



## **2008 Medicare Final Rules Call for Cuts in Payments for Physician Services and Part B Drugs Administered in Hospital Outpatient Departments**

On November 1, 2007, the Centers for Medicare & Medicaid Services (CMS) released the display copy of the 2008 Medicare Physician Fee Schedule (MPFS) and Hospital Outpatient Prospective Payment System (HOPPS) final rules outlining the reimbursement changes for Medicare that will go into effect as of January 1, 2008.

To provide you with the most up-to-date information, AccessMED has summarized the key provisions included within the MPFS and HOPPS final rules below. If you and your organization are interested in receiving a product-specific analysis, please contact us at [Reimbursement.Highlights@AccessMED.com](mailto:Reimbursement.Highlights@AccessMED.com).

### **Part B Covered Drugs and Biologicals**

#### ***Drugs and Biologicals will Continue to be Paid at ASP+6% in the Physician-Office Setting BUT Payment will go Down to ASP+5% in the Hospital-Outpatient Department Setting***

According to the 2008 final rules, the Medicare payment for Part B covered drugs and biologicals furnished in the physician-office setting will remain at Average Sales Price plus six percent (ASP+6%). If furnished in the hospital outpatient department setting, payment for drugs and biologicals without pass-through status will be set at ASP+5%. CMS estimates the current average acquisition cost for hospitals to be approximately ASP+3%. As a result, CMS will pay ASP+5% to the hospital-outpatient department (HOPD) in CY 2008 and has indicated in the final rule that such payment will be moved to ASP+3% in 2009. Drugs and biologicals with pass-through status in the hospital-outpatient setting will continue to be paid at ASP+6%

#### ***No Further Clarification on Bundled Price Concessions***

In the 2007 MPFS proposed rule and final rule with comment period, CMS solicited and responded to comments regarding the issue of how to allocate price concessions across drugs that are sold under bundling arrangements for purposes of calculating the ASP but did not put in place a specific methodology for manufacturers to use, instead asking manufacturers to make reasonable assumptions in their calculations of ASP.

Partly in response to MedPAC's January recommendation that CMS act to provide greater consistency in ASP reporting as it relates to bundling arrangements, CMS proposed earlier this year that manufacturers must allocate the total value of all price concessions proportionately according to the dollar value of the units of each drug sold under a bundled arrangement. For bundled arrangements, where multiple drugs are discounted, the aggregate value of all the discounts would be proportionately allocated across all of the drugs sold under the bundled arrangement.

In the Final Rule issued last week, CMS did not finalize any specific treatment of bundled price concessions.

### ***CMS Clarifies Process & Timeline for Adding Compendia Sources***

As mandated by the statute, Medicare is required to provide coverage to off-label uses of drugs and biologicals in anti-cancer chemotherapeutic regimens. Currently, there are three compendia listed within §50.4.5 of the Medicare Benefit Policy Manual for CMS' consideration when determining coverage for off-label uses of anti-cancer products and they are:

- American Hospital Formulary Service Drug Information
- American Medical Association (AMA) Drug Evaluations
- United States Pharmacopoeia Drug Information (USP-DI)

As USP-DI has been succeeded by *DrugPoints*, it was anticipated that CMS would revise the list of recognized compendia for the use in 2008 and beyond. However, CMS has not released an updated list of recognized compendia within the 2008 MPFS final rule but instead introduced a new process for the request of such updates. Specifically, the following process has been finalized:

- Requests will be accepted for the revision of the list of accepted compendia from January 15 to February 15 of each year
- Requests will be published on the CMS website annually by no later than March 15 of each year for a 30-day public comment period
- The final decision will be made within 90 days after closure of the public comment period, or July 15.

The new process represents a shortened review time frame and it will be effective as of January 1, 2008.

### ***Reporting of Anemia Quality Indicators Required as of January 1, 2008***

CMS has finalized regulations relating to the Congressional mandate, that beginning January 1, 2008: "Each request for payment, or bill submitted, for a drug furnished to an individual for the treatment of anemia in connection with the treatment of cancer shall include (in a form and manner specified by the Secretary) information on the hemoglobin or hematocrit levels for the individual." In finalizing the regulations, CMS also broadened the requirement to include all claims for ESAs, not just those related to the treatment of cancer.

In response to commenters, CMS also clarified that either hemoglobin or hematocrit level may be submitted and that:

[CMS is] not determining in this regulation when a hematocrit or hemoglobin level should be drawn to inform a provider's decision to administer ESA therapy. The requirement is that "the most recent" hemoglobin or hematocrit level be reported on the claim. Thus, the provider should report the most recent level preceding the ESA administration. We recognize that in some instances the same hemoglobin or hematocrit value might be reported on more than one claim.

### ***No Significant Changes to the Competitive Acquisition Program (CAP)***

Earlier this year, CMS proposed a variety of modifications to the CAP program. Some of the most relevant CAP issues in the final rule relate to the transporting of CAP drugs; the use of e-prescribing in CAP; the updating of CAP prices and data reporting; and the financial burden of CAP participation for physicians. With regard to transporting CAP drugs, CMS expects to issue a proposal next year to allow the transportation of CAP drugs from one location to another in certain circumstances. The final rule also indicates that CMS will continue to track the development of the e-prescribing program in CAP to see whether it would be appropriate to incorporate some of the program's elements into the CAP at a later date. Additionally, CMS believes that the present processes for updating CAP prices and for data reporting are sufficient to address the needs of the Program. Nevertheless, as the Program grows, other options may be considered including more frequent price updates. Finally, the rule notes that CMS believes that

the drug administration payment is sufficient to cover any associated expenses of participating in the CAP.

## **Physician Services**

### ***Physician Services Payments Scheduled to Drop***

CMS announced within the 2008 MPFS final rule that the conversion factor for CY 2008 will be set at \$34.0682 which represents a negative 10.1 percent update to the 2007 conversion factor. Together with other adjustments made to the Relative Value Units (RVUs) that are used to compute Medicare physician services payment rates, the Medicare reimbursement for physician services including drug administration will likely be decreased in 2008. As in 2006 and 2007, such negative update to the conversion factor can be averted if Congress acts to prevent the cut via legislation.

### ***Physician Quality Reporting Initiative (PQRI) Expanded to the Full 2008 Calendar Year***

CMS finalized its July proposal to use the \$1.35 billion set aside for physician payment and quality improvement initiatives in the Physician Assistance and Quality Initiative Fund (PAQI), created by Tax Relief and Health Care Act of 2006 (TRHCA), to extend voluntary quality reporting bonus payments into 2008. In contrast to 2007, the proposal states that physicians could report applicable measures for a full year of services from January 1, 2008 through December 31, 2008, and allowed charges during such period would be the basis for calculating the bonus payments. CMS anticipates that the bonus payments will be approximately 1.5 percent of allowed charges for participating professionals (and does not expect that the ultimate percentage amount will exceed 2 percent). CMS also finalized a list of reportable quality measures for the 2008 program, including some structural measures which focus on whether a health care professional uses electronic health records and/or electronic prescribing. New measures will be available in the specifications document for 2008 measures, which will be available on the CMS PQRI website on or before December 31, 2007.

### ***IVIG Pre-Administration Services Payment Extended***

According to the MPFS final rule, the pre-administration services for IVIG furnished in the physician-office setting will continue to be paid in 2008 based on the practice expense RVUs established in 2007.

### ***Imaging Services Payment Calculation Unchanged***

The MPFS final rule maintains the assumptions of a 50 percent equipment utilization rate and an 11 percent equipment interest rate in the calculation of the practice expense RVUs. In the proposed rule, CMS declined to make specific proposals but rather requested comments on the equipment utilization and interest rate assumptions. Comments regarding the 11 percent interest rate were generally favorable, while those regarding the 50 percent utilization rate were varied. In response, CMS did not revise the assumptions but noted that the Agency will continue to examine the assumptions for accuracy.

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The 2008 MPFS and HOPPS final rules can be accessed on the CMS website at:

MPFS:

<http://www.cms.hhs.gov/center/physician.asp>

HOPPS final rule and related addenda:

<http://www.cms.hhs.gov/HospitalOutpatientPPS/HORD/itemdetail.asp?itemID=CMS1204971>

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