APhA
American Pharmacists Association

July 15, 2024

[Submitted electronically to physician_payment@cassidy.senate.gov]

The Honorable Sheldon Whitehouse
United States Senate
530 Hart Senate Office Building
Washington DC, 20510

The Honorable Bill Cassidy
United States Senate
455 Dirksen Senate Office Building
Washington DC, 20510

RE: Whitehouse and Cassidy Request for Information on Primary Care Provider Payment Reform

Dear Senators Whitehouse and Cassidy:

On behalf of the American Pharmacists Association (APhA), we would like to thank you both for your work to address inequities in Medicare beneficiaries' access to health care and to compensate health care professionals fairly. Pharmacists contribute to primary health care by providing a variety of health and wellness, medication management, and acute and chronic care management services. Pharmacists also increase access to care, especially in underserved areas, where 89%of Americans live within 5 miles of a pharmacy.[1] There is a significant opportunity for enhanced utilization of pharmacists in primary health care to address unmet care needs and improve patient health outcomes and experiences.

APhA is the largest association of pharmacists in the United States advancing the entire pharmacy profession. APhA represents pharmacists and pharmacy personnel in all practice settings, including physician offices, community pharmacies, hospitals, long-term care facilities, specialty pharmacies, community health centers, ambulatory clinics, managed care organizations, hospice settings, and government facilities. Our members strive to improve medication use, advance patient care, and enhance public health.

There is a plethora of examples of pharmacists practicing in primary care settings. The Department of Veterans Affairs (VA) has integrated more than 1,850 pharmacists into their patient-centered medical home (PCMH) model. VA has demonstrated that 27% of primary care return appointments could be averted by integrating a pharmacist, thus increasing access to care. Multiple VA studies show improvement in quality of care: significant reduction diabetes

[1] https://pubmed.ncbi.nlm.nih.gov/35965233/

metrics, such as a decrease in median A1c values to 7.7% from an A1c baseline of 10%, significant reductions in median systolic blood pressure and diastolic blood pressure from a baseline of 142/83 to 134/79.[2]

Pharmacists across the country practice within PCMH and accountable care organizations (ACOs). Within these settings, pharmacists often work in population health management, direct patient care services, or both. The peer-reviewed APhA resource, *Successful Integration of Pharmacists in Accountable Care Organizations and Medical Home Models: Case Studies*,[3] contains ten in-depth examples of pharmacist integration into team-based models in a variety of settings, including pharmacists' roles, types of services delivered, metrics pharmacists are impacting, and information on the financial models for supporting their work on the team.

The impact of pharmacists on outcomes for patients with chronic conditions is demonstrated in numerous studies.[4,5,6,7,8,9,10,11,12] Pharmacists are increasingly reaching out to their communities to provide services in locations such as churches, community centers, salons, and barbershops to meet patients where they live and work. Pharmacists, especially in community pharmacy settings, have an active role in providing prevention and wellness services, including assessment and administration of vaccines, conducting point-of-care testing, including Clinical Laboratory Improvement Amendments (CLIA)-waived tests for screening, test to treat services, and prescribing medications to meet public health needs under expanded scopes of practice such as naloxone for opioid overdose reversal, hormonal contraceptives, and human immunodeficiency virus (HIV) pre-exposure prophylaxis (PrEP) / post-exposure prophylaxis (PEP). Pharmacists also triage and refer patients to primary care providers based on screening and assessment services, when needed. All of these examples show the benefit of having pharmacists involved in primary care delivery.

Currently, pharmacists' services are not covered under Medicare Part B, however, many pharmacists practicing in primary care settings bill incident to physicians and other non-physician practitioners (NPP). However, there remains many opportunities to expand Medicare beneficiaries' access to care by leveraging pharmacists through innovative payment mechanisms. We would encourage you to consider the following comments and responses to the questions in your RFI:

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[2] https://accpjournals.onlinelibrary.wiley.com/doi/abs/10.1002/jac5.1177
[3] https://www.pharmacist.com/Portals/0/PDFS/Practice/APhA_Medical_Home_ACO_Report_Final.pdf
[4] https://www.nejm.org/doi/full/10.1056/NEJMoa1717250
[5] https://www.ahajournals.org/doi/full/10.1161/CIRCOUTCOMES.114.001283
[6] https://www.cdc.gov/dhdsp/pubs/docs/PPCP_Guide_June2021-508.pdf
[7] https://www.cdc.gov/dhdsp/evaluation_resources/guides/pharmacists_patient_care.htm
[8] https://psycnet.apa.org/doiLanding?doi=10.1037%2Ffsh0000185
[9] https://onlinelibrary.wiley.com/doi/10.1111/jep.13314
[10] https://www.tandfonline.com/doi/abs/10.1080/13561820.2019.1633289
[11] https://www.cdc.gov/dhdsp/pubs/docs/Best-Practices-Guide-508.pdf
[12] https://www.mcpiqojournal.org/article/S2542-4548(17

Hybrid payments for primary care providers:

- **How can Congress ensure we are correctly identifying the primary care provider for each beneficiary and excluding providers who are not a beneficiary's correct primary care provider or usual source of care?**

Congress should apply an attribution model to assign patients to their PCP. Congress must consider access to PCPs in specific geographic areas when attributing patients. For example, in many rural and underserved communities, the only local and accessible health care professional may be a pharmacist. Pharmacists in these communities often function as a PCP. Despite pharmacists functioning as PCPs in many communities, the current language in the proposed bill text (Sec. 3. Page 4. Line 18-20) does not include pharmacists in the definition of PCP and would limit their ability to participate in the hybrid primary care Medicare payment program. APhA recommends the inclusion of pharmacists in this definition to ensure that patients in rural and underserved communities can receive necessary care from their pharmacist.

- **How should the legislation address beneficiaries who routinely see two or more providers who could each plausibly be the "primary" care provider? For instance, a beneficiary who routinely visits both a family medicine provider and an OBGYN.**

Many pharmacists practice as members of interdisciplinary health care teams providing collaborative primary care services. Congress must implement an attribution program that can both identify when team-based care is being delivered *and* when individual professionals may be providing duplicative primary care services. To minimize unnecessary costs, patients should only be attributed to one PCP, but Congress and CMS must implement a program that can nimbly identify PCPs who may look different from one community to another *and* when a patient is receiving team-based care from an interdisciplinary health care team. As the example stated above, in some situations, pharmacists may be functioning as a patients' PCP and in other situations a pharmacist may be functioning as a member of an interdisciplinary health care team. Pharmacists in both situations must be fairly compensated for the care they are providing, and an attribution model is created that appropriately differentiates between these situations.

- **The legislation proposes to allow the HHS Secretary to define quality measures for hybrid payments and suggests four which may be pursued: (1) patient experience, (2) clinical quality measures, (3) service utilization, including measures of rates of emergency department visits and hospitalizations, and (4) efficiency in referrals, which may include measures of the comprehensiveness of services that the primary care provider furnishes.**
    - **Are these quality measures appropriate? Which additional measures should Congress be considering?**

APhA agrees these quality measures are appropriate for hybrid payments and represent necessary metrics to ensure patients are receiving timely and quality primary care services. However, they must ensure to attribute and reimburse pharmacists and other allied health professionals providing services that improve quality measures. Extensive published literature has proven that pharmacists positively contribute to these quality measures. Below are examples of studies highlighting the contribution pharmacists have made to these quality measures:

Patient Experience:

Evaluation of Patient Experience with Veterans Affairs Clinical Pharmacists Practitioners (CPP) Providing Comprehensive Medication Management[13]

> As patient experience is playing a larger role in assessing high-quality health care, the VA's pharmacist providers received a rating of 4 or 5 on a scale of 1 to 5 for comprehensive medication management (CMM) services in its first year. This high rating was demonstrated with scores ranging from the low to high 90th percentile across all patient experience domains.

Clinical Quality Measures:

A Cluster-Randomized Trial of Blood Pressure Reduction in Black Barbershops[14]

> At baseline, the mean systolic blood pressure (SBP) was >152 mmHg, and six months postintervention the mean SBP fell by 27 mmHg. A blood pressure level of less than 130/80 mmHg was achieved in 63.6% of barbershop patrons treated by a pharmacist in the intervention group versus 11.7% in the control group.

Cluster-randomized trial of a physician/pharmacist collaborative model to improve blood pressure control[15]

> The adjusted difference in mean systolic/diastolic blood pressure between the intervention, which included care by a pharmacist, and control groups for all subjects at 9-months was -6.1/-2.9 mmHg, and it was -6.4/-2.9 mmHg in subjects from racial or ethnic minorities. In addition, BP control and mean BP were significantly improved from minorities in intervention offices at 18 and 24 months ($P = 0.048$ to $P < 0.001$) compared with the control group.

Assessing the impact of medication management review service for females diagnosed with depression and anxiety[16]

[13] https://journals.sagepub.com/doi/abs/10.1177/08971900221117892
[14] https://www.nejm.org/doi/full/10.1056/NEJMoa1717250
[15] https://www.ahajournals.org/doi/full/10.1161/CIRCOUTCOMES.114.001283
[16] https://onlinelibrary.wiley.com/doi/epdf/10.1111/jep.13314

This single-blind, parallel randomized control trial showed medication management review services by pharmacists reduced treatment-related problems (TRPs), including adherence, in females with depression and anxiety. At baseline, the study population (n = 73, mean age 41.8) had 177 total TRPs identified, with 2.42 per patient, and 54.8% reported adherence. At follow-up, a significant decline in the number of TRPs was found in the intervention group versus the control group (0.58 versus 1.13, P< 0.001). Adherence was more likely in the intervention group, 88.9% vs 51.4% (P< 0.001). In addition, significant improvements in depression (P<0.001) and anxiety (P=0.003) were found in the intervention group treated by pharmacists.

The Impact of a pharmacist-driven, collaborative practice on diabetes management in an urban underserved population[17]

This mixed method assessment of a pharmacist-driven, collaborative practice on patients with Type II diabetes in a federally qualified health center showed significant improvement in hemoglobin A1C<9%, ACE inhibitor/angiotensin receptor and status use, and tobacco cessation at follow-up. Satisfaction from both providers and patients was also satisfactory. Pharmacists' services were rated by patients consistently >90% and were rated 9/10 or 10/10 97.4% of the time. Additionally, provider satisfaction was also high at 96% of the overall program.

Service utilization, including measures of rates of emergency department visits and hospitalizations

Three ways to advocate for the economic value of the pharmacist in health care[18]

The article summarizes the three themes identified in a literature search where pharmacist-provided care has shown a positive economic impact: decreased total health expenditures, decreased unnecessary care (e.g., fewer hospitalizations, emergency department visits, and physician visits), and decreased societal costs (e.g., missed or nonproductive workdays).

Efficiency in referrals, which may include measures of the comprehensiveness of services that the primary care provider furnishes

Comparison of pharmacists' scoring of fall risk to other fall risk assessments[19,20]

This cross-sectional study compared pharmacist-measured drug-associated fall risk versus different risk assessment measurements and found no significant difference between the Pharmacist Risk Score (PRS) and other fall risk assessments. Each fall risk assessment was highly correlated (P <0.001) with the number of reported falls and demonstrated that pharmacists' risk assessment is comparable to other assessments in

[17] https://www.tandfonline.com/doi/abs/10.1080/13561820.2019.1633289
[18] https://pubmed.ncbi.nlm.nih.gov/32863183/
[19] https://www.japha.org/article/S1544-3191(21)00467-2/abstract
[20] https://www.cdc.gov/steadi/pdf/Steadi-Implementation-Plan-508.pdf

distinguishing fallers from nonfallers. The Centers for Disease Control and Prevention (CDC) has developed the Steadi-Rx Older Adult Falls Prevention Guide for Community Pharmacists to promote pharmacists' involvement in screening, assessing, and coordinating care with other providers to prevent falls.

- **The legislation allows the Secretary to include four types of service in hybrid payments: (1) Care management services, (2) Communications such as emails, phone calls, and patient portals with patients and their caregivers, (3) Behavioral health integration services, and (4) Office-based evaluation and management visits, regardless of modality, for new and established patients.**
    - **Is this list of services appropriate?**

APhA agrees that this list of services is appropriate and is aligned with the quality measures described above. However, pharmacists must be included as eligible providers that can bill Medicare Part B directly for these services *and* barriers to pharmacists billing Medicare Part B incident to physicians and NPPs for these services must be addressed. As discussed, pharmacists' services are not currently covered for payment in Medicare Part B. In the Part B program, pharmacists are considered auxiliary personnel or clinical staff,[21] and some of their services are permitted by CMS to be billed by physicians and NPPs, under incident to physician or other practitioner service arrangements. Two CMS policies present barriers to pharmacist billing incident to physicians and NPPs, which hinder the ability to provide primary care services.

First, as detailed in the 2021 Physician Fee Schedule (PFS) final rule,[22] CMS categorizes pharmacists as "auxiliary personnel" or "clinical staff" and are not considered a "qualified health care professional" (QHP) due to there being no "Medicare statutory benefit allowing them to enroll, bill and receive direct payment for PFS services."[23] CMS also accepted Guideline Changes from a non-governmental entity that the lower-level evaluation and management (E/M) code 99211 is the only code available for time-based billing provided by clinical staff under Part B. The use of 99211 simply is not sustainable for clinical staff, such as highly trained pharmacists providing care to complex patients, who typically provide services with time commitments at the 99212-99215 levels, which essentially inhibits patients' access to high-quality team-based care that includes pharmacist-provided patient care services. Since these statements from CMS, physicians have been significantly challenged to utilize pharmacists to provide complex care services under an "incident to" relationship as E/M code 99211 reflects an average total time of 7 minutes. A growing number of state medical assistance programs, as approved by CMS through state plan amendments, include higher-level E/M office and other

[21] CMS. Medicare Program; CY 2021 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies. Published December 28, 2020. https://www.govinfo.gov/content/pkg/FR-2020-12-28/pdf/2020-26815.pdf. Accessed January 25, 2024.
[22] *ibid*
[23] *ibid*

outpatient services codes on their pharmacist fee schedule.[24,25,26] For example, pharmacists can bill Colorado Medicaid using an extensive list of current procedural terminology (CPT) codes including the entire E/M office or other outpatient services code set, 99202-99215.[27]

As APhA has emphasized in the past, it is not feasible that a pharmacist providing a 45-minute office visit to manage multiple chronic conditions and multiple medications for a Medicare beneficiary under an incident to arrangement with a physician would be limited to having the service billed as a Level 1 visit (99211), that only has an anticipated time commitment of 7 minutes—which has effectively eliminated any incentive and/or the ability for the majority of physicians/ NPPs and pharmacists to partner to provide complex health care services.

As CMS also stated in the 2021 final rule, "We understand and appreciate the expanding, beneficial roles certain pharmacists play, particularly by specially trained pharmacists with broadened scopes of practice in certain states, commonly referred to as collaborative practice agreements. We note that new coding might be useful to specifically identify these particular models of care." We recommend Congress include language that consider pharmacists as qualified healthcare practitioners (QHPs) and allows "auxiliary personnel" or "clinical staff" the ability to bill Medicare Part B 99202-99205 and 99212-99215 incident to physicians and NPPs that represents modern-day health care delivery to more accurately establish values for E/M services. Congress recently emphasized the following intention for federal funding at CMS regarding pharmacist-provided patient care services in the following:

Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations bill, 2025[28]

> "Pharmacists and Patient Care Services.—The Committee is aware that certain Medicare Part B services and care frameworks have provisions to include pharmacists and their patient care services. However, CMS has few mechanisms to identify and evaluate the contributions of pharmacists to patient care and outcomes or to identify barriers within current service requirements that prevent scalable involvement of pharmacists. *The Committee encourages CMS to create a mechanism to provide greater visibility into the scope and outcomes of the Medicare services currently provided by pharmacists [emphasis added].*"

Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations bill, 2023[29]

> "Pharmacist-Provided Incident to Physician Services.—The Committee is pleased with CMS's recognition in the calendar year 2021 physician fee schedule (PFS) final rule (FR 84583) that ''pharmacists could be considered QHPs [qualified health care professionals] or clinical staff, depending on their role in a given service,'' and that ''new coding might

[24] https://aws.state.ak.us/OnlinePublicNotices/Notices/Attachment.aspx?id=139383
[25] https://www.medicaid.nv.gov/Downloads/provider/NV_BillingGuidelines_PT91.pdf 20
[26] https://portal.ohmits.com/public/Public-Information/Fee-Schedules/Code/RPH/Format/HTML
[27] https://hcpf.colorado.gov/pharm-serv
[28] https://docs.house.gov/meetings/AP/AP00/20240710/117503/HMKP-118-AP00-20240710-SD002.pdf
[29] https://www.congress.gov/117/crpt/hrpt403/CRPT-117hrpt403.pdf

be useful to specifically identify these particular models of care.'' However, the Committee remains concerned with current CMS PFS requirements restricting physicians' and nonphysician practitioners' (NPPs) utilizing pharmacists under incident to models to bill at the lowest E/M code (99211), with an estimated time commitment of 7 minutes. The Committee understands this restriction has diminished providers' engagement with pharmacists in team-based care models across the country. *CMS should consider how to ensure physicians and NPPs can optimize the use of pharmacists. The Committee encourages CMS identify mechanisms to attribute, report, and sustain pharmacists' patient care contributions to beneficiaries in the Medicare Part B program [emphasis added]."*

Second, CMS policy sets supervision requirements for auxiliary personnel to bill Medicare Part B incident to a physician or NPP. Historically, CMS required direct personnel supervision which entailed the auxiliary personnel "have a relationship with the legal entity billing and receiving payment for the services" and the physician or NPP be "present in the office suite and immediately available to provide assistance and direction throughout the time the [auxiliary personnel] is performing services".[30] During the COVID-19 pandemic, CMS changed the definition of "direct supervision" related to physicians' services "to allow the supervising professional to be immediately available through virtual presence using two-way, real-time audio/video technology, instead of requiring their physical presence."[31] This change in the definition of "direct supervision" is currently scheduled to expire on December 31, 2024, and CMS is considering permanently addressing the definition of "direct supervision" in rulemaking in the future. APhA urges Congress to allow for virtual direct supervision of pharmacists when billing incident to physicians and NPPs.

APhA also encourages Senator Cassidy to join Senator Whitehouse in cosponsoring S.2477, the Equitable Community Access to Pharmacist Services Act (ECAPS) that would protect seniors access to pharmacist-provided patient care primary care services that saved millions of lives and avoided $450 billion by keeping seniors out of expensive emergency rooms.[32]

Thank you again for your work to address inequities in Medicare beneficiaries' access to health care and to compensate health care professionals fairly. APhA appreciates your consideration of our comments. If we can be of further assistance, please contact Doug Huynh, APhA, Director of Congressional Affairs at dhuynh@aphanet.org with any additional questions or to arrange a meeting with us.

Sincerely,

[30] CMS. Medicare Benefit Policy Manual Chapter 15 – Covered Medical and Other Health Services. Issued December 21, 2023. https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/bp102c15.pdf. Accessed January 25, 2024.
[31] CMS. Medicare and Medicaid Programs; CY 2024 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies. Published November 16, 2023. https://www.govinfo.gov/content/pkg/FR-2023-11-16/pdf/2023-24184.pdf. Accessed January 25, 2024.
[32] https://pubmed.ncbi.nlm.nih.gov/36202712/

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