



September 6, 2016

[Submitted electronically at www.regulations.gov]

Centers for Medicare & Medicaid Services

Department of Health and Human Services

Attention: CMS-1656-P

P.O. Box 8013

Baltimore, MD 21244-1850

Re: CMS-1656-P — Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Organ Procurement Organization Reporting and Communication; Transplant Outcome Measures and Documentation Requirements; Electronic Health Record (EHR) Incentive Programs; Payment to Certain Off-Campus Outpatient Departments of a Provider; Hospital Value-Based Purchasing (VBP) Program; Proposed Rule

ASHP is pleased to submit comments on the changes to the Hospital Outpatient Prospective Payment System (OPPS) and CY 2017 Payment Rates (the “proposed rule”). ASHP represents pharmacists who serve as patient care providers in acute and ambulatory settings. The organization’s more than 43,000 members include pharmacists, student pharmacists, and pharmacy technicians. For over 70 years, ASHP has been at the forefront of efforts to improve medication use and enhance patient safety.

ASHP thanks CMS for the opportunity to comment on the proposed rule. Our comments are designed to assist CMS in refining the OPPS rule to meet patient and clinician needs.

I. 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 2017 the payment rate for specified covered outpatient drugs (SCODs) and biologicals will remain at average sales price (ASP) plus 6 percent.

We have long supported reimbursement that is adequate to support core pharmacy services. Specifically, reimbursement must cover costs associated with 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 6 percent in the 2013 through 2016 Final Rules, and we urge the agency to finalize the proposed rule to reimburse for separately paid drugs at no less than ASP plus 6 percent in 2017. ASHP remains concerned that the proposed demonstration for Part B drug reimbursement would undercut the reimbursement levels CMS has laid out in the OPPS proposed rule, which could adversely impact access, quality, and patient outcomes.¹

¹ ASHP provided extensive comments to CMS regarding the proposed Part B demo, which can be accessed at <http://www.ashp.org/DocLibrary/Advocacy/GAD/GAD-CMS-1670-P-2016.pdf>.

II. Implementation of Section 603 Site Neutrality Requirements of the Bipartisan Budget Act of 2015

ASHP has concerns regarding the potential impact of CMS's proposed implementation of the Section 603 site-neutrality requirements on 340B eligibility for certain hospital outpatient departments (HOPDs). While we appreciate CMS's proposal to carve out certain HOPDs from the site-neutral provisions, properly classifying all HOPDs and establishing billing policies for those facilities may require substantial time. Reclassification of HOPDs may, in turn, impact 340B eligibility for some HOPDs. The proposed rule is silent regarding how the site-neutral changes would impact child-site status for HOPDs that are currently 340B-eligible but are facing facility reclassification or reclassification of some of their services pursuant to the proposed rule's site-neutral provisions. However, the change raises a number of questions. For instance, how would failing to qualify for an exception impact Medicare cost reporting for an HOPD? And how will 340B eligibility work for excepted HOPDs that provide nonexcepted services? Absent additional clarification and guidance regarding 340B eligibility for HOPDs reclassified under the site-neutral provisions, it seems likely that the issue could disrupt or complicate implementation of those provisions.

Considering that any shift in an HOPD's 340B eligibility could carry a significant adverse impact on care access, we urge CMS to work with the Health Resources and Services Administration (HRSA) to clarify the interaction of the proposed rule's site-neutral provisions with the current 340B eligibility requirements. We further recommend that CMS consider delaying finalization of the site-neutral provisions to allow sufficient time to operationalize policies necessary to properly implement the changes.

III. Quality Measures

a. Hospital Outpatient Quality Reporting (OQR) and Ambulatory Surgical Center Quality Reporting (ASCQR) Program Updates

ASHP is a proud inaugural member of the Measures Application Partnership (MAP) and is heavily engaged in the activities of the National Quality Forum. As a member of the National Quality Forum (NQF), ASHP strongly recommends that, with rare exceptions, CMS include only those measures that have been endorsed through NQF's rigorous consensus-building development process. NQF endorsement ensures that the great breadth of stakeholders involved in developing, testing, implementing, and using measures provide valuable feedback in maintaining and validating quality measures used in federal payment programs. Consensus achieved during the measure-development process, through broad acceptance and use of a measure or through public comment, does not incorporate the robust and comprehensive process used to establish NQF endorsement.

ASHP supports the adoption of both of the new OQR claims-based measures proposed by CMS: OP-35 "Admissions and Emergency Department Visits after Hospital Outpatient Surgery" and OP-36, "Hospital Visits After Hospital Outpatient Surgery." Although OP-35 has not been endorsed by NQF, NQF's conditional endorsement of the measure, coupled with CMS's assurances that the measure will be subject to the NQF trial period, justifies its inclusion as a means to monitor and improve outcomes for oncology patients.

Similarly, although the new Consumer Assessment of Healthcare Providers and Systems (CAHPS) survey questions are not officially NQF-endorsed, ASHP supports these questions, which the MAP described as

“high impact measures that will improve care quality and efficiency of care and be meaningful to consumers.”² We are pleased to note that CMS proposed the same measures for the ASCQR program, thereby facilitating alignment between the programs. Regarding the two pain-based questions, we understand CMS’s reasoning for including them, and we share CMS’s belief that patient-provider communication about pain is vital to ensuring quality care and to combating overprescribing and misuse of opioids. However, we recommend that CMS carefully monitor these two questions to ensure that they are not creating incentives for overprescribing and dispensing of opioids. Finally, we thank CMS for noting that it will submit these new survey measures to NQF for evaluation — we encourage the agency to take this step at the next available opportunity. Should NQF decline to endorse one or more measures, we would urge CMS to allow stakeholders an additional opportunity to comment on their inclusion in the OQR and ASC quality reporting programs.

b. Future Electronic Clinical Quality Measure (eCQM): Safe Use of Opioids-Concurrent Prescribing

ASHP has long advocated for safer opioid prescribing practices, including the use of data and technology-driven solutions, such as robust prescription drug-monitoring programs. As such, we commend CMS for considering innovative methods (e.g., eCQMs) for harnessing data to improve care quality. Given that eCQMs are a relatively new area of measure development, ASHP urges CMS to leave the measures posted for stakeholder input for a substantial length of time (i.e., more than 90 days) to allow stakeholders to conduct the necessary information-gathering. While we are not prepared to offer detailed comments on the eCQM at this time, we note that as this measure is further considered, pharmacists, as the key medication experts on the healthcare team, must be actively engaged in its development and implementation.

c. Hospital Value-Based Purchasing (VBP) Program

ASHP supports CMS’s proposal to remove the pain management dimension from the VBP’s Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) survey and replace it with questions better tailored to capture patient-provider communication regarding pain management. We share CMS’s concerns that incorporating pain questions into consumer satisfaction scores that affect payment could adversely impact responsible prescribing patterns. We support CMS’s plan to continue to monitor pain management data under the Hospital Inpatient Quality Reporting Program until it can develop new pain management questions. As CMS develops new HCAHPS questions regarding pain management, we encourage the agency to seek stakeholder feedback from a broad spectrum of stakeholders, including all members of the patient healthcare team.

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 301-664-8698 or by email at jschulte@ashp.org.

Sincerely,



Jillanne M. Schulte, J.D.
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² 81 Fed. Reg. 45717 (July 14, 2016).