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American College of Clinical Pharmacy
John K. McGlew
Director, Government Affairs

July 6, 2023

The Honorable Mike Crapo
239 Dirksen Senate Office Building
Washington, DC 20510-1205

The Honorable Cathy McMorris Rodgers
2188 Rayburn House Office Building
Washington, DC, 20515-4705

Dear Senator Crapo and Representative McMorris Rodgers,

On behalf of The American College of Clinical Pharmacy (ACCP), I thank you for this opportunity to respond to your June 12, 2023, bicameral Request for Information (RFI) seeking input on policy solutions to the increase in drug shortages.

ACCP is a professional and scientific society that provides leadership, education, advocacy, and resources enabling clinical pharmacists to achieve excellence in patient care practice and research. ACCP's membership is composed of more than 17,000 clinical pharmacists, residents, fellows, students, scientists, educators, and others who are committed to excellence in clinical pharmacy practice and evidence-based pharmacotherapy.

ACCP is committed to a patient-centered, team-based, and evidence-driven approach to medication use that aligns with emerging value-based pricing approaches to better ensure that the rational and economical use of medications is optimized for patients and for the health care system.

ACCP's members practice in a variety of team-based settings, including ambulatory care environments, hospitals, colleges of pharmacy and medicine, the pharmaceutical industry, government and long-term care facilities, and managed care organizations. Our focus is the optimization of medication regimens to achieve patient-centered therapeutic goals. ACCP members often combine their direct patient care responsibilities with duties designed to address drug shortages and find suitable treatment alternatives specific to the patient population. In institutions and practices where clinical pharmacists are integrated into health care teams, ACCP members contribute to institutional or practice-wide guidance or policies to mitigate drug shortages.

As you examine potential policy solutions to the market distortions and misaligned incentives that are leading to drug shortages, ACCP offers feedback on the following areas of inquiry:

How can federal agencies, such as the Centers of Medicare and Medicaid (CMS), better address the economic forces driving shortages? Are these agencies using their current authorities effectively?

The burden of chronic physical and mental health conditions has significant implications for the Medicare program. Over 68% of Medicare beneficiaries have two or more chronic conditions and

over 36% have four or more chronic conditions. In terms of Medicare spending, beneficiaries with two or more chronic conditions account for 93% of Medicare spending, and those with four or more chronic conditions account for almost 75% of Medicare spending.[1]

Medications are the fundamental treatment intervention in each of the eight most prevalent chronic conditions in Medicare patients. The importance of medications in the care and treatment of chronic illness will only increase as advances in biomedical research and innovation and breakthroughs in digital and personalized medicine bring new life-saving drugs and devices to patients and a new generation of cures and treatments.

In a 2021 report, USP/Vizient found that drug shortages can "result in significant harm, including increased medication errors, delayed administration of lifesaving therapies, inferior outcomes, and patient deaths." A subsequent study examined the clinical impact of drug shortages on patient care and found that shortages were associated with medication errors, adverse drug reactions, and inefficiencies.[2]

It is estimated that $528 billion dollars a year[3], equivalent to 16 percent of total health care spending, is consumed due to inappropriate or otherwise ineffective medication use. Despite this medication-misuse crisis, currently no effective incentives currently exist in Medicare to support a coordinated medication management process.

Traditional practice models and payment policies result in disjointed prescribing and distribution of medications from unconnected professional "silos." When combined with the continuing growth in the number and categories of medications - and greater understanding of the genetic and physiologic differences in how people respond to their medications – our existing medication management and delivery systems, including the Part D benefit, consistently fail to deliver the full promise medications can offer.

Problems related to medication misuse generally fall under three major categories: overuse of medications that don't improve health and may cause harm; underuse of critical drugs needed for acute or chronic health problems; and misuse of medications such as opioids.

All three are contributing to the growing issue of drug shortages, as well as driving higher costs and adversely impacting patient health. According to the Get the Medications Right Institute (GTMRx), "to prevent overuse of medications, health care providers shouldn't start or continue medications without a comprehensive evaluation of the patient's health issues and medications." [4]

We therefore urge Congress and CMS to consider opportunities to integrate coordinated, team-based comprehensive medication management (CMM) provided by clinical pharmacists into Medicare coverage and payment models. CMM is a direct patient care service, provided by clinical pharmacists working as members of the patient's healthcare team under a collaborative practice agreement that has been demonstrated to significantly improve clinical outcomes and enhance the safety of medication use by patients.

CMM is a well-established standard of care in our nation's leading private sector health systems,

[1] CDC PCD Article. Prevalence of Multiple Chronic Conditions Among Medicare Beneficiaries. Accessed 6/25/2023
[2] HSGAC Majority Staff Report. Accessed 6/29/2023
[3] Watanabe, J., McInnis, T., & Hirsch, J. (2018). Cost of Prescription Drug-Related Morbidity and Mortality. The Annals of pharmacotherapy, 52(9), 829-837. http://dx.doi.org/10.1177/1060028018765159 Accessed 6/26/2023
[4] GTMRx Blog. Accessed 6/29/2023

including Geisinger,[5] Kaiser Permanente,[6] Mayo Clinic,[7] and Johns Hopkins.[8] Nationally, within the Veterans Health Administration (VHA) - America's largest integrated health care system - clinical pharmacy specialists (CPS) hold scopes of practices that confer medication prescriptive authority and the responsibility to modify, start, stop and/or continue medications as per guideline recommendations, collaborative practice agreements, and the CPS' clinical judgment.
CPS have been systematically integrated into VHA Patient-Aligned Care Teams (PACT) to perform associated physical assessments, order lab tests, and initiate consults for other services. [9]

Drug shortages are also contributing to baseline shortages of health care workers, and limited staffing makes it difficult to respond to drug shortages. Hospitals have reported hiring dedicated staff whose only job is to monitor the market and to respond to drug shortages. Other providers may not have the resources to hire full-time employees and existing staff and may have to take on additional responsibilities in order to respond to shortages.[10]

Patients benefit from the delivery of CMM in terms of improved outcomes due to the increased individualized attention to medications and the role they play in the patient's therapeutic care plan. In addition, physicians and other care team members benefit when pharmacists apply their pharmacotherapeutic expertise in a collaborative process to help manage complex drug therapies.

In "getting the medications right," CMM directly contributes to enhanced productivity for the entire health care team, allowing all team members to fully focus on their own unique patient care responsibilities. A 2019 study in the Journal of the American Board of Family Medicine (JABFM) found that having clinical pharmacists offer comprehensive medication management (CMM) as part of the healthcare team led to improved physician work-life satisfaction, better healthcare quality, better access to care, and decreased workloads.[11]

Are there any guardrails that Congress should consider related to demonstration projects, including via the CMS' Innovation Center, that would help protect against drug shortages? Are there any proactive demonstrations that would prevent drug shortages?

The Medicare Part D drug benefit successfully expanded Medicare to include prescription medications in the early 2000s. The Medicare Part B program has long covered a limited number of physician-administered medications. However, Medicare has never had, and still lacks, a meaningful benefit to ensure that these expensive and complex prescription medications truly provide optimal value in improving patients' lives. We hope the time for that to change is now.

A significant number of the Merit-based Incentive Payment System (MIPS) performance measures established under the Medicare Access and CHIP Reauthorization Act (MACRA) directly relate to medication use. The CPC+ Program Year 2 Care Delivery Requirements administered by CMMI included access to CMM services for patients discharged from the hospital and those receiving longitudinal care management that would include the development of an individualized action plan addressing the patient's medication problem list, and a review of the plan with the primary care team.

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[5] Jones LK, Greskovic G, Grassi DM, Graham J, Sun H, Gionfriddo MR, Murray MF, Manickam K, Nathanson DC, Wright EA, Evans MA. Medication therapy disease management: Geisinger's approach to population health management. Am J Health Syst Pharm. 2017 Sep 15;74(18):1422-1435. doi: 10.2146/ajhp161061. PMID: 28887344.
[6] Witt, Daniel. (2008). The Kaiser Permanente Colorado Clinical Pharmacy Anticoagulation Service as a model of modern anticoagulant care. Thrombosis research. 123 Suppl 1. S36-41. 10.1016/j.thromres.2008.08.004.
[7] Peinovich M, Darracott R, Dow J. Developing pharmacy services in a home hospital program: The Mayo Clinic experience. Am J Health Syst Pharm. 2022 Oct 21;79(21):1925-1928. doi: 10.1093/ajhp/zxac200. PMID: 35896358; PMCID: PMC9384588.
[8] Maryland Primary Care Program (MDPDP): Participating Care Transformation Organizations (CTO) List. Accessed 1/25/2023
[9] GTMRx Institute CMM In Practice Case Example: William S. Middleton Memorial Veterans Hospital, Madison, WI. Accessed 6/25/23
[10] United States Government Accountability Office Report. Accessed 6/29/2023.
[11] The Journal of the American Board of Family Medicine July 2019, 32 (4) 462-473.

Clinical pharmacists are included as integrated team members in CMMI's Making Care Primary (MCP) Model - a 10.5-year CMMI multi-payer model with three participation tracks that build upon previous primary care models, such as the Comprehensive Primary Care (CPC), CPC+, and Primary Care First (PCF) models, as well as the Maryland Primary Care Program (MDPCP).

We would welcome the opportunity to share further information about the ongoing work of clinical pharmacists within CMMI's MCP model as reports become available.

Pharmacogenomics (PGx) allows clinicians to assess how a patient's genetic profile determines their responses to specific medications. Appropriate diagnosis and access to advanced diagnostics like PGx testing is essential to ensure safe and effective therapy for each patient. When applied as a component of CMM, PGx ensures that a patient's medications are individually assessed to determine that each is indicated, effective, consistent with patient expectations, and safe, in view of the comorbidities present, other concurrent medications, and the patient's ability to adhere to the prescribed regimen.

When integrated into CMM, PGx testing allows for targeted treatment decisions based on the unique characteristics of the patient's unique genetic profile. The integration of PGx within CMM reduces costs, improves outcomes and access to care, and enhances patient and provider quality of life and satisfaction. To ensure medication optimization, pharmacogenomics should be integrated into CMM.

"Cures 2.0" legislation (HR 6000) introduced during the 117th Congress includes Section 408: Medicare Coverage for Precision Medicine Consultations. Section 408 would require the Secretary of Health and Human Services (HHS) to create a pilot grant program within CMMI to test approaches to delivering personalized-medicine PGx consultations by qualified clinical pharmacists. We strongly support reintroduction of language in the 118th Congress to advance CMMI-led precision medicine initiatives.

We applaud your leadership for tackling these serious issues related to the growing crisis of drug shortages. We urge you to consider opportunities to advance payment policy to support the integration of team-based, medication optimization services, including the services of clinical pharmacists. CMM can help ensure that even when certain drugs are in short supply, hospitals, physicians, and pharmacists have the best possible tools available to identify and access safe, appropriate and effective pharmacological alternatives, and to minimize the risk of medication errors and adverse events that arise from potentially suboptimal treatment regimens.

We would welcome the opportunity to provide further information, data, and results from successful practices that provide CMM services.

Sincerely,

Director, Government Affairs

Cc: Michael S. Maddux, Pharm.D. FCCP, Executive Director