



August 31, 2015

Andrew M. Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1633-P
P.O. Box 8013
Baltimore, MD 21244-1850

VIA ELECTRONIC SUBMISSION:

Re: CMS-1633-P; Medicare and Medicaid Programs: Hospital Outpatient Prospective and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Proposed Rule

Dear Mr. Slavitt:

ASHP is pleased to submit comments on the changes to the Hospital Outpatient Prospective Payment System (OPPS) and CY 2016 Payment Rates (proposed rule) as published in the July 8, 2015 Federal Register.¹ ASHP represents pharmacists who serve as patient care providers in acute and ambulatory settings. The organization's more than 40,000 members include pharmacists, student pharmacists and pharmacy technicians. For over 70 years, ASHP has been on the forefront of efforts to improve medication use and enhance patient safety.

We have organized our comments by section of the proposed rule.

V. Proposed OPPS Payment Changes for Drugs, Biologicals, and Radiopharmaceuticals

ASHP is pleased that the Centers for Medicare & Medicaid Services (CMS) has proposed that for CY 2015 the payment rate for separately covered outpatient drugs (SCODs) and biologicals will remain at Average Sales Price (ASP) plus six percent.

We have long supported reimbursement that is adequate 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. We supported CMS's decision to reimburse for separately payable drugs and biologicals at ASP plus six percent in the 2013 through 2015 Final Rules and urge the Agency to finalize the Proposed Rule to reimburse for separately paid drugs at no less than ASP plus six percent in 2016.

¹ Federal Register Vol. 80, No. 130 pages 39200 – 39375

XV. Short Inpatient Hospital Stays

In the FY 2014 inpatient prospective payment system (IIPS) Final Rule, CMS implemented a “two-midnight” policy under which the agency considers any hospital admission spanning at least two midnights appropriate for inclusion under the IPPS. In general, unless the procedure appears on an inpatient only list, hospital stays less than two midnights are considered appropriate for payment under the OPSS only. This was a marked departure from the historical practice of physician judgement as the primary determination for hospital admission.

In the proposed rule, CMS proposes guidelines for circumstances under which the clinical judgement of an admitting physician and the medical record would support an inpatient admission of less than two midnights. ASHP is pleased that CMS is recognizing the importance of clinical judgment and patient need to allow for exceptions to the time-based two midnight rule. Pharmacists in hospitals and health systems are not always aware of when a patient is considered an inpatient versus outpatient and conversion between these two statuses often creates challenges within the hospital pharmacy. A clinical-based exceptions policy may mitigate some of these challenges when a patient’s admission to a hospital for less than 2 midnights is appropriate.

While the agency puts forth three general criteria to be met, we believe that a more detailed discussion by the agency is necessary as these admissions will be reviewed for appropriateness by CMS contractors. Further, we believe that incorporating Quality Improvement Organizations (QIOs) as the first line of review in these instances, instead of Recovery Audit Contractors (RACs) or Medicare Administrative Contractors (MACs) is an appropriate proposal and we recommend that CMS finalize this change in the final rule. However, we note an inconsistency in the language of the proposed rule. CMS announces an extension in the partial enforcement delay of the two midnight rule through December 31, 2015. However, the agency then states that QIOs shall begin patient status claims no later than October 1, 2015. ASHP recommends that CMS make the date that these reviews are effective consistent with any extension in partial enforcement delay. The agency should also consider whether or not a December 31, 2015 date is appropriate given the timing of the final rule or whether a delay should extend into CY 2016.

XIII. Hospital Outpatient Quality Reporting Program Updates

ASHP is an inaugural member of the National Quality Forum (NQF) Measures Application Partnership (MAP) and is heavily engaged in NQF activities. As a member of NQF ASHP strongly recommends that, with rare exceptions, CMS include only those measures that have been endorsed through the rigorous NQF consensus- development process. NQF endorsement ensures that the great breadth of stakeholders involved in developing, testing, implementing, and using measures provides valuable feedback in maintaining and validating quality measures used in federal payment programs.

ASHP applauds the planned inclusion OP-34 NQF#291 *Emergency Department Transfer Communication* (EDTC) for CY 2019. This measure focuses on ensuring accurate and timely information during transitions of care from acute care to ambulatory care settings. Inclusion of this measure in the program will assure the documentation of up-to-date patient information that is necessary for the care plan. ASHP believes this measure will help focus efforts on strategies to increase patient safety and reducing the burden of validating clinical information. Educating patients and caregivers will help maintain high levels of quality care, and reduce the risk of adverse events that may result in as admissions to acute care facilities.

We also strongly recommend the inclusion of at least one companion measure that captures communication of medication information. A selection of measures are available that are currently NQF endorsed and will help fill the gap in this care area that has paramount importance to patient safety. These measures are listed below:

- NQF 0097: *Medication Reconciliation*
- NQF 0554: *Medication Reconciliation Post-Discharge*
- NQF 2456: *Medication Reconciliation: Number of Unintentional Medication Discrepancies per Patient*

These measures will help minimize the potential for dangerous drug-drug, and/or drug-disease interaction through the communication of an accurate and current medication list. It has been shown that medication reconciliation conducted post-discharge and conducted by a pharmacist within 30 days reduces readmissions to the hospital – which is a specific goal of the Affordable Care Act.²

Although OP-17 *Tracking Clinical Results between Visits* is not a measure that is endorsed by NQF, ASHP believes this measure is significant and very important to patient safety and clinical outcomes. As such, we believe the measure should be included as patient care plans rely on current clinical data to make informed decisions on treatments pathways. However, ASHP strongly encourages HHS and NQF to collaborate to strictly define, classify, and move this measure through the NQF endorsement process. Pharmacists are the key medication experts with primary responsibility within the healthcare team to optimize drug therapy specific to a patient’s clinical parameters.³

XIV. Requirements for the Ambulatory Surgical Center Quality Reporting (ASCQR) Program

Within the Ambulatory Surgical Center Quality Reporting Program (ASCQR) ASHP supports measures related to health promotion and disease prevention and strongly supports NQF 0431 *Influenza vaccine coverage among healthcare personnel* (ASC-7). The Society’s official policy is to advocate for influenza vaccination for healthcare workers and the general U.S. population. (Policy 0601, 0615)⁴

Although ASC-5 Prophylactic intravenous antibiotic timing is not endorsed by NQF ASHP understands HHS’s rationale for including such a measure in the ASCQR program.

² Schultz, Diane. “Postdischarge Pharmacist Medication Reconciliation: Impact on Readmission Rates and Financial Savings.” *Journal of the American Pharmacists Association* 53, no. 1 (January 1, 2013): 78. doi:10.1331/JAPhA.2013.11250.

³ Congdon, H. B., T. C. Dowling, I. Cheng, and H.-A. Truong. “Impact of Medication Therapy Management on Underserved, Primarily Hispanic Patients with Diabetes.” *Annals of Pharmacotherapy* 47, no. 5 (April 11, 2013): 665–70. doi:10.1345/aph.1R648.

⁴ American Society of Health-System Pharmacists, *Best Practices for Hospital and Health-System Pharmacy*. Bethesda, MD: American Society of Health-System Pharmacists, 2012. <http://search.ebscohost.com/login.aspx?direct=true&scope=site&db=nlebk&db=nlabk&AN=543199..>

U.S. Department of Health and Human Services
Centers for Medicare & Medicaid Services
August 31, 2015
Page 4

ASHP appreciates this opportunity to provide comments. Please contact me if you have any questions on ASHP's comments on the Proposed Rule. I can be reached by telephone at 301-664-8806, or by e-mail at ctopoleski@ashp.org.

Sincerely,

A handwritten signature in black ink, appearing to read "Christopher J. Topoleski". The signature is fluid and cursive, with the first name "Christopher" being the most prominent part.

Christopher J. Topoleski
Director, Federal Regulatory Affairs