



March 18, 2020

The Honorable Nancy Pelosi
Speaker of the House
H-232, The Capitol
Washington, D.C. 20515

The Honorable Kevin McCarthy
House Minority Leader
H-204, The Capitol
Washington DC 20510

The Honorable Mitch McConnell
Senate Majority Leader
S-230, The Capitol
Washington D.C. 20510

The Honorable Chuck Schumer
Senate Minority Leader
S-221, The Capitol
Washington, D.C. 20515

RE: APhA Recommendations On Ways to Maximize the Use of Pharmacists to Prevent, Treat, Test and Respond to Coronavirus

Dear Speaker Pelosi, Minority Leader McCarthy, Majority Leader McConnell, and Minority Leader Schumer:

We are writing to support your efforts and to serve as a resource for Congress and the Administration in assisting both the federal and state governments to meet the public health challenges of the coronavirus. APhA has already issued preparedness and prevention guidance for pharmacists, patients and/or caregivers during the coronavirus pandemic, extending the reach of resources and information provided by Centers for Disease Control (“CDC”) and other reputable sources.¹ Pharmacists are well-positioned to provide information and educational resources related to coronavirus to the public. We can do more.

Under Section 1135 of the Social Security Act, the HHS Secretary may now temporarily waive or modify certain Medicare, Medicaid, and Children’s Health Insurance Program (“CHIP”) requirements to ensure that sufficient health care items and services are available to meet the needs of individuals enrolled in Social Security Act programs in the emergency area and time periods. It also allows providers who provide such services in good faith can be reimbursed and exempted from sanctions (absent any determination of fraud or abuse). **Accordingly, APhA urges Congress to include language in statute that directs the HHS Secretary to use the full authority of Section 1135 to maximize the use of pharmacists to prevent, treat, test and respond to the coronavirus.** America’s pharmacists stand ready and able to provide the patient care services necessary to help meet the public health needs created by the spread of the coronavirus (COVID-19).

APhA represents nearly 60,000 pharmacists, pharmaceutical scientists, student pharmacists, pharmacy technicians, and others interested in improving medication use and advancing patient care. APhA members provide care in all practice settings, including community pharmacies, specialty pharmacies, hospitals, long-term care facilities, community health centers, physician offices, ambulatory clinics, managed care organizations, hospice settings, and the uniformed services. APhA has a track record as a strong partner with the Department of Health and Human Services (“HHS”), CDC, Food and Drug Administration (“FDA”) and other agencies in

¹ APhA Issues Preparedness and Prevention Guidance During Coronavirus Pandemic. Press Release. March 6, 2020, available at: <https://www.pharmacist.com/press-release/apha-issues-preparedness-and-prevention-guidance-during-coronavirus-pandemic>

addressing public health needs of communities such as immunizations, emergency preparedness, substance use disorder/opioids, diabetes and other public health concerns.

In several states pharmacists currently have the training and authority to conduct influenza and group A *streptococcus* (“strep”) tests, providing either treatment or referral based on the results.² In addition, more than 360,000 pharmacists have been trained to administer vaccines across the lifespan.³ Pharmacists are trained to help to provide access points for care as the coronavirus test and vaccine becomes broadly available. Pharmacists are the most accessible health care provider and provide care and services in a wide variety of practice settings in communities across our nation – making them uniquely qualified to reduce clinical burdens and improve patient health. In fact, 90% of all Americans live within five miles of a community pharmacy.⁴ In addition to being medication experts, pharmacists also provide a broad array of services beyond dispensing medications, including disease state and medication management, smoking cessation counseling, health and wellness screenings, preventive services, and immunizations.⁵ Our members are well-situated to work collaboratively with HHS to intervene and provide meaningful services to curb the spread of the coronavirus and play an integral role in containment and mitigation.

To assist patients during this time, APhA supports Congress and the Administration’s efforts and issuing of guidance to health plans to reduce regulatory and payment barriers for prescription refills, the need for prior authorization, and home delivery. As you likely know, many pharmacies also provide prescription delivery services which will allow patients to stay at home if clinically advisable, thus minimizing disease transmission.

APhA offers the following additional immediate actions that Congress can take to help curb the looming crisis:

1. Allow Pharmacist Administration of the Coronavirus Test as a Rapid Diagnostic Test

Congress could enact legislation to expand public access to coronavirus testing through utilization of pharmacists to collect samples according to CDC guidelines for the currently available tests, and submit them to approved labs, interpret and communicate the results to patients, make appropriate referrals and guide patients on prevention and appropriate next steps. Once a rapid diagnostic coronavirus test is available for point of care testing, we encourage utilization of pharmacists to assess patients, conduct testing, interpret the results and provide available treatment or referrals, according to CDC guidance. This would align with what pharmacists are currently authorized to do in 17 states for strep throat or influenza.⁶ In Idaho, pharmacists are already authorized to prescribe products to treat strep and flu pursuant to a rapid diagnostic test and using an evidence-based protocol. Florida permits pharmacists to also test for strep and flu along with some skin conditions. Beyond statewide authority, many other states have collaborative practice authority (“CPA”) broad enough to allow pharmacists to order or administer laboratory tests pursuant to the terms of the CPA with a prescriber.

² NASPA. Pharmacist Prescribing: “Test and Treat.” February 8, 2019, available at: <https://naspa.us/resource/pharmacist-prescribing-for-strep-and-flu-test-and-treat/>

³ APhA 2019 Annual Report.

⁴ NCPDP Pharmacy File, ArcGIS Census Tract File. NACDS Economics Department.

⁵ Avalere. Exploring Pharmacists’ Role in a Changing Healthcare Environment. May 21, 2014, available at:

<https://avalere.com/insights/exploring-pharmacists-role-in-a-changing-healthcare-environment>

⁶ NASPA. Pharmacist Prescribing: “Test and Treat,” February 8, 2019, available at: <https://naspa.us/resource/pharmacist-prescribing-for-strep-and-flu-test-and-treat/>

In addition, once antiviral medications are approved and available to treat individuals with coronavirus, Congress should encourage states and payers to recognize and utilize pharmacists in the evaluation of patients and the prescribing of appropriate medications as it currently does in several states with antivirals to treat influenza. With these medications the timely prescribing and use of medications is critical for success.

2. Allow All Pharmacies to Receive a Certificate of Waiver and to Offer the Coronavirus Test as a Clinical Laboratory Improvement Amendments (“CLIA”)-waived Point-of-Care (“POC”) Test

In addition, under Medicare, a pharmacy may possess a CLIA Certificate of Waiver so that they may expand patient access to CLIA-waived tests and improve public health. For example, patients may come to a pharmacy that has a Certificate of Waiver and ask to obtain a CLIA-waived POC test for an infectious disease. One recent study involved pharmacists in three states, where pharmacists in waived pharmacies worked with a physician under a state-approved collaborative practice agreement (CPA) to help identify patients for an influenza POC test and subsequent identification and management of patients who tested positive for influenza.⁷ This model improves identification of patients with infectious conditions earlier, particularly for patients without a primary care provider or who are screened outside of regular clinic office hours and could serve a vital role in assisting to identify patients with the coronavirus and get them to appropriate treatments. Forty-four states allow for pharmacist POC testing for influenza and strep. Accordingly, APhA strongly recommends Congress and the Administration allow all pharmacies to receive a Certificate of Waiver, when appropriate, for the coronavirus point of care testing when it is available, thereby removing administrative barriers to test access. Offering the coronavirus test as a CLIA-waived point-of-care POC test for an infectious disease would assist the health system and medical providers in triaging patients. Congress should grant CMS the authority to ensure pharmacies and pharmacists are able to recoup both the costs associated with the CLIA-waived coronavirus test and the pharmacist’s time under this model.

3. Recognize and Utilize Pharmacists as Capable Vaccine Providers for the Coronavirus Vaccine When Available

Pharmacists are important members of the “immunization neighborhood” and improve patient access to vaccinations recommended by the CDC Advisory Committee on Immunization Practices (“ACIP”) across the lifespan. As a reminder, ACIP and CDC “...defines a health care provider as anyone who provides or administers vaccines: primary care physicians, specialists, physician assistants, nurse practitioners, registered nurses, and pharmacists.”⁸ Thanks to changes in state laws, pharmacists are playing an increasingly critical role in increasing influenza-vaccination rates across the United States, with an additional 4.1 million additional adults vaccinated in 2013 because states allowed pharmacists to administer the flu vaccine, which resulted in between 81,000-134,000 fewer influenza infections among adults in that year, depending on vaccine effectiveness. Additionally, the odds that an adult would receive the flu shot increased by 7.8 percent in states that allowed pharmacists to be immunizers.⁹ In addition to influenza vaccination, pharmacists administer vaccines across the lifespan in accordance with ACIP recommendations, as authorized by state laws and regulations. Congress should encourage and work with states to remove any barriers to pharmacists and other health care professionals’

⁷ ME Klepser, et al. Effectiveness of a pharmacist-physician collaborative program to manage influenza-like illness. J Am Pharm Assoc. 2016; 56:14-21, available at: <https://www.ncbi.nlm.nih.gov/pubmed/26802915>

⁸ CDC. ACIP Shared Clinical Decision-Making Recommendations. Frequently Asked Questions. Last reviewed: February 10, 2020, available at: <https://www.cdc.gov/vaccines/acip/acip-scdm-faqs.html>

⁹ Drozd EM, Miller L, Johnsrud M. Impact of Pharmacist Immunization Authority on Seasonal Influenza Immunization Rates Across States. Clin Ther. 2017 Aug 3. pii: S0149-2918(17)30771-3, available at: <https://www.ncbi.nlm.nih.gov/pubmed/28781217>

ability to access and administer coronavirus vaccine when it becomes available. In addition, Congress should direct CMS to require Part D and Medicare Advantage plans to recognize and compensate/reimburse pharmacists, as they do physicians and other immunization providers, and maximize the inclusion of pharmacists as in-network clinicians to provide the coronavirus vaccine when it becomes available. Furthermore, CMS should remove any barriers for pharmacists to be immunizers of the coronavirus vaccine, when available, whether under Part B or Part D. CMS permits an entity or individual, such as a pharmacist/pharmacy, who wishes to furnish mass immunization services, but may not otherwise qualify as a Medicare provider, to enroll as a “mass immunizer.” Currently, pharmacies as mass immunizers are restricted from billing Medicare for any services other than pneumococcal pneumonia vaccines (“PPVs”), influenza virus vaccines, and their administration.¹⁰ Accordingly, due to this public health emergency, Congress should direct CMS to immediately act to ease the requirements to become an immunizer and allow pharmacists and pharmacies to meet the demand for distributing the coronavirus vaccine once it becomes available, whether under Part B or Part D. In addition, CMS should require Part D sponsors to submit and CMS to aggregate data from Medicare Advantage (“MA”)-Prescription Drug (“PD”) and Part D plan sponsors to better monitor, measure and attribute the impact different providers, including pharmacists, have on coronavirus vaccination rates of Medicare beneficiaries and encourage private plans to do the same.

4. Remove Administrative Barriers that Impact Pharmacists Delivery of Care for Patient Preparedness

On March 12, 2020, APhA called on all of the nation’s health insurers and pharmaceutical benefit managers (“PBMs”) to immediately remove/waive any administrative barriers on pharmacists and patients for access to early medication refills from their pharmacy of choice to ensure patients have the medications necessary for chronic diseases to address their needs during the ongoing coronavirus pandemic.

We appreciate the steps already taken by some states and payers authorizing pharmacists to dispense emergency refills or waiving early medication refill limits on 30-day prescription maintenance medications, and the guidance in this area issued by the CDC and Department of Homeland Security. APhA also appreciates the recent actions taken by CMS reminding Medicare Advantage and Part D plans of their ability to: 1) remove prior authorization requirements; 2) waive prescription refill limits, and 3) relax the restrictions on home or mail delivery of prescription drugs.

However, Congress could direct HHS to help ease confusion by implementing uniform measures to ease the burdens on pharmacists and patients across the country. Without immediate changes to implement broad, system-wide authorization for early or emergency refills for chronic medications, patients may have to endure long waits at the pharmacy while the pharmacist addresses the administrative barriers. Not only does this frustrate patients and increase their risks of exposure in public places, but it challenges pharmacists’ ability to deliver patient care services.

In addition to all of the above, we urge Congress to help provide appropriate and effective protective equipment (N-95 masks, gloves, etc.) to pharmacists and other health care professionals providing direct patient care to individuals. This will address a significant concern

¹⁰ Centers for Medicare & Medicaid Services (CMS) Internet-only manual (IOM), Publication 100-08, Medicare Program Integrity Manual, Chapter 15, Section 15.4.6.2 -- Mass Immunizers Who Roster Bill. September 29, 2019, available at: <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/pim83c15pdf.pdf>

of providers who are serving the needs of their communities, and at the same time are concerned with spreading coronavirus to their own families.

Conclusion

Again, pharmacists stand ready and able to help. We look forward to working with you as well as the President's Coronavirus Task Force to intervene and provide meaningful services to meet the public health challenge created by the coronavirus – which can serve as an effective mechanism to combat additional public health emergencies in the future. If you have any questions, or if we can be of any assistance, please do not hesitate to contact Alicia Kerry J. Mica at amica@aphanet.org or 703.772.8962.

Sincerely,



Thomas E. Menighan, BSP Pharm, MBA, ScD (Hon), FAPhA
Executive Vice President and CEO

CC: The Honorable Charles Grassley, Chairman, U.S. Senate Committee on Finance
The Honorable Ron Wyden, Ranking Member, U.S. Senate Committee on Finance
The Honorable Lamar Alexander, Chairman, U.S. Senate Committee on Health,
Education Labor and Pensions
The Honorable Patty Murray, Ranking Member, U.S. Senate Committee on Health,
Education Labor and Pensions