APhA
American Pharmacists Association

AMERICAN PHARMACISTS ASSOCIATION

STATEMENT FOR THE RECORD

BEFORE THE U.S. SENATE COMMITTEE ON HEALTH,
EDUCATION, LABOR AND PENSIONS

THE PATH FORWARD: BUILDING ON LESSONS LEARNED FROM THE COVID-19 PANDEMIC

TUESDAY, JULY 27, 2021

American Pharmacists Association

Chair Murray, Ranking Member Burr, and Members of the Committee, the American Pharmacists Association (APhA) is pleased to submit the following Statement for the Record for the U.S. Senate Health, Education, Labor and Pensions (HELP) Committee hearing, "The Path Forward: Building on Lessons Learned from the COVID-19 Pandemic."

APhA is the largest association of pharmacists in the United States advancing the entire pharmacy profession. APhA represents pharmacists in all practice settings, including 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.

APhA thanks the Committee for holding this important hearing as we face continuing threats from new COVID-19 variants and to prepare for and prevent future pandemics. During the COVID-19 public health emergency (PHE), pharmacists have demonstrated the ability to significantly expand access to care and equity in care, and they will continue to do so and more if regulatory and statutory barriers are removed. The pandemic has demonstrated how essential and accessible pharmacists are in the United States. Pharmacists and pharmacies' lights stayed on from the start of the pandemic and they are unquestionably essential components of public health infrastructure.

As you know, the fight against COVID-19 has demanded the federal government take action to allow pharmacists and other health care professionals to do more of what they are trained to do. By being more flexible about certain requirements and expanding scope of practice through new authorities, the federal government made it easier for pharmacists to provide care to patients during the COVID-19 PHE. The problem is many of these flexibilities and authorities are not considered permanent and further action is needed to expand access to pharmacist-provided services.

U.S. Department of Health and Human Services (HHS) Secretary Xavier Becerra recently extended by 90 days the federal PHE declaration, which was scheduled to end on July 20, 2021.[1] It will now expire on October 18, 2021, unless it is further extended. The PHE declaration has an important impact on patients' access to care. Many of pharmacists' temporary authorities authorized under the federal Public Readiness and Emergency Preparedness (PREP) Act, such

[1] https://www.phe.gov/emergency/news/healthactions/phe/Pages/COVID-19July2021.aspx

as COVID-19 testing and immunization, are set to remain in place until 2024.[2] However, HHS can repeal these temporary PREP Act authorities at any time and state pharmacist associations have already begun to encounter barriers to delivering these COVID-19 "covered countermeasures" in the states. For example, despite a clarification that federal authority for pharmacists to order and administer COVID-19 covered countermeasures remains in place under the PREP Act, irrespective of state laws or regulations,[3] several states have begun to impose barriers on the ability of pharmacists to provide COVID-19 point-of-care testing. While the Biden Administration has made it clear that COVID-19 testing to detect, diagnose, trace, and monitor infections and mitigate the spread of COVID-19 is a priority— NONE of the recent $1.6 billion announced[4] is going to community pharmacies.[5] In addition, several states' and other federal temporary COVID-19 practice authorities are tied to emergency use authorizations by the Food and Drug Administration (FDA) and the federal PHE declaration—in other words, when the PHE ends, many of these practice authorities would expire when the PHE is not renewed (e.g., flexibility to provide telehealth services, refill-too-soon edits, extended days' supply, home or mail delivery, prior authorization, signature log requirements, and in-person audits) and, unfortunately, many federal agencies, such as the Centers for Medicare and Medicaid Services (CMS), have already initiated regulatory actions moving in this direction. Congress needs to act immediately to make these temporary authorizations, whether authorized by the PREP Act or federal PHE, permanent to ensure patients will be able to receive the healthcare services they need at pharmacies across the country during the current and future PHEs.

Accordingly, APhA urges Congress to expeditiously use its authority to pass legislation to make permanent:

- **Pharmacists' ability to order, authorize, test, treat, and administer immunizations and therapeutics against infectious diseases;**
- **Removal of operational barriers that address workforce and workflow issues which previously prevented pharmacists from engaging in patient care;**
- **Including pharmacists under existing and future telehealth flexibilities; and**
- **Maintaining compounding flexibilities to address current and future drug shortages.**

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[2] https://www.phe.gov/Preparedness/legal/prepact/Pages/COVID-Amendment-6.aspx
[3] https://www.phe.gov/emergency/events/COVID19/COVIDvaccinators/Pages/COVID-and-Childhood-Vaccines.aspx
[4] https://www.hhs.gov/about/news/2021/07/22/biden-administration-invest-more-than-1-billion-support-covid-19-testing-mitigation-vulnerable-communities.html
[5] No funding for COVID-19 testing went to the Federal Retail Pharmacy program which includes a network of 40,000 pharmacies - https://www.cdc.gov/vaccines/covid-19/retail-pharmacy-program/index.html

Securing Ability of Pharmacists to Order, Authorize, Test, Treat, Immunize, and Provide Other Services

Many of these new authorities and flexibilities, including pharmacists' ability to order and administer COVID-19 and childhood vaccines and COVID-19, influenza, and respiratory syncytial virus (RSV) point of care tests, as well as pharmacy interns and technicians to administer COVID-19 tests and vaccinations to persons aged 3 years or older as well as childhood vaccines to individuals ages 3 to 18 years old authorized under the PREP Act should continue as they have significantly increased patient access and care.

Removal of Operational Barriers for Pharmacists

The COVID-19 pandemic has stressed and strained our healthcare system and revealed generations of health inequities in communities of color, medically underserved, and rural areas. In order to protect public health, detect and respond to future epidemics, and improve the equitable delivery of healthcare, every pharmacist needs to be able to support healthcare teams.

At the onset of the PHE, CMS encouraged insurance plans to practice flexibility regarding prior authorization protocols, refills, deliveries, and pharmacy audits. These practices have reduced the administrative burden on clinicians and allowed for more efficient patient care, testing, and vaccine delivery. Given the benefits to patients and the healthcare system, we recommend that Congress pass legislation to require all Medicare Advantage (MA) and Part D plans to continue offering these flexibilities to prevent decreased medication adherence in vulnerable populations, especially older adults and people of color. CMS has also issued policies relaxing Medicare Part D audit requirements for signature logs. Accordingly, we recommend Congress make the following policies permanent for MA, Part D plans and contracted pharmacy benefit managers (PBMs):

- Relaxing to the greatest extent possible prior authorization requirements, where appropriate;
- Suspending plan-coordinated pharmacy audits during any PHE; and
- Waiving medication delivery documentation and signature log requirements to limit unnecessary contact with sick and potentially infectious patients.

Including Pharmacists under Existing and Future Telehealth Flexibilities

The rapid shift to telehealth services during the COVID-19 PHE has illustrated the value of telehealth long-term, particularly for patients with mobility issues and those in rural and/or medically underserved areas. Prior to the PHE, pharmacists were already actively involved in virtual care delivery for Medicare beneficiaries through provision of Part B services such as Chronic Care Management (CCM), Transitional Care Management (TCM), Continuous Glucose Monitoring (CGM), Remote Patient Monitoring (RPM), and Behavioral Health Integration (BHI), as well as Medication Therapy Management Services in the Part D program. The onset of the COVID-19 pandemic has brought about additional opportunities to leverage pharmacists in telehealth services, including medication management services, chronic disease management, education on healthy lifestyle interventions, patient counseling on point-of-care diagnostic tests, and more. While CMS's recent Calendar Year (CY) 2022 Medicare Physician Fee Schedule Proposed Rule would continue a limited amount of these flexibilities for the short-term, (e.g., for mental health care services), Congress needs to act to make many of these changes permanent.

Accordingly, APhA recommends Congress take the following steps to enhance patient access to telehealth services:

- Make permanent the authority allowing direct supervision to be provided to pharmacists and other practitioners using real-time interactive audio and video technology under incident to physician services arrangements;
- Make permanent the authority allowing Medicare-enrolled pharmacies offering accredited diabetes self-management training (DSMT) programs to offer DSMT services via telehealth;
- Designate pharmacists as practitioners (providers) for the Medicare Telehealth Benefit, and add patient care services provided by pharmacists using telehealth to the Medicare Telehealth List;
- Ensure Medicare payment for pharmacist-provided telehealth and in-person services is commensurate with the time and complexity of the services provided;
- Allow for telephonic or video prescription counseling of patients to facilitate contactless care—including CMS's newly proposed Remote Therapeutic Monitoring (RTM) for "Therapy (Medication) Adherence;" and
- Make permanent Medicare coverage and payment of audio-only telephone calls for opioid treatment program therapy, counseling, and periodic assessments.

Maintaining Compounding Flexibilities to Address Current and Future Drug Shortages

Drug shortages are another factor that can negatively affect patients in terms of medication cost and the availability of their treatments. APhA urges the Committee to consider mechanisms to both better control the price of medications in shortage and improve tracking and prediction systems used to identify drugs in shortage. For example, FDA issued temporary guidance granting flexibility for pharmacists to compound certain necessary medications under 503A and 503B for hospitalized patients without patient-specific prescriptions to address COVID-19. Many of our members have told us FDA's compounding flexibility is the only reason hospitals were able to keep up with patient demand and the importance of this flexibility continues to rise due to the recent increases in hospitalization rates stemming from the COVID-19 variants. Accordingly, FDA's recent flexibility to compound medications under both sections 503A[6] and 503B[7] is likely to be necessary for the foreseeable future, and we strongly urge the Committee to pass legislation to codify this flexibility to address current and future drug shortages. We also believe maintaining stability within the supply chain during the global COVID-19 pandemic is crucial. Therefore, we also urge the Committee to focus on solutions that harness existing relationships with international trading partners to promote supply chain resiliency and diversity while avoiding measures that could undermine our ability to work with the international community.

S. 1362 / H.R. 2759, the *Pharmacy and Medically Underserved Areas Enhancement Act*

The COVID-19 pandemic has further illustrated how difficult it is for some patients living in medically underserved communities to access care and achieve optimal medication therapy outcomes.

A strong body of evidence has shown that including pharmacists on interprofessional patient care teams with physicians, nurses, and other health care providers produces better health outcomes and cost savings. Pharmacists are one of the most accessible health care providers in the nation, with nearly 90% of Americans living within five miles of one of the nation's 88,000 pharmacies.[8]

Despite the fact that many states and Medicaid programs are turning to pharmacists to increase access to health care, Medicare Part B does not cover many of the impactful and valuable patient care services pharmacists can provide. As proven during the COVID-19 pandemic,

[6] https://www.fda.gov/media/137125/download
[7] https://www.fda.gov/media/137031/download
[8] NCPDP Pharmacy File, ArcGIS Census Tract File. NACDS Economics Department.

pharmacists are an underutilized and accessible health care resource who can positively affect beneficiaries' care and the entire Medicare program.

Accordingly, APhA strongly urges the Committee to include S. 1362, the *Pharmacy and Medically Underserved Areas Enhancement Act*, recently introduced by Senators Charles Grassley and Robert Casey, in the Committee's legislative health care infrastructure package to allow pharmacists to deliver vital patient care services in medically underserved areas to help break down the barriers to achieving health care equity in this country, improve patient care, health outcomes, the impact of medications,[9] and consequently, lower health care costs and extend the viability of the Medicare program.

By recognizing pharmacists as providers under Medicare Part B, S. 1362 would enable Medicare patients in medically underserved communities to better access health care through state-licensed pharmacists practicing according to their own state's scope of practice. In medically underserved communities, pharmacists are often the closest health care professional and the most accessible outside normal business hours. S. 1362 recognizes that pharmacists can play an integral role in addressing these longstanding disparities to help meet health equity goals[10] and ensure that our most vulnerable patients have access to the care they need where they live. Helping patients receive the care they need, when they need it, is a common sense and bipartisan solution that will improve outcomes and reduce overall costs.

Conclusion

APhA would like to thank the Committee for holding this important hearing and for continuing to work with us by making key COVID-19 health care flexibilities permanent and including S. 1362 in your legislative healthcare infrastructure package to increase access to pharmacist-provided patient care services for medically underserved communities to promote health care equity. Please contact Alicia Kerry J. Mica, Senior Lobbyist, at AMica@aphanet.org or by phone at (202) 429-7507 as a resource as you consider this legislation. Thank you again for the opportunity to provide comments on this important issue.

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[9] *See,* Avalere Health. Exploring Pharmacists' Role in a Changing Healthcare Environment. May 2014, available at: http://avalere.com/expertise/life-sciences/insights/exploring-pharmacists-role-in-a-changing-healthcare-environment Also, *See,* Avalere Health. Developing Trends in Delivery and Reimbursement of Pharmacist Services. October 2015, available at: http://avalere.com/expertise/managed-care/insights/new-analysis-identifies-factors-that-can-facilitate-broader-reimbursement-o

[10] The White House. Executive Order On Advancing Racial Equity and Support for Underserved Communities Through the Federal Government. January 20, 2021, available at: https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/20/executive-order-advancing-racial-equity-and-support-for-underserved-communities-through-the-federal-government/