Government Relations

GR News

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CMS Announces Final Rule Changes to Policies & Payments for Hospital Outpatient Services and Ambulatory Surgical Centers

Effective CY January 1, 2011

On November 2, 2010, the Centers for Medicare & Medicaid Services (CMS) posted an advance copy of the **FINAL rule** for Medicare payment for hospital outpatient and ambulatory surgical center (ASC) services in calendar year (CY) 2011. These final rules affect hospital outpatient and ASC payments for services paid under the Hospital Outpatient Prospective Payment System (HOPPS) and the ASC payment system. The final rules were published on November 24, 2010, in the *Federal Register*. The final rules include the -0.25% reduction as required by law under the Affordable Care Act (ACA). Certain hospitals that did not meet the quality-reporting requirements will be reduced by 2%.

**Background HOPPS:** The HOPPS payments cover facility resources including equipment, supplies, and hospital staff but do not pay for the services of physicians and non-physician practitioners who are paid separately under the Medicare Physician Fee Schedule (MPFS). All services under the HOPPS are technical and are classified into groups called ambulatory payment classifications (APCs). Services in each APC are grouped by clinically similar services that require the use of similar resources.

**Important nuclear medicine final CMS policies include:**

- **CMS continues to package** payments for ALL diagnostic (Dx) radiopharmaceuticals (RP) and contrast agents in with the major procedure payment, regardless of their per-day costs. CMS states that (1) the statutorily required OPPS drug packaging threshold has expired, giving CMS authority to set what CMS refers to as “policy packaged” services; (2) CMS believes that diagnostic radiopharmaceuticals and contrast agents function effectively as supplies that enable the provision of an independent service; and (3) section 1833(t)(14)(A)(iii) of the act requires that payment for specified covered outpatient drugs (SCODs) be set prospectively based on a measure of average hospital acquisition cost.

- **Transitional pass-through (new), drugs, biologicals, diagnostic (Dx) RPs and contrast agents** for 2011 include: one Dx RP continues pass-through status, HCPCS (Healthcare Common Procedure Coding System) Level II code *A9582 lobenguane, I-123, dx, per study dose, up to 15 millicuries,* and one contrast agent HCPCS Level II code *A9583 Injection, Gadofosveset trisodium, per ml.* CMS did not propose any changes to transitional pass-through policies for 2011.

- **CMS finalized the use of “FB” modifier policy when hospitals receive “free/full credit” RPs.** The Integrated Outpatient Code Editor includes edits that require a hospital to report a diagnostic radiopharmaceutical with a nuclear medicine scan in order to receive payment for the nuclear medicine scan. CMS notes that hospitals have asked how to bill for a nuclear
medicine scan when the hospital receives a diagnostic radiopharmaceutical free of charge or with full credit, in light of the RP edits. CMS observes that the two options currently available to hospitals are not satisfactory:

(1) the hospital does not bill for either the nuclear medicine scan or the diagnostic radiopharmaceutical in order to bypass the RP edits which results in the hospital not receiving HOPPS payment for the scan or the diagnostic RP; or

(2) the hospital could report the RP with the nuclear medicine scan and receive an APC payment that includes payment for the radiopharmaceutical, leading to inaccurate billing and incorrect payment, since the hospital should not receive HOPPS reimbursement for a free item.

To clarify this policy in CY 2011, CMS is instructing hospitals to report the “FB” modifier on the line with the procedure code for the nuclear medicine scan in which the no cost/full credit diagnostic radiopharmaceutical is used.

Modifier -FB is described as an “Item Provided Without Cost to Provider, Supplier or Practitioner, or Credit Received for Replacement Device (Examples include, but are not limited to: Covered Under Warranty, Replaced Due to Defect, Free Samples).” In those cases in which the diagnostic RP is furnished without cost or with full credit CMS is instructing the hospital to report a token charge of less than $1.01. When a hospital bills an -FB modifier with the nuclear medicine scan the payment amount for procedures would be reduced by the full “policy-packaged” offset amount (see above under transitional pass-through) appropriate for the diagnostic radiopharmaceutical.

- CMS will continue the policy for separately payable therapeutic (Tx) radiopharmaceuticals in 2011, setting the prospective payment rate utilizing voluntary manufacturer-submitted average sales price (ASP) information if available through the existing drug ASP process.

- Separately payable drugs and biologicals without pass-through status (including pharmacy overhead) are finalized to be paid at 105 percent of the ASP in place of the current rate of 104 percent of ASP and changed from the proposed 106 percent of ASP. Details of the methodology can be found on page 155 of the final rule as published in the Federal Register on November 24, 2010.

Some manufacturers urged CMS to recognize that radiopharmaceutical dosimetric doses for radioimmunotherapy regimes A9542 and A9544 are misclassified as diagnostic and should be unpackaged. CMS disagreed stating, “While these products are not used to diagnose disease, they are used to determine whether future therapeutic services would be beneficial to the patient and to determine how to proceed with therapy.” Therefore, CMS did not modify its 2010 policy for payment of A9542 or A9544 in CY 2011.

Further, on page 77, commenters suggested that CMS should unpack age the drug tositumomab and create a HCPCS J code separate from the currently packaged code G3001 Administration and supply of tositumomab, 450 mg. The commenters argued that tositumomab should be recognized as a drug and, therefore, paid as other drugs following the ASP methodology. CMS disagreed with the commenters’ assertion that tositumomab is a drug. CMS also stated that it is
not classified as a radiopharmaceutical. CMS believes it is a supply and offered no changes to G3001 in CY 2011.

- CMS finalized an increased drug threshold for drugs, biologicals, and Tx RPs that are paid separately. The 2010 threshold is $65, and CMS **finalized a $70 threshold** updated for inflation. Payments for drugs at or below the threshold will continue to be bundled into payments for their associated procedures.

  Of note, J2805 *Injection, Sincalide, 5 micrograms changed from status indicator packaged, “N” to separately paid “K”. This drug is often used in conjunction with hepatobiliary imaging and is over the $70-per-day cost threshold for separate payment in 2011.*

- **Myocardial perfusion PET technical rates to decrease by 22 percent for CY 2011.** Commenters objected to the proposed decrease in the payment rate for myocardial PET imaging. Several alternate suggestions for limiting major fluctuations were offered to CMS. CMS therefore examined the data for myocardial PET under APC 0307. CMS found that the charges were stable, that the cost-to-charge ratio (CCR) used to estimate cost from charges for these codes declined, and that the cost of HCPCS code A9555 (Rb82 rubidium), the radiopharmaceutical that is used in a myocardial PET scan, also declined. Specifically, the median CCR for 78492 declined from 0.2342 in the CY 2010 HCRIS (Healthcare Cost Report Information System) data to 0.1708 in the CY 2011 final rule claims data. Moreover, the estimated per-day cost of rubidium declined from $418.05 in the CY 2010 final rule claims data to $330.06 in the CY 2011 final rule claims data. For CY 2011 CMS believes APC 0307 estimated codes are accurate and will not adopt any of the commenters’ suggestions for alternate methodology for payment. CMS will review these finding with the APC panel members at the winter 2011 APC panel meeting.

- **CMS reassigned CPT code 78807 to APC 0414 Level II Tumor/Infection Imaging (instead of APC 0406 Level I Tumor/Infection Imaging) for CY 2011 because the median cost for CPT code 78807 is similar to the median cost for CPT codes 78805 and 78806, which also are assigned to this APC. Based on the CY 2011 OPPS final rule claims data, CPT code 78805 has a median cost of approximately $519, CPT code 78806 has a median cost of approximately $539, and CPT code 78807 has a final rule median cost of approximately $428.**

- **Supervision requirements clarified for hospital outpatient diagnostic services.** In this final rule with comment period, in the interest of clarity, CMS is adopting the same change in definition of direct supervision and immediate availability for outpatient diagnostic services as CMS adopted for outpatient therapeutic services with an exception for diagnostic services performed under arrangement in non-hospital locations, for which direct supervision will continue to mean physical presence in the office suite (“in the office suite and immediately available to furnish assistance and direction throughout the performance of the procedure”). For all other outpatient diagnostic services, direct supervision will now mean immediately available, without reference to any physical boundary.

- **Supervision requirements for hospital outpatient therapeutic services.** CMS is providing for a limited exception to its general policy, which is to require direct supervision for the duration of all outpatient therapeutic services in both hospitals and critical access hospitals (CAHs). CMS will require direct supervision for the initiation of a service followed by general supervision after the
initiation period for a limited set of “non-surgical extended duration services,” including observation services, effective January 1, 2011. CMS issued instructions to contractors to not enforce the direct supervision requirement in CAHs for CY 2010. CMS is extending through CY 2011 the notice of non-enforcement for CAHs and expanding it to include small rural hospitals with 100 or fewer beds.

CMS also is modifying the definition of direct supervision for all hospital outpatient services to require immediate availability without reference to the boundaries of a physical location. The agency will be establishing through future rulemaking an independent committee and a process to consider on an annual basis industry requests for supervision levels other than direct supervision for certain individual services and to make recommendations to the agency.

For the CY 2011 payment determination, CMS did not add any new Hospital Outpatient Quality Data Reporting Program (HOP QDRP) measures.

- CMS is adding four quality measures to the current list of 11 measures to be reported by hospital outpatient departments, bringing the total number of measures to 15 that are to be reported for purposes of the CY 2012 payment determination. These new measures include an structural health information technology (HIT) measure and three claims-based imaging efficiency measures.

- CMS is also adding eight new measures to the list for purposes of the CY 2013 payment determination (for a total of 23 measures). Of these new measures, one is a structural measure on the use of electronic health records and six are chart-abstracted measures of timeliness and appropriate care in the emergency department. CMS also plans to require the reporting of these 23 measures for the 2014 payment determination.


To view a chart for Medicare Hospital Outpatient Prospective Payment System HOPPS (APC), FINAL 2010 Compared to FINAL 2011 Rates, Nuclear Medicine Procedures, Radiopharmaceuticals, and Drugs, please click here or paste this link into your Web browser: [http://interactive.snm.org/docs/Final_HOPPS_2010_vs_2011_Nov-2-10_v3.pdf](http://interactive.snm.org/docs/Final_HOPPS_2010_vs_2011_Nov-2-10_v3.pdf)

For more information on the CY 2011 final rule with comment period for the OPPS and ASC payment system, please see the CMS website at:

OPPS: [http://www.cms.gov/HospitalOutpatientPPS/HORD/list.asp#TopOfPage](http://www.cms.gov/HospitalOutpatientPPS/HORD/list.asp#TopOfPage)

ASC payment system: [http://www.cms.gov/ASCPayment/ASCRN/list.asp#TopOfPage](http://www.cms.gov/ASCPayment/ASCRN/list.asp#TopOfPage)