



September 2, 2008

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1404-P
P.O. Box 8013
Baltimore, MD 21244-1850

**Re: CMS-1404-P, Medicare Program: Proposed Changes to the Hospital Outpatient Prospective Payment System and CY 2009 Payment Rates; Proposed Changes to the Ambulatory Surgical Center Payment System and CY 2009 Payment Rates
Proposed Rule**

Dear Sir/Madam:

The American Society of Health-System Pharmacists (ASHP) is pleased to submit written comments pertaining to the Proposed Changes to the Hospital Outpatient Prospective Payment System and CY 2009 Payment Rates (proposed rule). For more than 60 years, ASHP has helped pharmacists who practice in hospitals and health systems improve medication use and enhance patient safety. The Society's 35,000 members include pharmacists and pharmacy technicians who practice in inpatient, outpatient, home-care, and long-term-care settings, as well as pharmacy students.

The following is an overview of ASHP's recommendations relating to the proposed rule. ASHP recommends that CMS:

- **Reimburse all separately paid drugs at the rates applicable in physicians' offices. Specifically, CMS should reimburse separately paid drugs at no less than Average Sales Price (ASP) plus six percent.**
- **Package payment for all drugs that are not separately paid at ASP plus six percent and use the difference between these rates and CMS's costs derived from charges to create a pool to fund payment for three levels of pharmacy service costs.**
- **Not implement its proposed changes to hospital cost reports for drugs.**

- **Make separate payment for all drugs with Healthcare Common Procedure coding system (HCPCS) codes or, at a minimum, not increase the packaging threshold for drugs.**
- **Make separate payment for all drugs with Healthcare Common Procedure Coding System (HCPCS) codes or, at a minimum, not increase the packaging threshold for drugs.**
- **Not lower payment for blood clotting factors.**
- **Include only those measures that have been endorsed by the National Quality Forum (NQF) when selecting quality measures.**
- **Not adopt its proposed sub-regulatory process that would allow the Agency to update the technical specifications used to calculate quality measures.**

Drugs, Biologicals, and Radiopharmaceuticals with Continuing Pass-Through Status

ASHP supports continuing pass-through status in CY 2009 for the 16 drugs and biologicals listed in Table 21, in particular the following injections: levetiracetam, temsirolimus, ixabepilone, dorpenem, and fosaprepitant.

OPPS: Payment for Specified Covered Outpatient Drugs

At a previous meeting of the Advisory Panel on Ambulatory Payment Classification Groups (the Panel), ASHP, along with other stakeholders, asked the Panel to recommend that CMS reimburse all separately-payable drugs at no less than ASP plus six percent. The Panel agreed, and recommended that CMS continue to reimburse for separately payable drugs at a rate of ASP plus six percent for 2008. However, CMS refused to follow the Panel's recommendation, and effective January 1, 2008, reduced payments to ASP plus 5%.

CMS is now proposing to pay for the combined average acquisition and pharmacy overhead cost of separately payable drugs and biologicals at ASP plus four percent under the proposed rule. This proposal is in addition to the change in ASP calculation that occurred midway through the previous calendar year, whereby statutorily mandated alternative volume weighting is now used to compute the ASP for payment of Part B multiple source and single source drugs furnished after April 1, 2008, and for payment of single source drugs or biologicals treated as a multiple source drug.

Reimbursement of separately-payable drugs at ASP plus four percent is insufficient to cover pharmacy costs, in particular the costs of managing medications. In fact, the Medicare Payment Advisory Commission's (MedPAC) June 2005 Report to the Congress found that costs relating to pharmacy services overhead are significant, ranging from 26% to 28% of pharmacy departments' direct costs, with the rest of the costs attributed to the acquisition cost of drugs. Hospitals and health systems and their pharmacy departments bear the burden of the lower reimbursement rate, while providing necessary patient care, knowing that current reimbursement does not cover the costs incurred. Additionally, the current CMS methodology does not comply with the statutory requirement to reimburse drugs at the average acquisition cost for the drug for the year.

The July 2008 RTI International report referenced in the proposed rule further underscores the flaws in CMS's methodology, finding that CMS substantially underestimates the actual costs of acquiring and supplying separately paid drugs. When RTI's recommended adjustments are applied to CMS's calculations, the estimated mean unit cost of separately paid drugs is ASP plus 20 percent.

- **ASHP strongly recommends that CMS reimburse all separately paid drugs at the rates applicable in physicians' offices. Specifically, CMS should reimburse separately paid drugs at no less than ASP plus six percent.**

At the March, 2008 Panel meeting, ASHP, along with other stakeholders, presented a proposal to establish more appropriate payments for drugs and services. Under the proposal, CMS would continue to package payment for drugs that have a cost per day of less than \$60. However, CMS would package payment for the drug at ASP plus six percent instead of its costs derived from charges, which would ensure that OPPS rates for all drugs more accurately reflect hospitals' acquisition costs. CMS would then use the difference between payment for all drugs at ASP plus six percent and the estimated costs under the current methodology to create a pool to fund payments for pharmacy services.

As noted by CMS in the 2009 OPPS proposed rule, because CMS would redistribute pharmacy overhead cost when modeling payment rates for rate setting, the suggested methodology would be administratively simple for hospitals. This approach also would refine the existing OPPS methodology for estimating pharmacy overhead cost in a budget neutral manner, without redistributing money from the payment for nondrug components of other services to payment for drugs.

- **ASHP strongly recommends that CMS package payment for all drugs that are not separately paid at ASP plus six percent and use the difference between these rates and CMS's costs derived from charges to create a pool to fund payment for three levels of pharmacy service costs.**
- **ASHP also strongly recommends that CMS not implement its proposed changes to Medicare cost reports for drugs charged to patients by breaking**

the single standard cost center 5600 into two standard cost centers, Drugs with High Overhead Cost Charged to Patients and Drugs with Low Overhead Cost Charged to Patients.

The proposed rule would also require hospitals to use HCPCS codes for all drugs in the inpatient setting. These requirements would pose a substantial administrative burden to hospitals and will likely take at least two years to produce data for rate setting purposes.

- **ASHP recommends that CMS make separate payment for all drugs with HCPCS codes or, at a minimum, not increase the packaging threshold for drugs.**

Proposed Payment For Blood Clotting Factors

For CY 2008, CMS is providing payment for blood clotting factors under the proposed rule at ASP plus 5%, plus an additional payment for the furnishing fee that is also a part of the payment for blood clotting factors furnished in physicians' offices under Medicare Part B. CMS is now proposing to pay for blood clotting factors at ASP plus 4% and continue its policy for payment of the furnishing fee using an updated amount for CY 2009.

- **ASHP strongly recommends that CMS not lower payment for blood clotting factors.**

CMS is not able to include the actual updated furnishing fee in this proposed rule, so it is unclear whether the 1% decrease in payment proposed by CMS will be covered by the furnishing fee. Calculation of the fee is based on Consumer Price Index historical data that may or may not reflect current market conditions. If the fee drops based on historical data, hospitals may lose money when they supply the product.

Proposed Coding and Payment for Drug Administration Services

CMS presented a potential four-level drug administration APC structure to the APC Panel during the March 2008 meeting. The APC Panel recommended that CMS not implement the four-level configuration until more data becomes available. ASHP is pleased that CMS accepted the Panel's recommendation and instead is proposing a five-level drug administration APC structure. However, ASHP is concerned that CMS may not have adequate data to reconfigure the drug administration APCs to a five-level structure, and encourages CMS to ensure it has adequate data before making these APC changes.

Reporting Quality Data for Annual Payment Rate Updates

The Tax Relief and Health Care Act of 2006 (TRHCA) requires hospitals to report data for selected quality measures or incur a reduction in their annual payment update factor of 2.0 percentage points. TRHCA also requires CMS to establish a program under which hospitals report the data on the quality of hospital outpatient care using standardized measures of care, effective for payments beginning in CY 2009.

ASHP is pleased to see that, when developing measures appropriate for the measurement of the quality of care provided in hospital outpatient settings, CMS is considering whether the measures can be “harmonized” with measures that can be or are already adopted in the context of comparable inpatient and ambulatory care. The Society commends CMS’s intent to harmonize measures that assess the care that is given across settings and providers.

- **However, ASHP strongly recommends that CMS include only those measures that have been endorsed by National Quality Forum (NQF) when selecting quality measures.**

Hospital and health-system pharmacists play a vital role in helping organizations achieve medication-related measures. ASHP believes that health care quality improvement programs should adopt standard quality measures that are developed with the involvement of pharmacists, are evidence-based, and promote the demonstrated role of pharmacists in improving patient outcomes.

- **Furthermore, ASHP recommends that CMS not adopt its proposed sub-regulatory process that would allow the Agency to update the technical specifications used to calculate the measures.**

All changes to existing measures should allow for public comment and should be made through the regulatory process.

ASHP appreciates this opportunity to present its written comments on the proposed rule. Feel free to contact me if you have any questions regarding our comments. I can be reached by telephone at 301-664-8702, or by e-mail at jcoffey@ashp.org.

Sincerely,



Justine Coffey, JD, LLM