January 25, 2018

[Submitted electronically via CompetitionRFI@hhs.gov]
U.S. Department of Health & Human Services
200 Independence Avenue SW
Washington, DC 20201

Re: Request for Information — Promoting Healthcare Choice and Competition Across the United States

ASHP is pleased to submit comments to the U.S. Department of Health & Human Services (HHS) request for information (RFI) regarding healthcare choice and competition across the country. ASHP represents pharmacists who serve as patient care providers in acute and ambulatory settings. The organization's 45,000 members include pharmacists, student pharmacists, and pharmacy technicians. For more than 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 HHS regarding "barriers to choice and competition … and proposed solutions that could facilitate the development and operation of a healthcare system that provides high-quality care at affordable prices for the American people." 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 generally center on the need to maximize clinician resources to improve the system, rather than simply reallocating resources without making any corresponding systemic changes.

I. Improve Utilization of Pharmacists' Patient Care Services

Pharmacists can assist HHS and its subagencies with addressing several of the most pressing healthcare issues, including but not limited to drug pricing, chronic care management, and substance abuse identification, treatment, and prevention. ASHP encourages HHS to focus its efforts 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[1], and many of these beneficiaries take multiple medications. Lack of proper medication oversight and management can result in suboptimal therapeutic 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] *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.

1.5 million preventable adverse drug events (ADEs) occur annually in the United States, resulting in an estimated 7,000 deaths.[2] The New England Healthcare Institute has estimated the cost of ADEs and nonadherence to total $290 billion annually.[3] 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 to not only 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.[4] 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 $4.[5] Numerous studies attest to the benefits of fully engaging and integrating pharmacists into the health care system:

- **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%).[6]

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[2] *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.

[3] *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.

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

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

[6] 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).

- **Improvement in Transitions of Care**: Another study examined the development of a collaborative transitions-of-care program for heart failure patients[7] 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.[8]

- **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.[9]

- **The Diabetes Ten City Challenge** is a community-based, payer-driven, patient-centered healthcare model established in 2005 in 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.[10]

Despite this evidence, 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. To address this, we urge HHS to test and expand the concept of direct payment to pharmacists. The Centers for Medicare & Medicaid Services (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), the diabetes prevention program (DPP), and behavioral health integration (BHI) services.[11] A model test of direct payment would be a logical extension of these payment models and could be done through the Center for Medicare & Medicaid Innovation (CMMI). Additionally, although pharmacists do

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[7] S. Gunadi *et al*., *Development of a Collaborative Transitions-of-Care Program for Heart Failure Patients*, 72 Am. J. Health-Sys. Pharm (2015).
[8] *Id.*
[9] *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).
[10] T. Fera *et al*., *Diabetes Ten City Challenge: Final Economic and Clinical Results,* 49 J. Am. Pharm. Assoc. 383-391(2009).
[11] *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-physician clinician. Subsequently, CMS has further refined the CCM requirements in the respective Physician Fee Schedule final rules for calendar years 2016–2018.

not have Medicare numbers, they do have National Provider Identifier (NPI) numbers, which are already used for Medicare Part B billing purposes.[12]

II. Enhance Tools for Combatting Opioid Abuse

As noted above, due to regulatory barriers, pharmacists are not always effectively engaged in patient care, including treatment of mental health disorders and opioid abuse. For example, the Drug Enforcement Agency (DEA) just opened up prescribing of buprenorphine to physician assistants and nurse practitioners, but not to pharmacists, despite their medication expertise. As our nation struggles with an opioid epidemic, we urge HHS to work with its subagencies, including the Substance Abuse and Mental Health Services Administration (SAMHSA) and CMS, to better utilize pharmacists' services for pain management and substance abuse treatment. Studies have documented the positive impact of pharmacists in treating pain and mental health disorders, including substance abuse:

- **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.[13]

- **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.[14]

Pharmacists can play an integral part in combatting opioid use using a variety of approaches and tools. For patients with opioid needs exceeding 72 hours, a pharmacist can assist the provider in creating a patient-specific pain plan that includes the most optimal medication(s), duration, and a plan to discontinue, taper, or transition to a non-opioid therapy. This plan can then be electronically shared throughout all transitions of care including outpatient visits.

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[12] *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).

[13] 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).

[14] 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).

Moreover, there should also be a mechanism to submit the plan through the Prescription Drug Management Programs (PDMPs). To accomplish this, ASHP urges HHS to consider strengthening PDMPs, which could reduce overprescribing. Although PDMPs are in place in the majority of states, the platforms are not user-friendly, which creates barriers to usage for prescribers and dispensers. A robust, interoperable national PDMP system would allow prescribers and pharmacists to track patient-specific opioid use to prevent overprescribing and potential misuse at the point of prescribing. Additionally, better use of existing systems could also have a positive impact on overprescribing. We urge HHS to evaluate initiatives to enhance existing PDMPs and to improve current use of PDMPs by both prescribers and dispensers.

III. Reduce Onerous Reimbursement and Modifier Changes

Finally, hospitals and health systems face numerous financial and operational challenges that threaten patient access and care quality. Recent CMS actions related to the 340B Drug Pricing Program will exacerbate these strains for some entities. CMS's precipitous decision to drastically reduce reimbursement for 340B-purchased drugs by almost 30 percent not only threatens patient access to medications, but also creates a system where drugs for Medicare patients are reimbursed at different rates. Further, to accomplish the change, CMS imposed yet another new modifier, which will require changes to electronic health records in order to be implemented effectively. We urge HHS to protect patient access to medications and vital services by restoring a consistent reimbursement scheme for all Medicare outpatient drugs and reducing its reliance on burdensome modifiers.

IV. Conclusion

Again, we thank HHS for its efforts to improve our healthcare system. As HHS continues its work, ASHP is eager to assist 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

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