7272 Wisconsin Avenue
Bethesda, Maryland 20814
301-(657)-3000
Fax-(301)-664-8877
www.ashp.org

December 22, 2008

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

Re: CMS-1404-FC, Medicare Program: Changes to the Hospital Outpatient Prospective Payment System and CY 2009 Payment Rates, Final Rule with Comment Period

Dear Sir/Madam:

The American Society of Health-System Pharmacists (ASHP) is pleased to submit written comments pertaining to Changes to the Hospital Outpatient Prospective Payment System and CY 2009 Payment Rates, Final Rule with Comment Period (final 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.

In its final rule, the Centers for Medicare & Medicaid Services (CMS) is requesting additional comments related to the 340B Drug Pricing Program and its impact on the CMS methodology for calculating payment rates for separately payable drugs. More specifically, CMS is looking at whether the agency should use the equitable adjustment authority in section 1833(t)(2)(E) of the Social Security Act to adjust Outpatient Prospective Payments System (OPPS) payments to hospitals for separately payable drugs based on hospitals' participation in the 340B program, so that drug payment for the two classes of hospitals (340B participating and 340B nonparticipating) would reflect the average drug acquisition and pharmacy overhead costs specific to each class of hospital.

ASHP appreciates the fact that CMS recognizes the need to explore issues relating to payment accuracy, as well as issues surrounding hospital allocation of pharmacy overhead costs to drug charges and differential hospital drug costs based on hospital participation in the 340B program. However, ASHP is extremely concerned by CMS's apparent willingness to consider developing two separate payments, one for 340B

participating hospitals, and the other for those hospitals that do not participate in the 340B program.

340B Drug Pricing Program

Public Law 102-585, the Veterans Health Care Act of 1992, codified Section 340B of the Public Health Service Act. Section 340B allows certain disproportionate share hospitals to purchase outpatient drugs at reduced prices.

For a hospital to participate in the 340B program, certain requirements must be met. In particular, the hospital must have a disproportionate share adjustment percentage greater than 11.75 percent, as determined under Section 1886(d)(5)(F) of the Social Security Act. To meet this requirement, hospitals that participate in the 340B program must serve a unique population of largely indigent and uninsured patients. The 340B program is intended to allow these safety net hospitals that serve these patients to save on their drug costs by purchasing drugs at a lower price, and the intent of the program is to allow the savings to remain with the hospital, not to be passed on to public or private payers. The Congressional intent behind the 340B statute was to allow covered entities to use the discounts to "stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services."[1]

Impact on Safety Net Hospitals

Studies show that public hospitals provide a disproportionate amount of uncompensated care. According to a June 2007 study funded by the National Association of Public Hospitals and Health Systems (NAPH),[2] for the acute care safety net hospitals that participated in the survey, 20% of their annual expenses resulted from uncompensated care costs, as opposed to other U.S. hospitals, where 5% of costs resulted from uncompensated care. Additionally, according to the NAPH Hospital Characteristics Survey for FY 2006, while 2% of acute care hospitals in the United States are NAPH hospitals, they provide 21% of the uncompensated hospital care in the United States.

The discounts safety net hospitals receive through the 340B program are one way these public hospitals are able to offset uncompensated care costs. However, if CMS develops two separate payments under OPPS, one for 340B participating hospitals and the other for non-340B hospitals, CMS will essentially be allocating the savings from the 340B program to the Medicare program, rather than to the safety net hospitals providing uncompensated care. Such a reallocation of 340B savings was not the intent of the 340B program. These savings should remain with the covered entity.

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[1] H.R.Rep. 102-384,102d Cong., pt. 2, at 12 (2d Sess. 1992).
[2] *Health Care Safety Net Providers Face Significant Challenges* , Obaid Zaman, M.P.P., Sari Siegel, Ph.D., Linda Cummings, Ph.D.

Accuracy of OPPS Payment

ASHP agrees with CMS that the accuracy of OPPS payments to all hospitals for the acquisition and pharmacy overhead costs of separately payable drugs should be addressed. Reimbursement of separately-payable drugs at Average Sales Price (ASP) plus four percent is insufficient to cover pharmacy costs, in particular the costs of managing medications, including ensuring patients receive the correct dosage of a medication, determining drug interactions and contraindications, and verifying the appropriateness of a drug therapy. 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. If CMS lowers reimbursements to ASP plus two percent, according to the proposed methodology, hospitals and health systems will bear an even larger burden.

Because CMS includes 340B hospitals in its analysis when determining the payment rate, CMS underestimates the aggregate costs of drugs for many hospitals, and the drug reimbursement rate under OPPS is too low. 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.

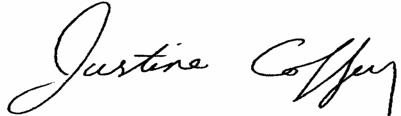
- **ASHP strongly recommends that CMS exclude 340B- qualified sites' drug acquisition data from the calculation of drug reimbursement rates under OPPS, and reimburse all separately paid drugs at no less than ASP plus six percent.**

However, as noted previously, if CMS develops two separate payments, one for 340B participating hospitals and the other for those hospitals that do not participate in the 340B program, CMS will essentially be allocating the savings from the 340B program to the Medicare program, rather than to those safety net hospitals that provide the uncompensated care. Such a reallocation of 340B savings was not the intent of the 340B program, and these savings should remain with the covered entity.

- **ASHP strongly recommends that CMS not use the equitable adjustment authority in section 1833(t)(2)(E) of the Social Security Act to adjust OPPS payments to hospitals for separately payable drugs based on hospitals' participation in the 340B program, so that drug payment for the two classes of hospitals (340B and non-340B) would reflect the average drug acquisition and pharmacy overhead costs specific to each class of hospital. Instead, payments to both 340B and non-340B hospitals should be made at equivalent rates.**

ASHP appreciates this opportunity to present its written comments on the final 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