



August 1, 2022

[Submitted electronically to OASHPrimaryHealthCare@hhs.gov]

RE: Office of the Assistant Secretary for Health Request for Information (RFI): HHS Initiative To Strengthen Primary Health Care

To whom it may concern:

The American Pharmacists Association (APhA) appreciates the opportunity to submit comments on the Request for Information (RFI) for the Health and Human Services (HHS) Initiative To Strengthen Primary Health Care.

APhA is the largest association of pharmacists in the United States advancing the entire pharmacy profession. APhA represents pharmacists in all practice settings, including but not limited to community pharmacies, hospitals, long-term care facilities, specialty pharmacies, community health centers, physician offices, ambulatory clinics, managed care organizations, hospice settings, and government facilities. Our members strive to improve medication use, advance patient care, and enhance public health.

Pharmacists make up the third largest health care profession and have the second most training behind physicians, graduating with a Doctor of Pharmacy (PharmD) degree. Some pharmacists pursue additional training through one to two-year pharmacy residency programs. With extensive training in the properties and appropriate use of medications, their application to acute and chronic disease management, and prevention and wellness services, pharmacists provide a variety of primary health care services, in coordination and collaboration with others in their communities. This includes: chronic condition management, especially where medications are a treatment modality; medication management services – optimizing medication regimens and addressing medication safety issues; coordinating medications during care transitions; providing patient education; delivering prevention and wellness services, including vaccinations and health screenings; conducting point-of-care testing; and treating minor illnesses, where authorized.

As one of the most accessible and trusted health care providers in their communities,¹ pharmacists have a significant role to contribute in optimizing primary health care and reaching underserved communities to meet health equity needs. Yet, pharmacists often seem to be overlooked by policymakers and others. The National Academies of Sciences, Engineering, and Medicine (NAM) report that will be used to inform the HHS plan, *Implementing High-Quality Primary Care: Rebuilding the Foundation of Health Care*,² acknowledges that, “it is surprisingly difficult....to describe the broader primary care workforce in detail, because national data

¹ Berenbrok LA, Tang S, Gabriel N, Guo J, Sharareh N, Patel N, Dickson S, Hernandez I, Access to Community Pharmacies: A Nation-Wide Geographic Information Systems Cross-sectional Analysis, *Journal of the American Pharmacists Association* (2022), doi: <https://doi.org/10.1016/j.japh.2022.07.003>.

² National Academies of Sciences, Engineering, and Medicine. 2021. *Implementing High-Quality Primary Care: Rebuilding the Foundation of Health Care*. Washington, DC: The National Academies Press.

neglect many professions, such as behavioral health specialists, pharmacists, health coaches, and others who make up interprofessional primary care teams.” Accordingly, APhA was extremely disappointed that the RFI neglected to mention pharmacists at all, and **strongly advocates that pharmacists’ contributions be acknowledged in the HHS plan, as well as other HHS initiatives.** Continuing to leave pharmacists out of public documents such as this RFI, creates significant barriers to awareness of, and optimizing pharmacists’ roles in improving patient health outcomes.

APhA and its members are aligned with the HHS goal state of the practice of primary health care, and APhA offers the following comments on the topic areas for feedback:

1. Successful models or innovations that help achieve the goal state for primary health care

Pharmacist prescribing of medications for public health needs

Nationwide, states are increasingly authorizing pharmacists to prescribe medications, primarily through statewide protocols, to meet public health needs, such as naloxone for opioid overdose prevention, HIV PEP/PrEP medications for HIV pre- and post-exposure prophylaxis, and oral contraceptives.³

COVID-19 vaccinations, testing, and treatments

During the COVID-19 pandemic, pharmacists have stepped up significantly to meet health needs in their communities. HHS has repeatedly recognized the important role that pharmacists play in addressing pandemic efforts by authorizing pharmacists to order and administer COVID-19 tests⁴ and recognizing pharmacies as points of care for COVID-19 testing services.⁵ In addition, HHS also has authorized pharmacists to order and administer COVID-19⁶ and childhood vaccines⁷ in states where this authority did not already exist—which has enhanced the position of community pharmacies and pharmacists as primary access points for patients to receive preventive immunizations and pharmacist-provided patient care services. It’s estimated that through June 2022, 255 million (43%) of U.S. COVID-19 vaccinations were given by community pharmacists and their teams, and this number is higher when pharmacists in other practice settings are added.⁸ Most recently, HHS authorized pharmacists to order and administer select COVID-19 therapeutics to ensure that more patients, especially those in underserved areas, can access these lifesaving treatments.⁹

Chronic condition management

Pharmacists collaborate with patients’ health care teams to provide chronic condition management services, either in embedded models where the pharmacist is co-located with physicians and other health care professionals, or in community pharmacies where pharmacists work virtually with other providers. Based on lessons learned during the pandemic, pharmacists are also developing relationships with public health departments, community-based organizations, and community health workers to address social determinants of health and focus on improving health equity. Using a whole person approach, pharmacists collaborate with

³ National Alliance of State Pharmacy Associations. <https://naspa.us/restopic/scope/>.

⁴ Office of the Assistant Secretary, “Guidance for Licensed Pharmacists, COVID-19 Testing, and Immunity under the PREP Act,” (April 8, 2020), available at: <https://www.hhs.gov/sites/default/files/authorizing-licensed-pharmacists-to-order-and-administer-covid-19-tests.pdf>

⁵ FDA. FAQs on Diagnostic Testing for SARS-CoV-2. Q: When FDA authorizes under an EUA a SARS-CoV-2 test for use at the point of care, does that mean it is CLIA waived? (Updated 5/9). Content current as of: 09/2/2020, available at: <https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/faqs-testing-sars-cov-2>

⁶ OASH. Guidance for Licensed Pharmacists and Pharmacy Interns Regarding COVID-19 Vaccines and Immunity under the PREP Act. September 3, 2020, available at: <https://www.hhs.gov/sites/default/files/licensed-pharmacists-and-pharmacy-interns-regarding-covid-19-vaccines-immunity.pdf>

⁷ HHS. Third Amendment to Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19. August 19, 2020, available at: <https://www.hhs.gov/sites/default/files/third-amendment-declaration.pdf>

⁸ CDC. COVID-19 Vaccinations in the United States. https://covid.cdc.gov/covid-data-tracker/#vaccinations_vacc-total-admin-rate-total.

⁹ HHS. Ninth Amendment to Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19. September 9, 2021, available at: <https://public-inspection.federalregister.gov/2021-19790.pdf>

patients to manage and optimize often complex medication regimens and monitor patient progress toward meeting clinical goals, thereby helping patients achieve better health outcomes for various conditions, such as diabetes, hypertension, cardiovascular disease, mental health conditions, and substance use disorders.^{10,11} APhA's *Successful Models for Pharmacist Integration into ACOs and Medical Homes: Case Studies*, provides examples on how pharmacists work in these models.¹²

2. Barriers to implementing successful models or innovations

Payment for pharmacists' primary care services: As stated in the NAM report, "The greatest challenge to integrating the role of the pharmacist in primary care relates to financing barriers..." Pharmacists and their services are not currently recognized in Medicare Part B, and coverage is variable in state Medicaid and private sector plans. Lack of payment to cover the pharmacist's time to deliver professional services is a significant barrier that must be addressed to fully utilize pharmacists as medication experts in primary health care. Another barrier related to sustainable models for pharmacists' services is in valued-based payment models. While APhA supports these models, many are still dependent on fee-for-service (FFS) payment as a component, and lack of FFS payment for pharmacists further complicates their involvement. In addition, pharmacists' documentation of patient care data is often not accepted or attributed in quality metric calculations, preventing their contributions to care from being fully recognized in these models.

Health information technology access: Another barrier for some pharmacists, especially those in community pharmacies, is electronic health record (EHR) access and the ability to send and receive clinical information needed for providing patient care. A salient example is FDA's recent authorization of pharmacists to prescribe the COVID-19 antiviral, Paxlovid with certain limitations.¹³ Pharmacists must have access to lab values to review a patient's renal status before prescribing. Having EHR access to this information would greatly streamline service delivery and help provide timely access to this medication for eligible patients.

3. Successful strategies to engage communities

The Centers for Disease Control and Prevention has created helpful frameworks for fostering linkages between clinicians and their communities that should be considered in the development of the HHS Plan.^{14,15} Pharmacists are increasingly moving beyond the four walls of pharmacies, clinics, and other health care settings to reach individuals in their communities, with a special focus on addressing social determinants of health that prevent optimal health outcomes. From a prevention and wellness perspective, during the pandemic, APhA engaged pharmacists working with underserved populations to participate in a Learning Collaborative that was focused on successful strategies for improving vaccine confidence and patient willingness to receive COVID-19 vaccines. Lessons learned were used to develop resources and stories that are

¹⁰ Centers for Disease Control and Prevention. The Pharmacists' Patient Care Process Approach: An Implementation Guide. Atlanta, GA: U.S. Department of Health and Human Services; 2021, available at: https://www.cdc.gov/dhds/pubs/docs/PPCP_Guide_June2021-508.pdf

¹¹ Get the Medications Right Institute. The Outcomes of Implementing and Integrating Comprehensive Medication Management in Team-Based Care: A Review of the Evidence on Quality, Access and Costs, December 2021. Available at: <https://16bvl028dn7zhgp35k7rzh5c-wpengine.netdna-ssl.com/wp-content/uploads/2020/11/Outcomes-of-Implementing-ED.v4-1.pdf>.

¹² American Pharmacists Association. Successful Integration of Pharmacists in Accountable Care Organizations and Medical Home Models: Case Studies. March 2020. Available at: https://pharmacist.com/Portals/0/PDFS/Practice/APhA_Medical_Home_ACO_Report_Final.pdf?ver=0vbHcscSN_2-3x3UmFLZ5Q%3d%3d.

¹³ Food and Drug Administration. Fact Sheet for Healthcare Providers: Emergency Use Authorization for Paxlovid. Available at: <https://www.fda.gov/media/155050/download>.

¹⁴ Centers for Disease Control and Prevention. Community-Clinical Linkages for the Prevention and Control of Chronic Diseases: A Practitioner's Guide. Atlanta, GA: Centers for Disease Control and Prevention, U.S. Department of Health and Human Services; 2016. <https://www.cdc.gov/dhds/pubs/docs/ccl-practitioners-guide.pdf>

¹⁵ Centers for Disease Control and Prevention. Creating Community-Clinical Linkages Between Community Pharmacists and Physicians. Atlanta, GA: Centers for Disease Control and Prevention, U.S. Department of Health and Human Services; 2017. <https://www.cdc.gov/dhds/pubs/docs/ccl-pharmacy-guide.pdf>

located on the APhA Vaccine Confident website (<https://vaccineconfident.pharmacist.com>) for pharmacists to access. A similar approach could be outlined in the HHS Plan to help address primary health care challenges in underserved communities.

There are also many models where pharmacists provide patient care in their communities for prevention and management of chronic disease. In Los Angeles, pharmacist-provided medication management services to black men with uncontrolled hypertension in black barbershops resulted in large reductions in blood pressure compared to primary care practices.¹⁶ Care was convenient for the patients and endorsed by the black barbers who were leaders in their communities. This model is being replicated in other areas of the country as a mechanism of extending reach to vulnerable populations.

4. Proposed HHS Actions

APhA proposes the following actions for HHS to take to advance the health of individuals, families, and communities through strengthened primary health care:

- Use regulatory authority and support legislative efforts (H.R.7213 & H.R.2759/S.1362) to implement financial coverage for pharmacists' patient care services so that pharmacists can contribute their expertise and access to meeting primary health care needs: **2-5 years (Payment)**
- Promote the many ways pharmacists can help to meet primary health care needs to foster awareness and engagement of pharmacists by key stakeholders in their communities, particularly in underserved communities: **<2 years (Service integration)**
- Identify mechanisms to support adoption of EHR capable systems in pharmacies and address pharmacists' needs to exchange critical clinical information: **<2 years (Interoperability)**
- Permit data from pharmacists' services to be included in quality measurement for value-based payment programs: **<2 years (Measurement of health care)**

Conclusion

Thank you for the opportunity to provide these comments in support of HHS's Initiative To Strengthen Primary Health Care. Pharmacists play a vital role in providing primary health care services, and through removal of barriers and HHS action, they can be further optimized to contribute to primary health care services. APhA would welcome the opportunity to work with HHS on this plan, including identifying pharmacists who could inform HHS' work. If you have any questions or require additional information, please contact Anne Burns, Vice President, Professional Affairs at aburns@aphanet.org.

Sincerely,



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Interim CEO and Executive Vice President

¹⁶ Victor RG, Lynch K, Li N, Blyler C, Muhammad E, Handler J, Brettler J, Rashid M, Hsu B, Foxx-Drew D, Moy N, Reid AE, Elashoff RM. A Cluster-Randomized Trial of Blood-Pressure Reduction in Black Barbershops. N Engl J Med. 2018 Apr 5;378(14):1291-1301. doi: 10.1056/NEJMoa1717250.