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Highlights of the 2012 OPPS Final Rule

On Nov. 1, 2011, the Centers for Medicare & Medicaid Services (CMS) released the hospital outpatient prospective payment system (OPPS) final rule for 2012. In the final rule, payment rates for 2012 increase by 1.9 percent. Hospitals that do not meet the quality data reporting requirements will receive an update that is reduced by 2.0 percentage points. CMS projects that total Medicare payments to hospital outpatient departments (HOPDs) will be approximately $41.1 billion in 2012.

Here are key changes from the OPPS 2012 final rule that went into effect Jan. 1, 2012.

Separately payable drugs, biologicals, and radiopharmaceuticals. For 2012 the final rule sets a payment rate of Average Sales Price (ASP)+4 percent for separately payable drugs, biologicals, and radiopharmaceuticals without pass-through status. CMS used the same methodology and policies to establish payments for drugs, biologicals, and radiopharmaceuticals in 2012 as it used in 2011, with adjustment for inflation as well as a new adjustment to minimize "intra-rulemaking fluctuation."

CMS also finalized its proposal to include the claims data from hospitals participating in the 340B program in its calculation of the payment rate for separately payable drugs and biologicals. The agency continues to encourage hospitals to bill all drugs and biologicals with HCPCS codes, regardless of whether they are separately payable or packaged.

Pass-through status for drugs and biologicals. In 2012, 38 drugs and biologicals have pass-through status. These products will be reimbursed at ASP+6 percent. The pass-through status of 19 drugs and biologicals expired Dec. 31, 2011 (see page 15 for more).

Diagnostic and therapeutic radiopharmaceuticals with pass-through status. CMS will continue to provide payment for both diagnostic and therapeutic radiopharmaceuticals with pass-through status based on the ASP methodology, resulting in a payment rate of ASP+6 percent for 2012. If ASP data are not available, CMS will provide pass-through payment at Wholesale Acquisition Cost (WAC)+6 percent, equivalent to payment for pass-through drugs and biologicals without ASP information. If WAC information is also not available, CMS will provide payment for the pass-through radiopharmaceutical at 95 percent of its most recent Average Wholesale Price (AWP).

Packaged drugs, biologicals, and radiopharmaceuticals. CMS increased the packaging threshold for drugs and biologicals from $70 per day to $75 per day. CMS will continue to package payment for all contrast agents and diagnostic radiopharmaceuticals regardless of their per day costs. The agency will also continue to package payment for non-pass-through implantable biologicals that are surgically inserted or implanted (through a surgical incision or a natural orifice) into the body, considering them to be devices.

Separately payable therapeutic radiopharmaceuticals. CMS will continue to reimburse all non-pass-through, separately payable therapeutic radiopharmaceuticals under the payment level set for separately payable drugs and biologicals (ASP+4 percent) based on ASP information, if available, for a "patient ready" dose and updated on a quarterly basis for products for which manufacturers report ASP data.

Payment for drug administration services. For 2012, CMS continues to use the full set of CPT codes for reporting drug administration services.

Physician supervision. CMS proposed to create an independent advisory review process to consider stakeholder requests for assignment of supervision levels other than direct supervision for specific outpatient hospital therapeutic services. The agency finalized several major elements of this proposal, including:

- The existing APC Panel will serve as the independent review entity.
- CMS decisions based on the APC Panel recommendations will be issued through sub-regulatory guidance and posted on the OPPS website for public review and comment. These decisions would be effective either in July or January following the most recent APC Panel meeting.
- CMS will charge the APC Panel with recommending a supervision level (general, direct, or personal) to ensure an appropriate level of quality and safety for delivery of a given service, as defined by a HCPCS or CPT code.
- In recommending a supervision

level to CMS, the APC Panel will assess whether there is a significant likelihood that the supervisory practitioner would need to reassess the patient and modify treatment during or immediately following the therapeutic intervention, or provide guidance or advice to the individual who provides the service.

Highlights of the 2012 MPFS Final Rule

CMS issued the final 2012 Medicare Physician Fee Schedule (MPFS) on Nov. 1, 2011. With an effective date of Jan. 1, 2012, the final rule:

- Projects a 27.4 percent reduction to physician payment rates in 2012 under the sustainable growth rate (SGR) formula. The 2012 conversion factor is $24.6712.
- Implements the third year of a four-year transition to practice expense (PE) relative value units (RVUs) calculated using Physician Practice Information Survey (PPIS) survey data.
- Identifies and revises potentially misvalued services under the PFS.
- Implements a new process for identifying misvalued codes.
- Expands the imaging multiple procedure payment reduction (MPPR) policy to the professional component of advanced imaging services.
- Implements provisions affecting the Physician Quality Reporting System (PQRS), Electronic Prescribing (eRx) Incentive Program, and Electronic Health Records (EHR) Incentive Program.
- Begins implementation of a value-based payment modifier.

Table 4 on page 17 shows the cumulative effect on total Medicare payments to physicians involved in cancer care when all of the changes except the cut to the conversion factor take effect. ACCC members can review in-depth analyses of the final 2012 OPPS and MPFS rules, as well as listen to an audio summary by logging in to the Members-only section of ACCC's website at: *www.accc-cancer.org.*

President Obama Signs Executive Order on Drug Shortages

Oct. 31 President Obama signed an executive order that the administration hopes will help curb the growing number of critical shortages of vital medicines used to treat life-threatening illnesses, including cancer. The order directs the FDA to:

- Broaden reporting of potential shortages of prescription drugs
- Speed up regulatory reviews that can help prevent or respond to shortages
- Work with the Department of Justice, which examines whether potential shortages have led to illegal price gouging or stockpiling of life-saving medications.

The White House also announced administration support for bipartisan legislation (H.R. 2245 and S. 296) that would require manufacturers to notify the FDA of potential drug shortages.

ACCC continues to advocate on Capitol Hill to help resolve the oncology drug shortage crisis.