June 27, 2016

[Submitted electronically to www.regulations.gov]
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Docket CMS — 5517 — P for "Medicare Program; Merit-Based Incentive Payment System (MIPS) and Alternative Payment Model (APM) Incentive Under the Physician Fee Schedule, and Criteria for Physician-Focused Payment Models."

ASHP is pleased to submit comments to the Centers for Medicare & Medicaid Services (CMS) regarding its proposed changes to Medicare's quality payment programs (QPPs) as a part of the ongoing implementation of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA). 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 appreciates CMS's ongoing efforts to incentivize high-quality care by rewarding patient outcome and quality improvements. We support the development and implementation of consistent, evidence-based quality programs and standards, including those set forth as part of the Merit-Based Incentive Payment System (MIPS).

We remain concerned, however, that these models cannot reach their stated goals unless all providers are effectively integrated into team-based care. Pharmacists, as the healthcare team's medication-use experts, directly contribute to many of the quality metrics under both MIPS and Alternative Payment Models (APMs). Nevertheless, because pharmacists are neither MIPS "eligible clinicians" nor required providers under APMs such as Accountable Care Organizations (ACOs), their expertise and contributions may be underutilized and/or unavailable to certain patients.[1] Given pharmacists' essential role in improving patient care and outcomes as well as in meeting public health priorities (e.g., identifying, treating, and preventing opioid misuse and abuse), ASHP advocates for QPPs that include metrics and payment methodologies that recognize these services and that align with other CMS and Centers for Disease Control and Prevention (CDC) programs.

[1] *See* 42 U.S.C. §1848(k)(3)(B)(Defining "eligible professional" narrowly to mean only certain clinician groups, but not listing pharmacists); *See also* 42 U.S.C. §1899(h)(Defining an "ACO Professional" narrowly to include only certain clinicians as "required" providers. Thus, while pharmacists can participate in ACOs, because their inclusion is not statutory, they often face challenges to participating fully in healthcare teams within ACOs).

I. Pharmacists Are Integral to Care Quality and Value.

ASHP strongly encourages CMS to strengthen its QPPs by ensuring that all members of the healthcare team, including pharmacists, are able to participate fully and to track their contributions to quality and outcomes improvements. ASHP advocates for the effective integration of pharmacists and their services into both healthcare teams and Medicare's QPPs. Pharmacists are the medication experts of the healthcare team and, without their participation, coordinated care delivery systems, including APMs, are unlikely to reach their cost and quality goals.

With medications becoming increasingly complex and costly, and the annual cost of nonadherence and medication-related adverse drug events (ADEs) approaching $300 billion, pharmacists' patient care services are essential to improving patient outcomes, care quality, and cost containment.[2] Federal agencies, including CMS and CDC, have recognized the value of pharmacists' services in numerous areas, including the prevention and treatment of ADEs, the provision of medication therapy management (MTM) services, anticoagulation clinics, opioid monitoring and treatment programs, and, most recently, the implementation and monitoring of antibiotic stewardship programs.[3] Evidence shows that the inclusion of pharmacists' specialized medication knowledge and patient skills on healthcare teams decreases drug-related morbidity, mortality, and costs.[4] For every dollar invested in clinical pharmacy services in all types of practice settings (hospital, clinics, government, etc.), an average savings of $4.00

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[2] *See, e.g.,* New England Healthcare Institute,"Thinking Outside the Pillbox: A System-Wide Approach to Improving Patient Adherence for Chronic Disease" (August 2009), *available at* http://www.nehi.net/publications/17-thinking-outside-thepillbox-a-system-wide-approach-to-improving-patient-medication-adherence-for-chronic-disease/view; Avalere Health, "Exploring Pharmacists' Role in a Changing Healthcare Environment" (May 2014), *available at* http://avalere.com/expertise/life-sciences/insights/exploring-pharmacists-role-in-a-changing-healthcare-environment; Porter, ME and Lee, TH, "The Strategy that will Fix Health Care" Harvard Business Review (2013), *available at* http://hbr.org/product/the-strategy-that-will-fix-health-care/an/R1310B-PDF-ENG; C.R. Preslaski, I. Lat, R, MacLaren, J. Poston, "Pharmacist contributions as members of the multidisciplinary ICU team, Chest (2013), *available at* http://www.ncbi.nlm.nih.gov/pubmed/24189862; American Diabetes Association, "Effect of Adding Pharmacists to Primary Care Teams on Blood Pressure Control in Patients with Type 2 Diabetes: A Randomized Controlled Trial," Diabetes Care (2010), *available at* http://care.diabetesjournals.org/content/early/2010/10/05/dc10-1294.abstract.

[3] *See, e.g.,* U.S. Dept. of Health & Human Resources (HHS), "National Strategy for Quality Improvement in Health Care" (March 2011), *available at* http://www.ahrq.gov/workingforquality/nqs/nqs2011annlrpt.pdf; Agency for Healthcare Research and Quality, Aims of the National Quality Strategy (May 2016), *available at* http://www.ahrq.gov/research/findings/nhqrdr/nhqdr15/aims.html; HHS, "National Action Plan for Adverse Drug Event (ADE) Prevention" (2014), *available at* http://health.gov/hcq/pdfs/ade-action-plan-508c.pdf; HHS, "Medicare and Medicaid Programs; Hospital and Critical Access Hospital Changes to Promote Innovation, Flexibility, and Improvement in Patient Care," 81 Fed. Reg. 39447 (June 16, 2016), *available at* https://www.gpo.gov/fdsys/pkg/FR-2016-06-16/pdf/2016-13925.pdf.

[4] Bond, C. A. and Raehl, C. L., "Clinical Pharmacy Services, Pharmacy Staffing, and Hospital Mortality Rates," Pharmacotherapy (2007), at p. 481–493.

is realized to the health system.[5] However, as proposed, CMS's QPPs do not allow for effective tracking and attribution of pharmacists' services and their corresponding contributions to quality and value.

ASHP applauds CMS's inclusion of two MIPS measures that recognize pharmacists and their vital contributions to the patient care team — the Medication Reconciliation Post-Discharge Quality Measure and the Population Management CPIA Measure. These measures specifically name pharmacists, illustrating pharmacists' role in helping physicians achieve quality goals, specifically the maximum target composite performance scores (CPS) under MIPS. However, it is important to note that many other MIPS and APM measures, such as care coordination and public health and clinical database reporting, are strongly influenced by pharmacists' services — despite the fact that pharmacists are not specifically named in these measures. Additionally, pharmacists play an integral role in the comprehensive management of chronic conditions such as diabetes, the provision of anticoagulation clinic services, and the comprehensive assessment and management of patients' comorbid conditions, yet few APM quality measures or payment methodologies adequately account for these contributions. ASHP urges the development of QPPs that include metrics and payment methodologies which acknowledge and incentivize these contributions to quality, outcomes, and cost.

II. Barriers Exist to Full and Effective Pharmacist Engagement in Medicare Quality Payment Programs.

As CMS continues to develop its QPPs, we encourage the Agency to consider the barriers that pharmacists may face to effective integration into healthcare teams, as well as the importance of integrating pharmacists' medication expertise into Physician-Focused Payment Models (PFPMs) launched under the QPPs.

A. Current Barriers to Pharmacists' Participation in Care Teams and APMs.

Despite the clear benefits of including pharmacists in APMs (e.g., ACOs) and other coordinated care delivery systems, integration is constrained by current payment models. For pharmacists embedded in physician office practices, "incident to" billing under fee-for-service is an option in some cases, but by itself is not sufficient to support a pharmacist's practice. Additionally, in Federally Qualified Health Centers (FQHCs), which serve many Medicaid beneficiaries, FQHC-specific billing requirements may also prevent pharmacists from providing "incident to" services, preventing FQHCs from using clinician resources fully. Medication management and other services that pharmacists provide improve care quality and patient outcomes, but current payment models often fail to incentivize pharmacist participation, thereby creating substantial barriers to pharmacist inclusion on care teams.

In hospital settings, pharmacists may face fewer initial barriers to APM participation, but they do encounter challenges in tracking and quantifying their contributions to improved outcomes and quality. For instance, under the proposed QPPs, despite their contributions, pharmacists would be ineligible for incentive payments associated with patient care gains. Additionally, questions remain regarding which

[5] Schumock GT, Butler MG, Meek PD, et al., "Evidence of the Economic Benefit of Clinical Pharmacy Services 1996–2000," Pharmacotherapy (2003), at p. 113–320.

APMs will qualify for MACRA incentives. Specifically, will CMS treat demonstration programs such as the recently proposed Part B medication payment demonstration (the "Part B Demo") as an APM under MACRA? Will the medication-related programs broadly outlined in the second phase of the Part B Demo qualify? Considering their strong medication focus, it is likely that the success of those programs will be heavily dependent on pharmacist engagement. Yet, at present, pharmacists are excluded from incentive programs that would reward program successes, including improved patient outcomes and resource utilization.

B. CMS Should Prioritize PFPMs that Use All Members of the Healthcare Team.

ASHP thanks CMS for adopting an expansive definition of PFPMs "to allow the inclusion of other entities and additional targets."[6] We agree that this approach will offer greater flexibility in PFPM proposals and "lead to models that promote broader participation in PFPMs, greater potential for care redesign, and greater potential for cost reduction."[7]

We recognize that the QPPs are a work in progress, and we believe that we can best assist CMS by working with our members to identify and propose PFPMs that fully and effectively use pharmacists to enhance patient care and improve outcomes in a cost-conscious manner. ASHP plans to work with other pharmacy organizations to nominate pharmacists with expertise in value-based care models to the Comptroller General's Physician-Focused Payment Model Technical Advisory Committee (PTAC). We recognize that CMS does not control or influence PTAC's review of proposed PFPMs; however, after PTAC submits its recommendations, we urge CMS to prioritize implementation/adoption of PFPMs that include payment methodologies that acknowledge and account for the contributions of every member of the healthcare team, including pharmacists. Such an approach could reduce barriers to clinician participation while boosting care coordination and integration.

As CMS continues its work on the proposed QPPs, ASHP is eager to collaborate with other industry stakeholders and assist CMS in any way possible. Please contact me at jschulte@ashp.org or (301)-664-8698) if you have any questions or wish to discuss our comments further.

Sincerely,

Jillanne M. Schulte, JD
Director, Federal Regulatory Affairs

[6] 81 Fed. Reg. 28347 (May 9, 2016).
[7] Id.