



August 28, 2009

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1414-P
P.O. Box 8013
Baltimore, MD 21244-1850

Re: CMS-1414-P, Medicare Program: Proposed Changes to the Hospital Outpatient Prospective Payment System and CY 2010 Payment Rates; Proposed Changes to the Ambulatory Surgical Center Payment System and CY 2010 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 2010 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. Pharmacists in hospitals and health systems are experts in medication use who serve on interdisciplinary patient-care teams. They work with physicians, nurses, and other health-care professionals to ensure that medicines are used safely and effectively.

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

- **ASHP strongly recommends that CMS reimburse 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).**
- **ASHP strongly recommends that a larger percentage of the estimated \$395 million total in pharmacy overhead cost included in the claims data for packaged drugs and biologicals above the aggregate ASP dollars of these packaged products should be attributed to separately payable drugs and biologicals to provide an adjustment for pharmacy overhead costs of these separately payable products.**

- **ASHP recommends that CMS should exclude data from hospitals that participate in the 340B program from its rate-setting calculations for drugs, while continuing to reimburse all hospitals at the same rate, since the intent of the program is for the 340B savings to remain with the hospital, allowing the hospital to better serve indigent patients.**
- **ASHP strongly recommends that CMS allow pharmacists to provide direct supervision for hospital outpatient therapeutic services they may perform themselves under state law and within their scope of practice.**
- **As a member of the National Quality Forum (NQF), ASHP strongly recommends that CMS include only those measures that have been endorsed through the rigorous consensus-building process of NQF.**

Payment for Specified Covered Outpatient Drugs

ASHP continues to be concerned about pharmacy reimbursement rates under the Hospital Outpatient Prospective Payment System (HOPPS). In 2008, CMS lowered reimbursement rates for drugs without pass-through status administered in hospital outpatient departments to average sales price (ASP) plus five percent, and in 2009, CMS lowered reimbursement rates even further, to ASP plus four percent.

ASHP was pleased to see that CMS's HOPPS proposed rule for CY 2010 did not further lower reimbursement rates, and instead maintained the rates at ASP plus four percent for CY 2010. However, reimbursement of separately-payable drugs at ASP plus four percent is insufficient to support core pharmacy services, in particular the costs of ensuring safe medication use, including ensuring patients receive the correct dosage of a medication, screening for drug interactions and contraindications, and verifying the appropriateness of a drug therapy. Additionally, there are significant inventory carrying costs, and United States Pharmacopeia Chapter 797 and Occupational Safety and Health Administration requirements, with increased preparation time and additional disposable equipment used to prepare drugs, increasing the costs associated with separately payable drugs. Finally, with the lower reimbursement rates that resulted from the transition from Average Wholesale Price to ASP in 2005, ASHP's members are reporting that physician offices seem to be less able to support the costs associated with the administration of these drugs, resulting in increased patient referrals to outpatient hospital clinics.

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 is insufficient 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, since CMS does not have survey data on hospital acquisition cost required by the Social Security Act (section 1833(t)(14)(A)).

The July 2008 RTI International report further underscored 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 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.**

In response to CMS proposals for the CY 2008 and CY 2009 OPPS, ASHP, along with other stakeholders, presented proposals to CMS to establish more appropriate payments for drugs and services. At the Advisory Panel on Ambulatory Payment Classification Groups' (APC) meeting in February, 2009, ASHP, along with the other stakeholders, reiterated its request for more appropriate payments, and presented its proposal that CMS package payment for all drugs that are not separately paid at ASP plus 6 percent, and use the difference between these rates and CMS's costs derived from charges to create a pool that is used to fund payment for pharmacy service costs more appropriately. CMS would then reimburse hospitals for pharmacy service costs using this pool by making payment based on three tiers of complexity.

ASHP is pleased that CMS is not proposing to further lower reimbursement rates for separately payable drugs and biologicals. The Society is also pleased that CMS is proposing to take a percentage of the estimated \$395 million total in pharmacy overhead cost included in CMS's claims data for packaged drugs and biologicals above the aggregate ASP dollars, and redistribute the money to separately payable drugs and biologicals to provide an adjustment for the pharmacy overhead costs of the separately payable products.

- **ASHP strongly recommends that a larger percentage of the estimated \$395 million total in pharmacy overhead cost included in the claims data for packaged drugs and biologicals above the aggregate ASP dollars of these packaged products should be attributed to separately payable drugs and biologicals to provide an adjustment for pharmacy overhead costs of these separately payable products.**

Furthermore, because CMS includes 340B hospitals in its analysis when determining the payment rate, CMS underestimates the aggregate costs of drugs for many hospitals. Sales under the 340B program are excluded from the ASP calculation, and should also be excluded from the calculation of drug reimbursement rates under the OPPS.

- **ASHP recommends that CMS should exclude data from hospitals that participate in the 340B program from its rate-setting calculations for drugs, while continuing to reimburse all hospitals at the same rate, since the intent of the program is for the 340B savings to remain with the hospital, allowing the hospital to better serve indigent patients.**

Physician Supervision

ASHP commends CMS for proposing that nonphysician practitioners, specifically clinical psychologists, nurse practitioners, physician assistants, clinical nurse specialists, or certified nurse-midwives, may provide direct supervision for hospital outpatient therapeutic services that they may perform themselves under State law and within their scope of practice and hospital-granted privileges. However, the Society strongly recommends that pharmacists be included as well, since pharmacists often provide hospital-based outpatient therapeutic services. This is particularly true when patients are receiving medication therapy in the hospital outpatient setting. Pharmacists receive six years of training before earning their Pharm.D. degree, and often complete a residency in a specialized area. Pharmacists meet the primary care needs of patients by providing medication management and, in states where it is authorized, collaborative drug therapy management. Pharmacists should be treated the same as other nonphysician practitioners, and should be able to provide direct supervision.

- **ASHP strongly recommends that CMS allow pharmacists to provide direct supervision for hospital outpatient therapeutic services they may perform themselves under state law and within their scope of practice.**

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 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 other CMS quality programs to align incentives and promote coordinated efforts to improve quality. The Society commends CMS’s intent to harmonize measures that assess the care that is given across settings and providers.

- **However, as a member of NQF, ASHP strongly recommends that CMS include only those measures that have been endorsed through the rigorous consensus-building process of NQF.**

ASHP is pleased that CMS prefers to adopt NQF-endorsed measures for CMS quality reporting programs. However, ASHP disagrees with the Agency that consensus among affected parties can also be reflected through consensus achieved during the measure development process, broad acceptance and use of a measure, or through public comment, which do not incorporate the robust and comprehensive process used to establish NQF endorsement. Additionally, under Office of Management and Budget Circular No. A-119, Revised, all federal agencies must use voluntary consensus standards in lieu of government-unique standards in their procurement and regulatory activities, except where inconsistent with law or otherwise impractical.

Hospital and health-system pharmacists play a vital role in helping organizations achieve medication-related quality 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.

Retirement of Hospital Outpatient Quality Data Reporting Program (HOP QDRP) Quality Measures

ASHP applauds the proposal to promptly retire a measure if CMS receives evidence that the continued collection of a measure that has been adopted for the HOP QDRP raises patient safety concerns. The Society further encourages CMS to establish consistent and transparent processes that address changes in evidence-based guidelines more quickly (i.e., consideration should begin before measure developers seek discontinuation). CMS should establish channels to exchange this type of information between the agency and measure developers.

Additionally, ASHP recommends that measures should be retired when an indicator is developed that more accurately assesses good quality care. Due to rapid changes in technology and research and the development of health care quality measures, it is important to use the most up-to-date measurement tools available. Since these measures are publicly reported, it is also important to limit the number of reported measures for a specific process of care in order to reduce confusion among patients, payers, and providers.

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
Director, Federal Regulatory Affairs