September 8, 2015

Mr. Andy Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1631-P
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue, SW
Washington DC 20201

VIA ELECTRONIC SUBMISSION:

Re: Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule & Other Revisions to Part B for CY 2016; Proposed Rule

Dear Mr. Slavitt:

ASHP is pleased to submit comments on the changes to the 2016 Physician Fee Schedule (proposed rule) as published in the July 15, 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.

II. Provisions of the Proposed Rule for PFS

K. Incident to Proposals: Billing Physician as the Supervising Physician and Ancillary Personnel Requirements

ASHP supports CMS's position that billing practitioners should have a personal role in the furnishing of "incident to" services. However, ASHP is concerned that the language as currently written in the proposed rule could result in disruptions to care. In the proposed rule, the agency writes:

> "Therefore, we are proposing to amend § 410.26(b)(5) to state that the physician or other practitioner who bills for incident to services must also be the physician or other practitioner who directly supervises the auxiliary personnel who provide the incident to services. Also, to further clarify the meaning of the proposed amendment to this regulation, we are proposing to

[1] Federal Register Vol. 80, No. 140 pages 41686 – 41965

remove the last sentence from § 410.26(b)(5) specifying that the physician (or other practitioner) supervising the auxiliary personnel need not be the same physician (or other practitioner) upon whose professional service the incident to service is based. "

Our primary concern comes from the second sentence. ASHP believes that this will negatively impact incident to services provided by pharmacists and result in considerable access to care issues. For example, a common example of such a disruption would be the customary way that anticoagulation clinics are structured. Typically, there is one supervising physician or practitioner under which the incident to services provided by a pharmacist are billed. The proposed rule could be interpreted to in such a way that every ordering physician would need to act as the supervising physician to whom the incident to services are billed. This could eliminate anticoagulation clinics and all other centralized service billing opportunities. One alternative to this is an interpretation that at least one Medicare Administrative Contractor (MAC) has in place. The MAC requires that a supervising practitioner must be in the same provider group tax ID number as the practitioner who bills for the incident to service. This along with all the other existing rules about the qualifications of the supervising provider assure that the quality of care provided is appropriate.

III. Other Provisions of the Proposed Regulations

E. Part B Drugs – Biosimilars

The proposed rule includes draft regulations to implement Section 3139 of the Affordable Care Act, the provisions of the law that define biosimilars and reference products and authorize Medicare payment for biosimilars using the average sales price (ASP) methodology. In the proposed rule, the Centers for Medicare & Medicaid Services (CMS) states that "We plan to use a single ASP payment limit for biosimilar that are assigned to a specific HCPCS code. In general, this means that products that rely on a common reference product's biologics license application will be grouped into the same payment calculation." Presumably this means that CMS would blend the ASP for biosimilars sharing a common reference product.

ASHP appreciates that CMS is considering coding and payment mechanisms for biosimilars as the first biosimilar has been approved and cleared to be marketed in the United States. However, we believe that there are still significant issues that must be addressed by both the Food and Drug Administration and CMS that makes immediate decisions on the coding and payment for biosimilars premature. As there is no legislative mandate that CMS promulgate payment and coding regulations for biosimilars in the proposed rule, ASHP strongly recommends that CMS remove this section from the rule and release their proposals under a separate notice for public comment. This release could more fully explain the agency's thought process and rationale for their proposals. The current proposed rule is over 275 pages and the proposals for coding and payment of biosimilars encompass less than one page of the proposed rule. ASHP believes that a more robust discussion must occur before CMS finalizes how biosimilars will be coded and paid for under Medicare Part B.

As the final rule for the Physician Fee Schedule must be issued before November 1, 2015 to ensure any changes can be fully implemented by January 1 of the following year, ASHP does not believe that there is sufficient time for CMS to fully consider the volume and complexity of the comments that they will receive on this section of the proposed rule. Further, the FDA has yet to issue any guidance on the

interchangeability of biosimilars with a reference product and has only recently issued guidance on issues related to the naming convention under which biosimilars will operate. The use of temporary HCPCS Q-codes for current and biosimilars approved in the near-term will be sufficient for payment until CMS has developed a final payment policy based on robust stakeholder comment and input.

L. Medicare Shared Savings Program

ASHP is a proud inaugural member of the Measures Application Partnership (MAP) and is heavily engaged in the activities of the National Quality Forum (NQF). As a member of the NQF, ASHP strongly recommends that CMS include only those measures that have been endorsed through a rigorous consensus-building development process. NQF endorsement ensures that a great variety of stakeholders are involved in developing, testing, implementing, and using measures. These stakeholders 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. Multi-stakeholder initiatives such as the Million Hearts Campaign align with the National Quality Strategy and laid the foundation to focus efforts on high priority areas that affect population health.

b. Proposed New Measures To Be Used in Establishing Quality Standards That ACOs Must Meet to Be Eligible for Shared Savings

ASHP supports the inclusion of the clinical quality measure titled ***Statin Therapy for the Prevention and Treatment of Cardiovascular Disease*** in the Medicare Shared Savings Program. Therapeutics guidelines related to cardiovascular risk and treatment goals have recently changed.[2] We strongly agree that quality measures should reflect these changes in practice to optimize patient outcomes. ASHP commends CMS for taking steps to keep up-to-date with these changes and supports the decision to include this measure in the measure set.

ASHP recommends the measure be included as a single measure with three equally weighted denominators. We also support the use of the measure as a single benchmark. Initial incorporation into the program as a pay-for-reporting measure will provide sufficient time to address issues with implementation of the measure and address potential unintended consequences. ASHP strongly recommends HHS reevaluate inclusion of this measure after stakeholder have had an opportunity to submit measurement through the Group Practice Reporting Option (GPRO) interface before moving the measure to pay-for-performance status. Additional perspective on movement of measures from pay-for-reporting to pay-for-performance is provided below.

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[2] Stone NJ, Robinson J, Lichtenstein AH, et al. 2013 ACC/AHA Guideline on the Treatment of Blood Cholesterol to Reduce Atherosclerotic Cardiovascular Risk in Adults: A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines. Circulation. November 2013. doi:10.1161/01.cir.0000437738.63853.7a.

c. Proposed Policy for Measures No Longer Aligning With Clinical Guidelines, High Quality Care or Outdated Measure May Cause Patient Harm

ASHP greatly supports the CMS decision to adopt a general policy on implementation of changes to clinical practice guidelines that may impact reporting of quality measures. We strongly agree that the method outlined, involving the measure developer, will aid in rapidly responding to changes in recommended therapy and reduce delays to addresses changes by waiting for proposed rule cycles.

However, we also provide suggestions for additional criteria and concerns that should be addressed with respect to incorporating changes in clinical guidelines. ASHP adheres to high standards of clinical practice guideline development as outlined in the Institute of Medicine report "Clinical Practice Guidelines We can Trust" and methodology for comparative effectiveness research developed by the Agency for Healthcare Research and Quality (AHRQ).[3,4] Part of these standards include disclosure of conflicts of interest and perceived biases of writing committee members, incorporating a variety of stakeholders including in the guidelines development process and ensuring standards in evaluating evidence and grading recommendations. ASHP strongly recommends involving guidelines developers in the process of quality measure development and implementation. We suggest collaboration with agencies such as AHRQ that maintains the National Guideline Clearinghouse to anticipate potential changes to guidelines that may affect quality measures. Working with these stakeholders will help anticipate changes that may reduce the burden implementation of proposed rule changes to clinical quality measures, and create a more efficient process to streamline incorporation of accurate measures.

ASHP also requests further details on the determination and criteria and for *"whether evidence suggests that continued application of the measure may result in harm to patients".* The American Diabetes Association (ADA) in their guidelines Standards of Medical Care in Diabetes recommend a team-based patient centered approach to achieve goals of therapy. Specifically they suggest that less stringent A1C goals may be appropriate for patients in whom the general goal of an A1C <7% is difficult to attain despite interventions that include diabetes self-management education.[5] Further treatment goals are highly dependent on patient engagement and setting reasonable targets results in attainable outcomes.[6] In clinical practice, often times, simply the publication of evidence-based recommendations will stimulate discussion and criticism that can change the initial recommendations. Clinical practice guidelines provide guidance their intent is not meant to be prescriptive. ASHP strongly requests CMS to

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3 Institute of Medicine (U.S.). Clinical Practice Guidelines We Can Trust. Washington, DC: National Academies Press; 2011.

4 Owens DK, Lohr KN, Atkins D, et al. AHRQ series paper 5: grading the strength of a body of evidence when comparing medical interventions--agency for healthcare research and quality and the effective health-care program. J Clin Epidemiol. 2010;63(5):513-523. doi:10.1016/j.jclinepi.2009.03.009.

5 American Diabetes Association. Standards of Medical Care in Diabetes--2014. Diabetes Care. 2014;37(Supplement_1):S14-S80. doi:10.2337/dc14-S014.

6 Teoh H, Home P, Leiter LA. Should A1C Targets Be Individualized for All People With Diabetes?: Arguments for and against. *Diabetes Care*. 2011;34(Supplement_2):S191-S196. doi:10.2337/dc11-s217.

consider and address these issues when implementing incentives for quality measures that use surrogate endpoints and markers for disease management based on clinical guidelines.

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