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CMS issues hospital outpatient and ASC payment final rule for 2012

» Medicare's base reimbursement for all outpatient services paid under HOPPS increased by 1.9%, and Medicare's base reimbursement for all ASC services increased by 1.6%.

» An independent advisor review process has been established for considering requests that specific outpatient services be subject to a physician supervision level that may differ from current requirements.

» For hospital outpatients, individualized written notifications advising patients if a physician is not on-site 24/7 are required only for those patients receiving observation services, surgery, or any other procedure requiring anesthesia, rather than all outpatients (as previously required).

» Every hospital with a dedicated Emergency Department must post a patient notice in a conspicuous area of the Emergency Department if a doctor of medicine or osteopathy is not present at all times.

» A process has been established for certain physician-owned hospitals to apply for an exception to the rule that limits the number of operating rooms, procedure rooms, and hospital beds to the number licensed on March 23, 2010.

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On November 1, 2011 the Centers for Medicare & Medicaid Services (CMS) published a final rule containing the annual updates to payment rates and policies affecting hospital outpatient services and ambulatory surgery center (ASC) services for 2012.[1] Although 1,552 pages of the technical payment details in the advance copy of the final rule may seem overwhelming, the final rule contains significant policy changes along with general payment updates that will affect hospital and ASC compliance officers. This article provides an overview of these payment and policy developments, most of which became effective January 1, 2012.

Hospital outpatient payment updates

The final rule includes a number of changes and guidance with respect to reimbursement for outpatient hospital services. These include a general payment increase, guidance on categorization of hospital outpatient visits, reimbursement changes for cancer hospitals, outlier payment thresholds, "inpatient only" list revisions, and drug and device reimbursement updates.

Payment increase for outpatient services

Since 2000, Medicare has paid for outpatient services under the Hospital Outpatient Prospective Payment System (HOPPS). The final rule increases Medicare's base reimbursement for all outpatient services paid under HOPPS by 1.9%. The rate would have increased by 3% to reflect the Consumer Price Index inflation increase, but that is partially offset by a 1.1% reduction mandated by the Patient Protection and Affordable Care Act of 2010 (PPACA).[2]

HOPPS payment for hospital outpatient visits

CMS will continue to pay for several different types of hospital outpatient visit services, including: (1) new and established patient clinic visits; (2) Type A Emergency Department visits; (3) Type B Emergency Department visits; (4) critical care; and (5) trauma team activation.[3] CMS notes that it has seen an upward trend in the number of Type A Emergency Room visits, but is continuing to permit hospitals to follow their internal guidelines for determining the level of visit service.

Despite widespread requests to the contrary, CMS will continue to distinguish between new and established clinic visits on the basis of whether the patient had been registered during the prior three-year period as an inpatient or outpatient of the hospital.

Critical care payments will continue to include the packaging of certain ancillary services, including chest x-rays, blood gases, nasogastric tube placement, ventilator management, and other ancillary services. These ancillary services may be separately payable if billed without critical care.

Other reimbursement changes

The final rule includes reimbursement changes for cancer hospitals. PPACA required CMS to study whether cancer hospitals' costs associated with providing outpatient care exceed the cost of non-cancer hospitals' provision of outpatient care. After studying how the cancer centers' costs and payments compared to those for non-cancer hospital providers, CMS found that a payment fix was warranted. Commenters, however, warned that CMS's original proposal for the payment fix would have resulted in a potential financial impact on beneficiaries and on the payment that non-cancer hospitals would receive due to CMS's budget neutral implementation. The 2012 final rule increased total payments to cancer hospitals by 11.3% (or roughly $71 million), a greater increase than the 9% originally proposed. In order to avoid impacting beneficiary copayment liability, CMS is providing the cancer hospital payment adjustment as an aggregate payment to each cancer hospital at cost report settlement, instead of through enhanced Ambulatory Patient Classification (APC) payments, as originally proposed.

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HOPPS provides for outlier payments on a service-by-service basis. For 2012, the outlier threshold is met when the cost of furnishing a service or procedure by a hospital satisfies two conditions: (1) it exceeds 1.75 times the APC payment amount; and (2) it also exceeds the APC payment amount plus a $1,900 fixed-dollar threshold (which was reduced from a $2,025 fixed-dollar threshold for 2011). The outlier payment is calculated at 50% of the amount by which the cost of furnishing the service exceeds 1.75 times the APC payment rate.

Despite the requests of several commenters, CMS has declined to eliminate the "inpatient-only" list, or a list of procedures that are reimbursed only on an inpatient basis. CMS insists that the list remains a valuable tool for protecting patient safety and reducing potential burdens on beneficiaries (including increased co-payment liability) should many of the services currently found on the inpatient-only list be performed on an outpatient basis. CMS has, however, removed 10 procedures from the inpatient-only list, many upon the APC Advisory Panel's recommendations. The APC Panel consists of up to 15 members who are full-time employees of hospitals and other Medicare providers subject the HOPPS. The purpose of the APC Panel is to review the APC groups and their associated

weights and to advise the Secretary of the Department of Health and Human Services and the Administrator of CMS concerning the clinical integrity of those groups and weights.

CMS will continue to reduce the APC payment for device-dependent APCs when the hospital's vendor supplies a replacement device at no cost or for a reduced cost. The final rule includes only three device categories eligible for pass-through payment in 2012: (1) retrograde imaging/illumination colonoscope (which pass-through payment expires 12/31/12); (2) powdered bone marrow biopsy needle; and (3) telescopic intraocular lens.

Drugs without pass-through status will be paid under the final rule at the average sales price (ASP) plus 4%, with the exception of (1) certain diagnostic radiopharmaceuticals, contrast agents, and implantable biologicals; and (2) drugs with an average daily cost below the drug packaging threshold ($75 in 2012) that will not be paid separately. Drugs with pass-through status will be paid at ASP plus 6%.

Physician supervision requirements

In addition to the reimbursement changes, CMS has finalized two significant changes to the physician supervision requirements for outpatient therapeutic services performed in hospitals and critical access hospitals (CAHs).

First, CMS has finalized its proposed rule to establish an independent advisor review process for considering requests that specific outpatient services be subject to a supervision level that may differ from current requirements. Currently, there are only two levels of supervision for hospital outpatient therapeutic services: (1) general supervision, which is required after an initial period of direct supervision for the provision of nonsurgical extended duration therapeutic services; and (2) direct supervision, which is required in all other cases.

CMS will seek recommendations for changes to specific services from the APC Advisory Panel, to which two small, rural, prospectively-paid hospital members and two CAH members will be added to represent their interests. Based on the APC Panel's recommendations, the supervision level of each therapeutic service performed in a hospital outpatient setting may be heightened to personal supervision, relaxed to general supervision, or remain unchanged at direct supervision. Because the definitions of personal supervision and general supervision have yet to be defined for the hospital outpatient setting (except for general supervision in relation to extended duration services), CMS finalized its proposed definitions of personal supervision and general supervision to track those definitions originally established for purposes of the Medicare Physician Fee Schedule. Any changes to individual supervisions levels will be made through a sub-regulatory process with a 30-day public comment period. Importantly, these changes will not be listed in the Federal Register.

In response to concerns that Medicare's requirement of direct physician supervision for nearly all outpatient hospital therapeutic services could limit access for beneficiaries in rural areas, CMS agreed to continue through 2012 the non-enforcement of physician supervision rules for CAHs and for small and rural hospitals that have 100 or fewer beds.

Patient notification requirements

In the 2008 IPPS final rule and the 2009 IPPS final rule, CMS added new provisions to require that all hospitals and CAHs: (1) furnish all patients written notice at the beginning of their inpatient hospital stay or outpatient service if a doctor of medicine or osteopathy is not present in the hospital 24-hours a day, 7 days a week; and (2) in such notice, describe how the hospital or CAH will meet the medical needs of any patient who develops an emergency medical condition at a time when no doctor of medicine or osteopathy is present in the hospital or CAH. These

requirements were made applicable to both inpatient hospital stays and outpatient services because CMS argued that these provisions promoted the health and safety of all individuals who receive services in these institutions.

Further, in the 2011 OPPS final rule, CMS again stated that it saw no reason to treat the safety of hospital inpatients differently than hospital outpatients, and thus applied these patient safety requirements to hospital inpatients and outpatients. Hospitals argued that it was unduly burdensome to provide such disclosures to all outpatients, and that the individual notice requirement applicable to patients in the Emergency Department (ED) made the patient registration process more cumbersome and time-consuming than is desirable in the ED setting. Accordingly, CMS has revisited this issue in the 2012 final rule.

In the final rule, CMS has revised these prior regulations requiring hospitals to notify all outpatients if a doctor of medicine or osteopathy is not on-site 24-hours a day, 7 days a week. The rule still requires hospitals to provide such written notice to all inpatients. However, CMS states that it has reconsidered the patient safety requirements related to patient notification of physician presence, and it agrees that outpatients need to receive such disclosures only where the risk of an emergency or the length of the outpatient visit makes the situation more like that of hospital inpatients.

Therefore, for hospital outpatients, the final rule requires individualized written disclosures only for those patients receiving observation services, surgery, or any other procedure requiring anesthesia. For those outpatients who are presented with a disclosure notice, the hospital must, *prior to providing the outpatient service*, receive a signed acknowledgement that the patient understands that a doctor of medicine or osteopathy may not be present during all hours in which services are furnished. For an outpatient who is not expected to meet the criteria to receive a written notification, but whose condition later changes, a written notification will be required at the time of such change. The written notice must include a statement that the hospital does not have a doctor of medicine or a doctor of osteopathy present in the hospital 24-hours per day, 7 days a week, and must indicate how the hospital will meet the medical needs of any patient who develops an emergency medical condition at a time when there is no doctor of medicine or doctor of osteopathy present in the hospital.

In the final rule, CMS has also adopted the requirement that every hospital with a dedicated ED must post a patient notice in a conspicuous area of the ED likely to be noticed by all individuals entering the dedicated ED, if a doctor of medicine or osteopathy is not present at all times. In the event that there is a later decision to admit a patient from the ED as an inpatient, the final rule requires that the individualized written disclosure and acknowledgment to be made at the time the patient is admitted.

A hospital that is a main provider and that has one or more remote locations of the hospital or satellites is to make the determination of whether notice is required separately at each location.

Hospital Quality Reporting Program

Hospital Outpatient departments currently must report 23 quality measures to CMS or face a 2% reduction in their Medicare outpatient reimbursement update. The final rule adds three more measures, bringing the total to 26, that need to be reported in 2012 for purposes of the calendar year 2014 and 2015 payment determinations. The three new measures are:

- a chart abstracted measure on cardiac rehabilitation patient referral;
- a measure relating to the use of a safe surgery checklist; and
- a measure collecting Outpatient department volume for selected surgical procedures.

Electronic submission of clinical quality measures

CMS continues to express desire to move from chart-abstracted clinical quality measures (CQMs) to electronic health record (EHR)–based data submission for the reporting of quality measures. This will affect the EHR incentive program for eligible hospitals and CAHs. CMS expects to require such a transition for the Inpatient Quality Reporting Program prior to requiring the transition for the Outpatient Quality Reporting Program. In the final rule, CMS finalizes its proposal to permit eligible hospitals and CAHs that participate in the EHR Incentive Program to meet the CQM reporting requirement by participating in the 2012 Medicare EHR Incentive Program Electronic Reporting Pilot.

Additional Value-Based Purchasing program policies

PPACA required CMS to establish a hospital *inpatient* Value Based Purchasing program (VBP) to more closely align Medicare reimbursement to quality and outcomes. Under the VBP, CMS will distribute an estimated $850 million to Medicare participating hospitals, based on their overall performance on a set of quality measures that have been linked to improved clinical processes of care and patient satisfaction. The VBP was established in May 2011, but this final rule includes some modifications to the VBP, including the addition of a clinical process measure to guard against infections caused by urinary catheters. The final rule also modifies CMS' scoring/weighting system. CMS will calculate 2014 incentive payments to hospitals based on three areas:

- clinical processes of care (which will account for 45% of the hospital's score);
- patient experiences (30%); and
- patient outcomes (25%).

Stark whole hospital and rural provider exceptions

The federal physician self-referral prohibition (or Stark Law) generally prohibits physicians from making referrals for certain Medicare designated health services to entities with which they or their immediate family members have a financial relationship, unless an exception applies. Two of the Stark Law exceptions (the "whole hospital" and "rural provider" exceptions) were narrowed under PPACA, in part by limiting the ability of physician-owned hospitals to increase the number of operating rooms, procedure rooms, and hospital beds beyond that for which the hospital was licensed on March 23, 2010. (If a hospital did not have a provider agreement in effect as of March 23, 2010, but did have such agreement in effect on December 31, 2010, the measuring date is the effective date of the provider agreement.)

The final rule provides a process for certain physician-owned hospitals to apply for an exception, thereby permitting them to expand their capacity. In order to qualify for such an exception, a hospital must meet various criteria related to population growth in the surrounding area, number of Medicaid admissions, average bed occupancy, and other factors. Any permitted expansion cannot result in the number of operating rooms, procedure rooms, and beds for which the hospital is licensed exceeding 200% of the hospital's baseline numbers. A hospital can apply for an exception only once every two years, and public input is permitted.

Ambulatory surgery center payment updates

Approximately 5,000 Medicare-participating ASCs are in operation in the United States. Since 2008, Medicare has paid ASCs under a system based on hospital outpatient rates that are adjusted downward to account for lower costs associated with ASC procedures. The

2012 final rule increases Medicare's base reimbursement for all ASC services by 1.6%. The rate would have increased by 2.7% to reflect the Consumer Price Index inflation increase, but is partially offset by a 1.1% reduction mandated by PPACA.

ASC Quality Reporting

The final rule creates a quality reporting program for ASCs. Any ASC that does not submit certain quality data to CMS will begin incurring a reduction in Medicare reimbursement. There will initially be five quality measures, all of which need to be reported by each ASC beginning in October 2012, or else the ASC will face a 2% reduction in Medicare reimbursement in 2014. These five measures include:

- Patient burns
- Patient falls
- Hospital transfer/admission
- Prophylactic IV antibiotic timing
- Wrong site/wrong patient/wrong procedure/wrong implant incidents

Two additional measures (safe surgical checklist use and facility volume data on certain procedures) must reported beginning in 2013 based on 2012 data. In 2014, an additional measure (influenza vaccination coverage among health care personnel) will be added.

ASC procedure codes and ancillary services

CMS received requests to add over 200 new procedures to the list of Medicare-payable services in an ASC setting, but the agency agreed to add just six:

- 37201 and 37202, both of which are for types of transcatheter therapy;
- 37207 and 37208, which involve transcatheter placement of intravascular stents;
- 59074, which is for fetal fluid drainage; and
- G0365, which involves vessel mapping of vessels for hemodialysis access.

The final rule also makes some additions and subtractions to the list of ASC procedures that are deemed "office-based." Office-based procedures can be performed at either an ASC or a physician office, so CMS has historically capped ASC payment for these procedures to avoid any incentive to move simple cases from physician offices to ASCs simply for reimbursement reasons. Procedures that are now permanently deemed "office based" under the final rule include facet joint injection codes 0213T—0218T, arterial and venous angioplasty codes 35475 and 35476, tongue lesion ablation code 41530, and labyrinthotomy code 69801.

CMS has also updated the list of covered ancillary services at ASCs. An ancillary service, such as imaging, is reimbursable in an ASC setting if it is integral to the performance of a covered surgical procedure and the reimbursement for that ancillary service is not already packaged into the payment for the procedure. The final rule updates the list of ASC covered ancillary services to reflect the payment status for the services under the HOPPS. Although separately payable (non-packaged) radiology services would normally be paid at the *lower* of the standard ASC rate or the Medicare physician fee schedule (MPFS) technical component rate, nuclear medicine services are always paid at the ASC rate, even if it is higher than the MPFS rate. For 2012, the same rule will apply to exams that use contrast material.

Although the rule is final, CMS accepted comments on certain aspects of the rule until January 3, 2012, and will respond to them in the 2013 rule.

1. 76 Fed Reg. 74122 (Nov. 30, 2011).
2. Pub. Law No. 111-148 (2010). PPACA was amended by the Health Care and Education Reconciliation Act of 2010. Pub. Law No. 111-152, 124 Stat. 1029 to 124 Stat. 1084 (2010).
3. For the definitions of type A and type B, see https://www.cms.gov/HospitalOutpatientPPS/downloads/OPPS_Q&A.pdf