September 6, 2016

[Submitted via www.regulations.gov]
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1654-P
P.O. Box 8013
Baltimore, MD 21244–8013

Re: Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2017; Medicare Advantage Pricing Data Release; Medicare Advantage and Part D Medical Low Ratio Data Release; Medicare Advantage Provider Network Requirements; Expansion of Medicare Diabetes Prevention Program Model; Proposed Rules

ASHP is pleased to submit comments on the Centers for Medicare & Medicaid Services' (CMS's) proposed changes to the Physician Fee Schedule (PFS) for calendar year (CY) 2017 (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. We support many of the proposed changes to the PFS and hope that the comments below will assist CMS in refining the PFS to meet our shared patient care and quality goals.

I. Coding: Chronic Care Management (CCM) and Behavioral Health Integration (BHI)

ASHP thanks CMS for its commitment to enhancing the availability of CCM and Transitional Care Management (TCM) services. In particular, we are pleased by CMS's implementation of complex CCM codes in response to our concerns regarding the sufficiency of current CCM payments to cover the provision of more complex and/or time-consuming interventions. To assist with the appropriate use of the new codes for complex CCM, we strongly support CMS's proposal to solicit additional feedback on the provision of complex CCM and the new G-codes for BHI through notice-and-comment rulemaking. Although the inclusion of the comparison chart between the previous CCM requirements and the proposed changes was helpful, the chart did not include information related to the supervision of complex CCM services.[1] Based on the proposed rule's brief discussion of supervision requirements for CCM and BHI services, our understanding is that CMS intends to allow general supervision of non-face-to-face complex CCM and BHI services as well as of certain face-to-face services under the proposed G-codes. We request that CMS confirm that our interpretation is correct. ASHP again thanks CMS for its work in enhancing the availability and quality of chronic care services, and we look forward to working with CMS as it refines CCM, TCM, and BHI requirements.

[1] 81 Fed. Reg. 46211 (July 15, 2016).

Additionally, ASHP appreciates CMS's efforts to develop coding structures that work with, rather than dictate, practice. Thus, we support the implementation of the new BHI codes. However, considering that CCM services can be provided for some behavioral health issues and that the same visit can be used to initiate both CCM and BHI services, we are concerned that there is potential for confusion about which codes to use in certain cases.[2] ASHP encourages CMS to provide additional information or guidance regarding coding for BHI as well as the interaction of BHI and CCM codes to ensure both coding compliance and quality of care.

II. Diabetes Prevention Program Proposed Expansion

ASHP commends CMS for the proposed expansion of the Medicare Diabetes Prevention Program (DPP). Diabetes is a significant public health issue, and evidence demonstrates that pharmacists can and do play a major role in both its prevention and its management.[3] Thus, ASHP encourages CMS to develop and adopt program guidelines that maximize the ability of qualified individuals to provide DPP services. We support the requirement that DPP providers be certified by the U.S. Centers for Disease Control and Prevention (CDC) and have National Provider Identifier (NPI) numbers, but we are concerned about the Medicare supplier enrollment requirements. Our understanding is that it can be extremely difficult to enroll non-Medicare eligible clinicians, such as pharmacists, because regional Medicare Administrative Contractors (MACs) are unaccustomed to these types of enrollees.[4] Further, application processing delays can extend the already lengthy Medicare enrollment process. These difficulties are also evidenced by the proposed rule's discussion of the problems that non-Medicare eligible clinicians such as nurses and pharmacists encounter when billing for Diabetes Self-Management Training (DSMT) services.[5] If CMS intends to finalize the proposed Medicare supplier enrollment requirements, we urge the agency to facilitate the process by reaching out to MACs and preparing them for new, and potentially unfamiliar, groups of DPP supplier enrollees.

Additionally, while we appreciate CMS's need to expand DPP thoughtfully, the proposed criteria for DPP eligibility may disqualify a number of beneficiaries who could derive significant benefit from the program. Specifically, CMS proposes to disqualify individuals with multiple chronic conditions from DPP

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[2] 81 Fed. Reg. 46205 (July 15, 2016).

[3] *See, e.g.,* Simpson SH et al., "Effect of Adding Pharmacists to Primacy Care Teams on Blood Pressure Control in Patients with Type 2 Diabetes: A Randomized Controlled Trial," DIABETES CARE (Oct. 7, 2010); Morello CM, Hirsch JD, Lee KC, "Navigating Complex Patients Using an Innovative Tool: The MTM Spider Web," J. AM. PHARM. ASSOC, (2013), *available at* https://www.pharmacypracticeaccredit.org/system/rich/rich_files/rich_files/22/original/navigating-20complex-20patients-20japha.pdf.

[4] Pharmacists have previously encountered difficulties of this type in other contexts. For example, in 2014, CMS proposed a fraud, waste, and abuse provision that required Part D prescribers enroll in Medicare for their prescriptions to be considered valid. Pharmacists, who can prescribe under collaborative practice agreements in some states, would, in effect, have been prevented from providing those services under the new rule. In response, CMS released an interim final rule with alternative registration options for pharmacists and facilitated the registration process with regional MACs. *See* CMS, "Medicare Program; Changes to Requirements for Part D Prescribers" 80 Fed. Reg. 25958 (May 6, 2015), *available at* https://www.federalregister.gov/articles/2015/05/06/2015-10545/medicare-program-changes-to-the-requirements-for-part-d-prescribers.

[5] 81 Fed. Reg. 46215 (July 15, 2016).

eligibility.[6] Given that evidence suggests that many of DPP's elements — including weight management and lifestyle changes — can improve health outcomes related to other chronic conditions, limiting participation of individuals with multiple chronic conditions may be a missed opportunity for quality and care improvement.[7] If CMS intends to expand DPP meaningfully, we suggest the weight loss and participation benchmarks could be acceptable parameters for DPP eligibility.

III. Diabetes Self-Management Training (DSMT) Expansion

In the proposed rule, CMS notes that beneficiary use of DSMT benefits remains low. As stated above, many DSMT providers, including nurses and pharmacists, struggle to bill for these services. If the core group of DSMT providers — certified diabetes educators — is unable to offer services, it seems likely that DSMT use will remain stagnant. The American Medical Association (AMA) and the National Committee for Quality Assurance (NCQA) have both recommended expansion of DSMT provided by diabetes educators. As CMS expands the DPP program and makes changes to supplier enrollment, we encourage the agency to consider similar enrollment changes to enhance access to DSMT providers, including certified diabetes educators.

IV. Medicare Shared Savings Program (MSSP)

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, validating, and implementing measures. These stakeholders provide valuable feedback in maintaining and validating quality measures used in federal payment programs. Thus, the robust and comprehensive process used to establish NQF endorsement is preferable to consensus achieved through other means, such as broad acceptance and use of a measure or public comment. Several of the quality measures CMS proposes for CY 2017 have not been endorsed by NQF. While we recognize the need to include some measures that are not yet NQF-endorsed, we strongly urge CMS to make inclusion of such measures the exception, rather than the rule.

a. Medication Reconciliation Measure

ASHP supports the inclusion of the clinical quality measure titled "Medication Reconciliation Post-Discharge" in the MSSP for the purpose of ensuring care coordination and patient safety. Initial incorporation into the program as a pay-for-reporting measure should provide sufficient time to address any unanticipated implementation issues. ASHP supported the inclusion of this measure in the Medicare quality payment programs (QPPs) measure set, and we share CMS's view that consistency between the MSSP and the new QPP is essential to accurate quality and outcome tracking and measurement. Moving

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[6] *Id.* at 46417.

[7] Numerous studies and articles note the correlation between weight loss and improved health outcomes related to chronic conditions. *See, e.g.,* Centers for Disease Control and Prevention, "Healthy Weight," *available at* http://www.cdc.gov/healthyweight/losing_weight/; American Heart Association, "Weight Management and Blood Pressure," *available at* http://www.heart.org/HEARTORG/Conditions/HighBloodPressure/PreventionTreatmentofHighBloodPressure/Weight-Management-and-Blood-Pressure_UCM_301884_Article.jsp#.V866dPkrKCg;

forward, we urge CMS to continue its efforts to align measures across its programs to the greatest extent possible.

b. Removal of ACO Measures That Do Not Align with Core Quality Measures Collaborative Set

ASHP supports the replacement and removal of measures to ensure consistency and alignment with the Core Quality Measures Collaborative. This includes replacing ACO-39 with ACO-12, as there is overlap and redundancy across those measures relating to medication reconciliation. In addition, ASHP supports the removal of measures listed in the proposed rule that are duplicative to those measures listed in the Cardiovascular Measures Consensus Core Set.

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 301-664-8696 or by email at jschulte@ashp.org.

Sincerely,

Jillanne M. Schulte, J.D.
Director, Federal Regulatory Affairs