbal notification of the patient's rights in a language the patient (or their representative) can understand; post notifications of patient rights in conspicuous places; and, **disclose to patients the referring physician's financial interest or ownership, if any, in the ASC facility.** ASCs will also have to provide patients (or their representatives) with verbal and written information about the ASC's policies on advanced directives, including a description of applicable State law and, if requested, official State advance directive forms. To facilitate patients' ability to report grievances, the proposed condition will require ASCs to establish clear procedures for documenting, submitting, investigating and disposing of a patient grievance.

- *Condition for Coverage – Infection Control.* Though there is already a requirement for infection control within the Physical Environment standard applicable to ASCs, CMS is proposing to establish a separate condition because, in CMS' view, "infection control is critically important to overall patient and staff health and safety."¹⁵ This proposed condition would make ASCs accountable for maintaining an infection control program to minimize infections and communicable diseases. The program must be directed by a qualified professional with training in infection control and be part of ASC's QAPI program.
- *Condition for Coverage – Patient Admission, Assessment, and Discharge.* CMS proposes to add a new condition that will require ASCs to develop specific assessments for each patient's medical needs. Toward this end, the ASC must ensure that each patient has a comprehensive medical history and physical assessment performed by a physician (or other qualified practitioner) within the 30 days immediately preceding the scheduled surgery. Upon admission, each patient must also have a pre-surgical assessment which assesses and documents the patient's physical and mental ability to undergo the surgery and whether the patient has any allergies. After surgery, the patient must undergo a thorough assessment of his or her condition. Prior to discharge, each patient must be provided with written discharge instructions and discharge order that has been signed by the physician (or other qualified practitioner) who performed the procedure. Finally, the ASC must ensure that the patient has a safe transition home and that the post-surgery needs will be met at home.

¹⁴ See Conditions for Coverage for Portable X-ray Services. 42 C.F.R. §§ 486.100 through 486.110

¹⁵ 72 Fed. Reg. 50476 (Aug. 31, 2007)

Definitions – Overnight Stay

Finally, CMS has also proposed to clarify the definition of "ambulatory surgical center" and to add a definition for "overnight stay." The ASC definition would change the current definition to read:

- *Ambulatory surgical center* or *ASC* means any distinct entity that operates exclusively for the purpose of providing surgical services to patients not requiring an overnight stay following the surgical services, has an agreement with CMS to participate in Medicare as an ASC, and meets the conditions set forth in subparts B and C of this part.

This underlined language previously read "not requiring hospitalization." In addition, CMS proposed defining "overnight stay" as follows:

- *Overnight stay* means the patient's recovery requires active monitoring by qualified medical personnel, regardless of whether it is provided in the ASC, beyond 11:59 p.m. of the day on which the surgical procedure was performed.

In explaining the definition, CMS reasoned that a "patient's location at midnight is a generally accepted standard for determining his or her status as a hospital inpatient or a skilled nursing facility patient and as such, it is reasonable to apply the same standard in the ASC setting."¹⁶ ASC industry organizations such as FASA have expressed concerns that these changes "apparently would prohibit Medicare-certified ASCs from performing any procedures – including procedures for non-Medicare patients – requiring active medical monitoring beyond midnight, even if such stays are permitted for non-Medicare patients in the state where the ASC is licensed."¹⁷

Guidance on ASC Form 855B Filings

In addition to all of the other changes with respect to Medicare rules for ASCs that have occurred within the past year, CMS issued Transmittal 233 on January 18, 2008 (effective February 20, 2008),¹⁸ which provides guidance for Form 855B filings by ASCs. The guidance touches both on special verification procedures for initial enrollment applications of ASCs and on the processing of change of ownership (CHOW) applications by ASCs.

Conclusion

The past year has seen significant regulatory developments regarding the way ASCs are paid by Medicare and the conditions that they must meet to remain entitled to Medicare payment. If you have any questions about the issues raised in this Health Law Update, please contact any of the attorneys in our Healthcare Industry Practice Area, listed below.

¹⁶ *Id.* at 50472.

¹⁷ See Sep. 14, 2007 letter from FASA to CMS. Available at www.fasa.org/docs/08ratecomments.pdf.

¹⁸ Pub. 100-08 – Medicare Program Integrity Manual; Transmittal 233 (January 18, 2008) To access the transmittal, visit <http://www.cms.hhs.gov/transmittals/downloads/R233PI.pdf>

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