August 28, 2014

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1612-P
P.O. Box 8013
Baltimore, MD 21244-1850

VIA ELECTRONIC SUBMISSION:

Re: Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule, Clinical Laboratory Fee Schedule, Access to Identifiable Data for the Center for Medicare and Medicaid Innovation Models & Other Revisions to Part B for CY 2015

Dear Sir/Madam:

The American Society of Health-System Pharmacists (ASHP) is pleased to submit comments on the changes to the 2014 Physician Fee Schedule (proposed rule) as published in the July 14, 2014 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.

I. Reports of Payments or Other Transfers of Value to Covered Recipients

Continuing education (CE) for pharmacists is an essential component of ongoing professional development that improves patient outcomes. Accredited CE is the gold standard of continuing medical education that incorporates strong criteria to ensure that the education being provided is based firmly in science and free of commercial bias.

ASHP specializes in developing customized educational activities for an interdisciplinary audience of healthcare professionals designed to address identified practice gaps. ASHP staff members stay apprised of key issues and trends shaping healthcare today and as such, identify educational needs that address contemporary professional practice gaps of various healthcare professionals. In addition to CE programming for pharmacists, ASHP also conducts continuing education activities for physicians, nurses, nurse practitioners, pharmacy technicians, dieticians, and other health care professionals. The content development for each activity is managed by a

[1] Federal Register Vol. 78, No. 139 pages 43282 – 43532

pharmacist and other professionals who are knowledgeable about the current issues in health care practice.

ASHP utilizes the identified practice gaps and educational needs to develop educational activities targeted to improve the knowledge and competency of healthcare professionals and to improve patient outcomes.

On February 1, 2013 the Centers for Medicare & Medicaid Services (CMS) published a final rule interpreting the Physician Payment Sunshine Act (Sunshine Act) provisions of the Affordable Care Act that require drug and device companies to report any payments or transfers of value made to physicians or teaching hospitals.[2] The Sunshine Act provides that any manufacturer of drugs or devices reimbursable by a federal health care program that provides a payment or other transfer of value to a covered recipient (defined as a physician or a teaching hospital) must submit annually certain information regarding the transfer. The purpose of the law is to create transparency and shed light on the nature and extent of the relationships between manufacturers and physicians, as well as to dissuade inappropriate relationships from forming.

In the Sunshine Act final rule, CMS acknowledged that there is a significant difference between an accredited or certified continuing education activity and one that is not. An indirect payment to a speaker at a continuing education program is not considered an "indirect payment," and does not need to be reported, when the following three conditions are met:

1. The program is accredited by the Accreditation Council for Continuing Medical Education (ACCME), the American Academy of Family Physicians (AAFP), the American Dental Association's Continuing Education Recognition Program (ADA CERP), the American Medical Association (AMA), or the American Osteopathic Association (AOA);
2. The applicable manufacturer does not select the covered recipient speaker nor does it provide the third party vendor with a distinct, identifiable set of individuals to be considered as speakers for the accredited or certified continuing education program; and
3. The applicable manufacturer does not directly pay the covered recipient speaker.

We agree with CMS that if manufacturers suggest speakers they are directing or targeting their funding to the speakers, so these payments will be considered indirect payments under the Sunshine Act. Conversely, when they do not suggest speakers, they are allowing the continuing

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[2] Medicare, Medicaid, Children's Health Insurance Programs; Transparency Reports and Reporting of Physician Ownership or Investment Interests; Final Rule: http://www.gpo.gov/fdsys/pkg/FR-2013-02-08/pdf/2013-02572.pdf

education provider full discretion over the CE programming, so the payment or other transfer of value is not considered an indirect payment for purposes of these reporting requirements.

In the 2015 PFS proposed rule, CMS proposes to eliminate the section of the Sunshine Act Final Rule that requires events to be accredited by one of five enumerated accrediting bodies (ACCME, AOA, AMA, AAFP or ADA CERP) in order to be "sunshine exempt." While we understand that CMS's intent with the agency's proposed PFS rule is to expand the definition of "Sunshine exempt" CE to take into account programs that may be accredited for nurses, optometrists, pharmacists, and others, we are concerned that the proposed rule would have the opposite effect. The proposed PFS, if finalized, would instead eliminate the current CE "safe harbor" from reporting by redefining CE payments as "indirect payments" which may be reportable – the opposite of CMS's stated intent.

While CMS states that indirect payments to speakers at CE events will be exempt from reporting, the agency does so in the preamble of the proposed rule and does not change the actual Federal Code. Therefore, these payments could be interpreted as a reportable "indirect payments" from a legal standpoint. Under the current final rule, indirect payments must be reported if the applicable manufacturer becomes aware of the identity of the recipient of the payment within 18 months of the payment. As CE presenters are always publicly listed, it is unlikely that a funder would be unaware of this information during, after, or even before a CE activity takes place. Therefore, ASHP assumes that these payments will need to be reported. This will have a "chilling" effect on both funding for CE and participation by potential speakers.

Because current CMS guidance that CE event attendees are only exempt from reporting for the educational value (or ancillary items) provided at accredited CE events per Section §403.904(g), the entire status of attendees is now jeopardized as a result of the proposal to eliminate this provision, and they may have to be consider (and reported) as indirect payments. CMS needs to clarify that this reporting exemption still exists for attendees and the types of events that qualify.

ASHP recommends that CMS ensure that indirect commercial support for CME programs, where the accredited provider exercise complete discretion on the content, remains exempted from reporting under the Open Payments system to encourage participation in CME. To this end, the agency should include language in the final rule that clarifies that the exemption applies under section 403.904(g)(1)(i) when an applicable commercial support provides funding or in-kind support to a CE provider, but does not select or pay for the covered recipient speaker, faculty, or attendee directly, or provide the CE provider with a list of speakers, faculty or attendees for consideration. CMS should clarify that this can be achieved if the supporter is unaware of the speakers, faculty, or attendees prior to signing a letter of commitment to fund an event. Further, we believe that these activities would remain exempt should the supporter become aware of the names of speakers, faculty, or attendees after formally committing support

K. Physician Payment, Efficiency, and Quality Improvements –Physician Quality Reporting System

ASHP applauds the inclusion of NQF# 419 Documentation of current medications in the medial record and NQF #97 Medication Reconciliation. The Society believes that ensuring the safe use of medicine by documentation of accurate medication lists and reconciling medications will improve patient outcomes, ensure patient safety, and improve communication and care coordination which are important priorities of the national quality strategy.[3]

ASHP strongly disagrees with the removal of the following measures from the PQRS program:

a. NQF # 270 Perioperative Care: Timing of Prophylactic Parenteral Antibiotic – Ordering Physician
b. NQF # 268 Perioperative Care: Selection of Prophylactic Antibiotic – First or Second Generation Cephalosporin
c. NQF #271 Perioperative Care: Discontinuation of Prophylactic Parenteral Antibiotics (Non-cardiac procedures)
d. Perioperative Care: Venous Thromboembolism (VTE) Prophylaxis (When indicated in all patients)

Addressing high cost cardiovascular conditions such as venous thromboembolism is a priority of the National Quality Strategy. There is some evidence indicating disparate practice patterns among clinicians when selecting the most appropriate prophylactic antibiotic.[4] Therefore, we believe it is important to continue monitoring prescribing practices of antibiotics because of the increased risk of nosocomial infections and multidrug resistant organisms.

M. Medicare Shared Savings Program

ASHP commends CMS in continuing pursuit of a high level of quality care in ambulatory settings through modifications and additions to the Medicare Shared Savings Program.

ASHP supports the inclusion of the three following measures:

a. All cause unplanned readmission for patients with diabetes mellitus
b. All cause unplanned readmissions for patients with heart failure
c. All cause unplanned readmissions for patients with multiple chronic conditions

These measures align with the National Quality Strategy priority of promoting the most effective prevention, treatment and intervention practices for the leading causes of mortality.

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[3] NQF.National Strategy for Quality Improvement in Healthcare. 2012 Annual Report to Congress. Washington DC: National Quality Forum; 2012.

[4] Lauber C, Lalh SS, Grace M, et al. Antibiotic prophylaxis practices in dentistry: a survey of dentists and physicians. *J Can Dent Assoc*. 2007;73(3):245

ASHP also agrees with the proposal to incorporate a more relevant measure NQF # 419 Documentation of Current Medications in the medical record in place of NQF #097 Medication Reconciliation. This proposal will assist in harmonizing quality measures across programs. Maintaining an accurate and current medication list at patient encounters will ensure the continuity of high quality healthcare.

ASHP strongly supports the proposal to add the Stewardship of Patient Resources as scored measures in the patient experience of care domain.

ASHP understands the issue regarding addressing measures that may be "topped-out" in the ACO program. Given that smaller ACO may an advantage in demonstrating improved performance we support the initial plan to address topped out measures using a flat percentage. We suggest that topped out measures be retained in the program as pay for reporting. New ACOs may elect to report these "topped-out" measures to identify and demonstrate areas of improvement and create population wide benefits for beneficiaries.

N. Value Based Payment Modifier and Physician Feedback

ASHP agrees with the decision to apply the Value-Based Payment Modifier (VM) to all physician and non-physician eligible professionals (EPs) in groups of 2 or more EPs and solo practitioners starting in 2017. This will encourage EPs to raise the quality of provided services in a collaborative manner with other clinicians within integrated healthcare teams

ASHP strongly agrees with the proposal to increase the amount of payment at risk under the VM from 2.0 percent to 4.0 percent in CY 2017. The organization also supports alignment of measures and quality reporting mechanisms for the VM with those available to groups and individuals under PQRS during the 2015 performance period. The organization understands the rationale for promoting systems-based care and applying the VM to all EPs rather than only to physicians to promote shared accountability.

ASHP agrees with the proposal to phase in quality tiers based on number of EPs in the group. Solo practitioners and groups between 2-9 EPs in category 1 will be held harmless from downward adjustments.

ASHP supports the inclusion of outcome measure of potential preventable hospital admissions for heart failure, chronic obstructive pulmonary disease, and diabetes; a composite rate for potentially preventable hospital admissions for dehydration, urinary tract infections, and bacterial pneumonia; and rates of the all-cause readmissions measure.

ASHP supports the change in the reliability policy for the hospital all-cause readmission measure from a minimum of 20 to 200 cases to be included in the quality composite. We believe that this will provide valid and reliable estimates for hospital admissions for each group.

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,

Christopher J. Topoleski
Director, Federal Regulatory Affairs