November 20, 2017

[Submitted electronically via CMMI_NewDirection@cms.hhs.gov
U.S. Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Re: Centers for Medicare & Medicaid Services: Innovation Center New Direction.

ASHP is pleased to submit comments to the Centers for Medicare & Medicaid Services (CMS) request for information (RFI) regarding the future direction of Center for Medicare and Medicaid Innovation (CMMI) projects. ASHP represents pharmacists who serve as patient care providers in acute and ambulatory settings. The organization's nearly 45,000 members include pharmacists, student pharmacists, and pharmacy technicians. For 75 years, ASHP has been at the forefront of efforts to improve medication use and enhance patient safety.

ASHP appreciates the opportunity to provide feedback to CMS to help focus future CMMI efforts to enhance patient care and outcomes. Pharmacists are integral members of the healthcare team, practicing across the continuum of care. Pharmacists' medication expertise is invaluable, and their education prepares them for patient care that extends far beyond simply dispensing medications. Nevertheless, pharmacists continue to face both regulatory and reimbursement barriers to practicing at the top of their scopes of practice. As a result, our healthcare system fails to use resources effectively, squandering both human and financial capital. Thus, our comments center on the need to maximize clinician resources to improve the system, rather than simply reallocating resources without making any corresponding systemic changes.

I. FOCUS AREAS FOR MODEL DESIGNS

ASHP shares CMS's commitment to addressing the high cost of drugs — and we support solutions that decrease costs while safeguarding patient care quality and access. ASHP is a member of the Steering Committee of the Campaign for Sustainable Rx Pricing (CSRxP), and we urge CMS to review and consider CSRxP's policy recommendations for addressing drug prices.[1] As CMMI reviews potential prescription drug models to test, we suggest that pharmacist patient care services can help reduce unnecessary drug spending while contributing to higher quality and better outcomes. ASHP encourages CMMI to prioritize projects that focus on engaging pharmacists to ensure that patients receive the full value of a drug through adherence and effective management of comorbid chronic conditions. Even the most innovative, groundbreaking, lifesaving medication works only if a patient takes it correctly.

Medications are the first line of therapy to treat patients with chronic diseases and acute complex diseases such as cancer and heart disease. Breakthroughs in new medications have led to more Americans living longer, healthier lives. However, these breakthroughs also carry new challenges. Nearly 70 percent of Medicare beneficiaries have one or more chronic conditions[2], and many of these beneficiaries take multiple medications. Lack of proper medication oversight and management can result in suboptimal therapeutic

[1] *See* Campaign for Sustainable Rx Pricing, http://www.csrxp.org/about-the-campaign/ (last accessed Nov. 15, 2017).
[2] *See* Centers for Medicare and Medicaid Services. *Chronic Conditions Among Medicare Beneficiaries Chartbook* (2012), *available at* https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Chronic-Conditions/Downloads/2012Chartbook.pdf.

outcomes and patient harm. For example, too many patients are unnecessarily readmitted to the hospital or visit the emergency department due to medication-related issues. The Institute of Medicine estimates that 1.5 million preventable adverse drug events (ADEs) occur annually in the United States, resulting in an estimated 7,000 deaths.[3] The New England Healthcare Institute has estimated the cost of medication-related adverse events and nonadherence to total $290 billion annually.[4] Addressing these costs would contribute substantially to improving the price tag for government programs while benefitting patients.

Pharmacists are uniquely qualified to provide the type of medication and disease management (including behavioral health conditions) needed not only to stem the waste on ADEs and nonadherence, but also to enhance patient outcomes through improved medication use. Pharmacists offer an in-depth knowledge of medications that is unmatched in the healthcare arena. Pharmacists today receive clinically-based doctor of pharmacy degrees (Pharm.D.), and many also complete postgraduate residencies and become board certified in a variety of specialties. Pharmacists in hospitals and ambulatory clinics work with physicians, nurses, and other providers on interprofessional teams to manage patients' medications and ensure appropriate care transitions. Patient care discussions often revolve around the pathophysiology of disease or chronic condition, but far too often patients receive little information regarding perhaps the most essential part of treatment — the medication prescribed to cure or manage the condition. In many cases, the prescribing clinician does not have the same medication expertise as a pharmacist. Thus, if the goal is to avoid overspending on drugs and to maximize the value of the drugs patients purchase, pharmacists must play a more prominent role in medication selection and modification, patient education, follow-up and monitoring of medication, and overall medication and chronic disease management.

Studies indicate that the inclusion of pharmacists on the healthcare team demonstrates a significant return on investment in both patient outcomes and real dollars.[5] For every dollar invested in clinical pharmacy services in all types of practice settings (hospital, clinics, government, etc.), health systems realize an average savings of four dollars.[6] Despite these facts, pharmacists are neither eligible to participate in Medicare Part B, nor are they required providers within accountable care organizations (ACOs). As a result, pharmacists are not directly reimbursed for patient care, making it more difficult for them to fully integrate into certain practice settings. Below, we offer some specific recommendations for a potential cross-cutting model tests that would fully engage pharmacists, allowing them to improve outcomes through improved medication use.

II. POTENTIAL MODEL DESIGNS

Below we provide some potential starting points in both the ambulatory and inpatient setting for CMMI to consider as it develops and tests new models. ASHP encourages CMMI to develop a dialogue with the

---

[3] *See* Institute of Medicine, *Preventing Medication Errors* (2007) *available at*: http://www.nap.edu/catalog/11623.html; For a comprehensive discussion of ADEs, *see* National U.S. Department of Health & Human Services, National Action Plan for Adverse Drug Event Prevention (2014), *available at* https://health.gov/hcq/ade-action-plan.asp.

[4] *See* New England Healthcare Institute**,** *Thinking Outside the Pillbox: A System-wide Approach to Improving Patient Medication Adherence for Chronic Disease* (2009), *available at* https://www.nehi.net/publications/17-thinking-outside-the-pillbox-a-system-wide-approach-to-improving-patient-medication-adherence-for-chronic-disease/view.

[5] C.A. Bond and C.L. Raehl, *Clinical Pharmacy Services, Pharmacy Staffing, and Hospital Mortality Rates,* 27 Pharmacotherapy 482-93 (2007).

[6] G.T. Schumock *et al*., *Evidence of the Economic Benefit of Clinical Pharmacy Services: 1996–2000,* 23 Pharmacotherapy 113–32 (2003)

researchers who shepherded these projects, as we believe they are best situated to assist in structuring new models and demonstrations at the intersection of pharmacy and patient care.

- **Pain management in an integrated health-system:** Pharmacist clinicians with prescribing authority for controlled substances provided chronic non-cancer-related pain medication management services in a for-profit integrated health system. In a one-year time period, the pharmacist clinicians were able to show an improvement in mean visual analogue scale pain scores and save the health system over $450,000.[7]

- **Depression management in a staff model health maintenance organization:** A randomized controlled trial was conducted to measure the impact of a collaborative care model that emphasized the role of clinical pharmacists to provide drug therapy management and treatment follow-up in patients with depression. In this collaborative model, after six months, those patients with depression randomized to the services of a pharmacist compared with the control group had a significantly higher medication adherence rate (67% vs. 48%), higher patient satisfaction, and favorable changes in resource utilization.[8]

- **Reduction of Hospital Readmissions:** A recent study found that patients assigned to receive pharmacist interventions in conjunction with physician hospital follow-up visits had a statistically significant lower rate of readmission within 30 days (9.2%) than those who did not receive pharmacist interventions (19.4%).[9]

- **Improvement in Transitions of Care**: Another study examined the development of a collaborative transitions-of-care program for heart failure patients[10] in a 390-bed community hospital. Pharmacists performed daily medication profile reviews for high-risk heart failure patients, including appropriate discharge counseling. The result was a reduction in 30-day heart failure readmissions and a cost savings of roughly $5,652 per patient.[11]

- **Telehealth:** Patients in rural and underserved areas frequently lack access to care. Therefore, we would encourage use of telehealth infrastructures to extend access to interprofessional teams that require inclusion of pharmacists. Project ECHO (Extension for Community Healthcare Outcomes,), exemplifies the type of telehealth model that extends the care of an interprofessional team that includes a pharmacist. Payment models should also address incorporation of innovative interprofessional telehealth models.[12]

---

[7] A.B. Adolphe *et al*., *Provision of Pain Management by a Pharmacist with Prescribing Authorit*y, 64 Am. J. Health-Sys. Pharm. 85-9 (2007).
[8] P.R. Finley *et al*., *Impact of a Collaborative Pharmacy Practice Model on the Treatment of Depression in Primary Care*, 59 Am. J. Health-Sys. Pharm. 1518-26 (2002).
[9] M.E. Arnold, et al., *Impact of Pharmacist Intervention in conjunction with Outpatient Physician Follow-up Visits after Hospital Discharge on Readmission Rate*, 72 Am. J. Health-Sys. Pharm., Supp. 1 (2015).
[10] S. Gunadi *et al*., *Development of a Collaborative Transitions-of-Care Program for Heart Failure Patients*, 72 Am. J. Health-Sys. Pharm (2015).
[11] *Id.*
[12] *See.e.g.,*Project Echo: Extension for Community Healthcare Outcomes Project*,* https://www.ruralhealthinfo.org/community-health/project-examples/733 (last accessed Nov. 20, 2017).

- **The Diabetes Ten City Challenge** is a community-based, payer-driven, patient-centered healthcare model established in 2005 at 10 American cities, providing pharmacy health management services for diabetic patients. Patients were teamed with community pharmacists to receive pharmaceutical care services providing education, long-term pharmacist follow-up, clinical assessment, goal-setting, monitoring, and collaborative drug therapy management with physicians. The pharmacists were part of an interdisciplinary healthcare team and communicated regularly to optimize patient care. Ongoing pharmacy management services significantly decreased hemoglobin A1c from 7.5% to 7.1%, decreased mean LDL from 98 mg/dl to 94 mg/dl, and decreased mean systolic blood pressure from 133 to 130 mmHg over a mean of 14.8 months. Average total healthcare costs per patient per year were reduced by $1,079.[13]

- **HRSA PSPC Collaborative:** The U.S. Health Resources and Services Administration's (HRSA's) Patient Safety and Clinical Pharmacy Services (PSPC) Collaborative is an effort to improve the quality of healthcare across America by integrating evidence-based clinical pharmacy services into the care and management of high-risk, high-cost complex patients.

III. PAYMENT WAIVERS FOR MODEL TESTS

Although we encourage CMMI to work from the examples listed in the section above as it identifies new models to test, we also urge CMMI to consider a broader project. Specifically, we believe that CMMI should use its Section 1115 waiver authority to test a model that allows direct reimbursement of pharmacists' services within their respective state's scope of practice.

ASHP and other stakeholders have long advocated for a legislative change to Medicare Part B that would allow pharmacists to improve medication use and address gaps in care by enabling pharmacists to bring their full expertise and training to bear for Medicare and Medicaid beneficiaries in underserved areas, pursuant to their state scope of practice. This provider status legislation (The Pharmacy and Medically Underserved Areas Enhancement Act (H.R. 592/ S. 109)), which has broad bipartisan support in both chambers of Congress, is currently pending.

However, the pending legislation should not deter CMMI from seizing an opportunity to explore the concept of direct payment to pharmacists. As it stands, the provider status legislation is keyed to HRSA-designated medically underserved areas, medically underserved populations, and health professional shortage areas. To structure the payment waiver, CMMI could use these built-in limitations, or, given that CMMI has expressed particular interest in Medicaid-focused projects, the model could be adapted for a Medicaid population. CMS has previously indicated support for flexibility around reimbursement to pharmacists through innovative non-direct payment models for chronic care management (CCM), transitional care management (TCM), and behavioral health integration (BHI) services.[14] A model test of direct payment would be a logical extension of

[13] T. Fera *et al*., *Diabetes Ten City Challenge: Final Economic and Clinical Results,* 49 J. Am. Pharm. Assoc. 383-391(2009).
[14] *See* CMS, "Revisions to Payment Policies Under the Physician Fee Schedule Final Rule," 79 Fed. Reg. 67548 (Nov. 13, 2014). The aforementioned final rule changed incident-to billing rules for chronic care management (CCM) provided to Medicare beneficiaries outside of normal physician office hours. Direct supervision is no longer a prerequisite for CCM services provided "after hours" by a non-

these payment models. Additionally, although pharmacists do not have Medicare numbers, they do have National Provider Identifier (NPI) numbers, which are already used for Medicare Part B billing purposes.[15] Finally, a model test of a payment waiver for pharmacists would also present an opportunity for CMMI and CMS to gauge how best to work with pharmacists as clinicians who do not directly bill Medicare Part B.

Should CMMI opt to test this type of payment waiver, ASHP and the other stakeholders in the Patient Access to Pharmacists' Care Coalition (PAPCC)[16], which has spearheaded provider status efforts in the pharmacy community, stand ready to cooperate with and assist CMMI in any way necessary.

IV. OTHER SUGGESTIONS

ASHP also suggests that CMMI consider constructing mechanisms for soliciting more substantive feedback from pharmacists. As noted above, pharmacists are not Medicare-eligible and, as a result, have sometimes been not been included in Medicare and Medicaid policy discussions. To avoid this in the future, we suggest that CMMI and CMS both consider adopting some practices that work well for other federal agencies, including regular listening sessions and more targeted outreach. In particular, CMS approached ASHP and other pharmacy professional organizations last year regarding the creation of a pharmacist workgroup, and we urge both CMMI and CMS to consider implementing this approach.

V. CONCLUSION

Again, we thank CMS for its efforts to improve care and increase healthcare innovation. As CMMI continues its work identifying, developing, and testing care models, ASHP is eager to assist CMS and CMMI in any way possible. Please contact me via email at jschulte@ashp.org or by phone at (301)-664-8698) if you have any questions or wish to discuss our comments further.

Sincerely,

Jillanne Schulte Wall

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

---

physician clinician. Subsequently, CMS has further refined the CCM requirements in the respective Physician Fee Schedule final rules for calendar years 2016–2018.

[15] *See, e.g.,* CMS, "Medicare Program; Changes to the Requirements for Part D Prescribers," 80 Fed. Reg. 25958 (May 6, 2015) (Allowing Part D claims to be processed when claims include a valid NPI); CMS, "Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2018; Medicare Shared Savings Program Requirements; and Medicare Diabetes Prevention Program," 82 Fed. Reg. 33950 (July 21, 2017) (Allowing pharmacists to act as coaches for the Diabetes Prevention Program and to use their NPI on Medicare claims).

[16] Patient Access to Pharmacists' Care Coalition, https://pharmacistscare.org/ (last accessed Nov. 15, 2017).