



June 26, 2020

[Submitted electronically to [PANDEMICPREPAREDNESS@HELP.SENATE.GOV](mailto:PANDEMICPREPAREDNESS@HELP.SENATE.GOV)]

The Honorable Lamar Alexander  
Chairman  
U.S. Senate Committee on Health, Education, Labor and Pensions  
428 Dirksen Senate Office Building  
Washington, DC 20510

**Re: Preparing for the Next Pandemic - What the United States has learned from the past twenty years of public health preparedness and response and how it can better prepare for future pandemics - A WHITE PAPER**

Dear Chairman Alexander:

The American Pharmacists Association (APhA) appreciates the opportunity to submit the following comments in response to the White Paper “Preparing for the Next Pandemic.”

APhA, founded in 1852, represents 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, physicians’ offices, hospitals, long-term care facilities, specialty pharmacies, community health centers, managed care organizations, hospice settings, and the uniformed services.

APhA agrees with the following specific recommendations included in the White Paper:

- RECOMMENDATION 1.4: Engage and partner with the private sector early to develop diagnostic tests, ensure flexibility to develop and use laboratory-developed tests in a public health emergency, and ensure that the stockpile is better prepared to address diagnostic needs.
- RECOMMENDATION 2.1: Ensure timely communication between health professionals, states, the CDC, and the public, as appropriate, of case data and information regarding how emerging infectious diseases affect populations, including who is at higher risk for severe disease and death, to help inform state and local response and address any potential disproportionate impact on minority populations.
- RECOMMENDATION 2.2: CDC, states, and health professionals should work together to identify barriers to earlier identification of cases, including whether case definitions and testing recommendations were overly narrow for too long.

- RECOMMENDATION 3.2: States should establish distribution plans and procedures to better inform and communicate with health care providers that request supplies. The Strategic National Stockpile should provide states, territories, and tribes with guidance on best practices to coordinate and distribute medical supplies, including procedures to request resources from the federal stockpile.
- RECOMMENDATION 3.3: Require appropriate levels of personal protective equipment and ancillary medical supplies to be stockpiled and replenished, both at the federal and state level. Additionally, stockpiled supplies and countermeasures should more frequently and consistently utilize the shelf-life extension program to extend the life of a product in reserve or better identify the expiration of such products and plan to use those products before expiration.
- RECOMMENDATION 3.4: The federal government, states, and the private sector must work more effectively together to distribute tests, treatments, and vaccines. Plans should be established in advance for how the federal government, states, and the private sector will coordinate to assess needs and distribute newly developed tests, treatments, or vaccines.
- RECOMMENDATION 4.2: Ensure that the United States does not lose the gains made in telehealth.
- RECOMMENDATION 4.4: Remove red tape and allow states to use Public Health Emergency Preparedness and Hospital Preparedness Program funds to respond to a public health emergency and report back to HHS on how they were used, rather than having to wait for written approval from Washington.

## **I. Responses to the Questions:**

APhA offers comments on the following specific sections and questions posed in the White Paper:

### **Tests, Treatments, and Vaccines – Accelerate Research and Development**

- Q3: What could the federal government have done to be better positioned with diagnostics, vaccines, and treatments for COVID-19?

From the beginning of the public health emergency (PHE), the federal government and our nation’s patients would have benefitted from fully utilizing pharmacists to provide COVID-19 diagnostic testing, treatments and planning for the administration of vaccines. Pharmacists are medication experts and the most accessible health care providers, with close to 90% of the U.S. population living within 5 miles of a pharmacy<sup>1</sup>, and patients do not usually require an appointment to see their pharmacist. In fact, for many underserved Americans, pharmacists are the only health professional they can access. Pharmacists offer immediate care that is close and convenient to home, and they are a bridge between our communities and providers, triaging medication and health needs, recommending treatments and needed vaccinations, and

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<sup>1</sup> NCPDP Pharmacy File, ArcGIS Census Tract File. NACDS Economics Department.

administering patient care services, including vaccines, or referring patients for further follow-up care.

While COVID-19 testing is occurring now at some pharmacies, there are significant barriers to ramping up more testing capacity, including a clear pathway to payment for pharmacist testing services. A sustainable business solution for pharmacists and pharmacies must be established for all practice settings, particularly when point-of-care tests become more widely available.

Under the current pathways for pharmacist testing and payment outlined by the Centers for Medicare and Medicaid Services (CMS),<sup>2</sup> pharmacists are not paid for specimens collected at the pharmacy, which are necessary for completing a COVID-19 point of care test, or the assessment of test results, as physicians are currently reimbursed. CMS also has stated pharmacists can work with a physician or other practitioner to provide assessment and specimen collection services “incident to” the physician or other practitioner who can bill Medicare for these services. However, because almost all community pharmacists generally do not have “incident to” arrangements with physician practices that would allow their services to be billed, APhA is concerned that without a clear avenue to pay pharmacists for their services including patient assessment, specimen collection (including for/to rule out influenza virus and respiratory syncytial virus (RSV)), performing the test, interpreting the results, and reporting the results to the patient and appropriate authorities, the Administration’s stated public health goal of widespread and accessible testing in communities by pharmacists will not be achieved.

These barriers exist despite clear April 8, 2020 federal testing guidance from the HHS Office of the Assistant Secretary for Health (OASH) “authorizing licensed pharmacists to order and administer COVID-19 tests, including serology tests, that the Food and Drug Administration (FDA) has authorized.”<sup>3</sup> Furthermore, pharmacists have also encountered additional state barriers to testing which prompted a May 19, 2020 Advisory Opinion from the HHS Office of the General Counsel, which states “the PREP Act, in conjunction with the Secretary’s March 10, 2020 declaration, preempts any state or local requirement that prohibits or effectively prohibits a pharmacist from ordering and administering a COVID-19 diagnostic test that the Food and Drug Administration (FDA) has authorized.”<sup>4</sup> In short, despite federal guidance authorizing COVID-19 pharmacist testing, there remains no clear regulatory path to ensure payment for all the necessary and required services for all pharmacists and pharmacies to conduct COVID-19 testing for all patients.

Legislation would help provide clarity to ensure testing and administration of vaccines to improve access for Medicare beneficiaries in all communities. Congress can fill the gap by authorizing pharmacists as recognized Part B providers of testing and vaccination services to

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<sup>2</sup> CMS. MLN Matters. Medicare Pharmacies and Other Suppliers May Temporarily Enroll as Independent Clinical Diagnostic Laboratories to Help Address COVID-19 Testing. May 8, 2020, available at:

<https://www.cms.gov/files/document/se20017.pdf>

<sup>3</sup> OASH. OASH's 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>

<sup>4</sup> HHS. Office of the General Counsel. ADVISORY OPINION 20-02. May 19, 2020, available at:

<https://www.hhs.gov/sites/default/files/advisory-opinion-20-02-hhs-ogc-prep-act.pdf>

enable appropriate payment for these services. Without this statutory authority, APhA fears that many pharmacists and pharmacies may not be able to serve as COVID-19 testing sites. If this gap is filled at the federal level, typically, private payers will follow, further solidifying broader access to testing for our communities.

- Q4: How can the federal, state, and private sector work together to more effectively distribute and administer treatments and vaccines?

More than 360,000 pharmacists have been trained to administer vaccines across the lifespan and are integral members of the “immunization neighborhood.” To successfully achieve our nation’s COVID-19 and routine vaccination goals, providing protection against vaccine preventable diseases will take collaboration, coordination, and communication among all stakeholders in the federal, state, and private sectors. Given the success to date of pharmacists administering vaccines, serving as knowledgeable accessible immunization providers within their communities and their collaboration with public health and other providers, a successful vaccination plan must involve pharmacists. An all-hands-on-deck approach will be needed. The federal government should provide a clear plan for vaccine distribution and reimbursement for pharmacist-provided administration at our nation’s pharmacies to ensure rapid vaccination to align with the Administration’s goal to reopen our country to its full capacity for COVID-19 and future PHEs. With the right resources from the federal, state, and private sectors, pharmacists will dramatically expand access for COVID-19 vaccination and re-institute our nation’s routine immunization program.

Pharmacists are playing an increasingly critical role in increasing influenza vaccination rates across the United States with more than 25% of annual influenza vaccinations administered within pharmacies and more than 50% of shingles vaccines administered by pharmacists. As a result, an additional 4.1 million additional adults were 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.<sup>5</sup>

- Q8: How can the United States better leverage public-private partnerships, industry, and academic institutions?

The federal government should partner with all of our nation’s community pharmacies and pharmacists to expand access to vaccines and treatments for COVID-19. As stated above, legislation authorizing pharmacists as recognized Part B providers of testing and vaccination services to enable appropriate payment for these services would greatly expand access to vaccines and treatments for COVID-19. In addition, the Committee should provide sufficient grant funding with consultation from the American Association of Colleges of Pharmacies (AACP) to ensure pharmacist curriculums and training are updated to address COVID-19 and future PHEs, additional and future infectious diseases and emergency responses, and continuing education to ensure that clinicians already in practice are up-to-date on clinical and regulatory

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<sup>5</sup> 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>

changes to empower pharmacists to fully and effectively support our nation's COVID-19 and future PHE response and help ensure that patients get the treatment they need.

- Q9: What the lessons learned from the current fast tracking of tests, treatments, and vaccines to make them available even more rapidly?

As previously stated, Congress should ensure the federal government fully utilizes pharmacists to make more rapid point of care diagnostic COVID-19 tests available to the American public. Congress should provide additional resources and work with the FDA to focus on assisting with Emergency Use Authorizations (EUAs) for authorization of more rapid point of care COVID-19 tests that can be performed in pharmacies as a patient care setting operating under a CLIA Certificate of Waiver or Certificate of Compliance.<sup>6</sup> Additionally, Congress should instruct the Federal Emergency Management Agency (FEMA) to have an active plan to promptly distribute these rapid point of care tests to our nation's pharmacies.

### **Disease Surveillance – Expand Ability to Detect, Identify, Model, and Track Emerging Infectious Diseases**

- Q1: What other barriers, in addition to limited testing capacity, and insufficient and outdated technology, make it difficult to detect and conduct public health surveillance of emerging infectious diseases?

As mentioned above, limited testing capacity could be addressed by legislation authorizing pharmacists as recognized Part B providers of testing and vaccination services to enable appropriate payment for these services. The Committee should also take actions to ensure every pharmacy has access to FDA-approved rapid point of care tests to dramatically increase testing for diagnostic, serology, and antibody testing.

Insufficient technology is also a concern for many pharmacies, but access to interoperable systems that can share patients' clinical information represents an additional barrier to conducting public health surveillance of emerging infectious diseases. For example, under the law, every eligible clinician must attest that certified Electronic Health Record (EHR) technology used was “[i]mplemented in a manner that allowed for the timely, secure, and trusted bi-directional exchange of structured electronic health information with other health care providers,” [including pharmacists] (as defined by 42 U.S.C. 300jj(3))<sup>7</sup>, including unaffiliated providers, and with disparate Certified Electronic Health Record Technology (CEHRT) and HIT

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<sup>6</sup> FDA. FAQs on Diagnostic Testing for SARS-CoV-2. Content current as of: 05/18/20, available at: [https://www.fda.gov/medicaldevices/emergency-situations-medical-devices/faqs-testing-sars-cov-2?utm\\_campaign=2020-0509%20FAQs%20on%20Testing%20for%20SARS-CoV-2%20Update&utm\\_medium=email&utm\\_source=Eloqua#5eb6cee7077f9](https://www.fda.gov/medicaldevices/emergency-situations-medical-devices/faqs-testing-sars-cov-2?utm_campaign=2020-0509%20FAQs%20on%20Testing%20for%20SARS-CoV-2%20Update&utm_medium=email&utm_source=Eloqua#5eb6cee7077f9)

<sup>7</sup> See 42 U.S.C. 300jj(3) defining health care provider as “The term “health care provider” includes a hospital, skilled nursing facility, nursing facility, home health entity or other long term care facility, health care clinic, community mental health center (as defined in section 300x–2(b)(1) of this title), renal dialysis facility, blood center, ambulatory surgical center described in section 1395l(i) of this title,[1] emergency medical services provider, Federally qualified health center, group practice, **a pharmacist, a pharmacy** ... and any other category of health care facility, entity, practitioner, or clinician determined appropriate by the Secretary.” (emphasis added) Available at: <https://www.law.cornell.edu/uscode/text/42/300jj>.

vendors. However, pharmacists are frequently blocked from the exchange of relevant clinical information that is critical to maximize the benefit of coordinated team-based care, including public health surveillance; safe and appropriate medication use; adherence for the elderly and other populations; medication reconciliation; wellness and prevention; chronic disease management programs; and case management for beneficiaries with multiple medications that require complex medication dosing regimens. Therefore, APhA strongly recommends the Committee pass legislation requiring that pharmacists be granted access to relevant patient information through interoperable HIT and certified EHRs under Medicare to conduct public health surveillance of emerging infectious diseases. In particular, connecting patient care teams through interoperable technology is vital as pharmacists continue to play a much larger role in COVID-19 testing and in future PHEs. For example, in order to comply with the HHS new reporting requirements<sup>8</sup> to ensure that public health officials have access to comprehensive and real-time data to inform decision making in their response to the PHE. Enabling such reporting will better monitor disease incidence and trends by initiating epidemiologic case investigations, assisting with contact tracing, assessing availability and use of testing resources, and anticipating potential supply chain issues.

### **Stockpiles, Distribution, and Surges – Rebuild and Maintain State and Federal Stockpiles and Improve Medical Supply Surge Capacity and Distribution**

- Q2: How can states and hospitals improve their ability to maintain a reserve of supplies in the future to ensure the Strategic National Stockpile is the backup and not the first source of supplies during emergencies?

Congress can take action to improve the ability of states and hospitals to maintain a reserve of necessary medications, without tapping the Strategic National Stockpile as a primary source, by passing legislation codifying FDA's recently issued temporary guidance granting flexibility for pharmacists to compound certain necessary medications under 503A and 503B of the Drug, Quality and Security Act (DQSA) for hospitalized patients without patient-specific prescriptions to address COVID-19 to address shortages and access concerns affecting drugs urgently needed for hospitalized patients.<sup>9</sup> While there has been notable progress against COVID-19, new outbreaks have recently occurred across the country. Many of our members have told us FDA's compounding flexibility is the only reason hospitals were able to keep up with patient demand. Accordingly, the recent flexibility to compound medications under both sections 503A and 503B of the DQSA are likely to be necessary for the foreseeable future.

As this health crisis continues, pharmacies, wholesalers and manufacturers are experiencing or are likely to experience shortages of critical over-the-counter (OTC) products and FDA-approved prescription drugs, including those distributed to hospitals, clinics and doctors to administer to patients in a clinical setting. Compounding pharmacists stand ready to provide

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<sup>8</sup> HHS. HHS Announces New Laboratory Data Reporting Guidance for COVID-19 Testing. June 4, 2020, available at: <https://www.hhs.gov/about/news/2020/06/04/hhs-announces-new-laboratory-data-reporting-guidance-for-covid-19-testing.html>

<sup>9</sup> FDA. Temporary Policy for Compounding of Certain Drugs for Hospitalized Patients by Pharmacy Compounders not Registered as Outsourcing Facilities During the COVID-19 Public Health Emergency (Revised). Updated May 21, 2020, available at: <https://www.fda.gov/media/137125/download>

needed medications for COVID-19 treatment and drugs in shortage in the U.S. because of this global crisis. Compounding pharmacies can help meet the increased demands for these products to prevent and mitigate shortages. Accordingly, we urge the Congress to pass legislation that would codify the flexibility FDA has granted for pharmacists to compound medications in shortage under 503A and 503B for hospitalized patients without patient-specific prescriptions to continue to address COVID-19 and future PHEs. Congress should also expand this flexibility to any additional drugs in shortage for all medically necessary conditions. Permitting pharmacists to compound drugs for “office stock,” for all drugs in shortage during the pandemic will help ensure our nation’s hospitals and other providers have the medications they need without disruption, avoid the need to tap the Strategic National Stockpile, and allow our hospitals to focus their efforts on patient care.

- Q3: What steps should be taken to ensure that health care providers and first responders have the supplies they need, such as personal protective equipment?

During this pandemic, pharmacists have been on the front lines every day serving our patients as essential healthcare providers deemed critical to societal continuity. Many have done so without adequate access to personal protective equipment (PPE). If Congress acts to utilize all of our nation’s pharmacists and pharmacies to combat COVID-19 and future PHEs, it should also provide sufficient funding to supply our nation’s pharmacists with adequate PPE for initial infectious disease testing as well as secure supply chains to cement the fundamental role pharmacies will play as first responders.

### **Public Health Capabilities – Improve State and Local Capacity to Respond**

- Q1: What specific changes to our public health infrastructure (hospitals, health departments, laboratories, etc.) are needed at the federal, state, and local levels?

As stated above, despite clear federal testing guidance from the OASH “authorizing licensed pharmacists to order and administer COVID-19 tests, including serology tests, that the Food and Drug Administration (FDA) has authorized,”<sup>10</sup> pharmacists have also encountered additional state barriers to testing. Also, despite the HHS Office of the General Counsel opinion that states “the PREP Act, in conjunction with the Secretary’s March 10, 2020 declaration, preempts any state or local requirement that prohibits or effectively prohibits a pharmacist from ordering and administering a COVID-19 diagnostic test that the Food and Drug Administration (FDA) has authorized,”<sup>11</sup> state barriers to pharmacist testing still remain. For example, California’s existing state law will not let the pharmacist at a pharmacy act as the “qualified laboratory director,”<sup>12</sup> as defined by CMS, to get the Certificate of Waiver necessary to conduct the COVID-19 rapid point of care test. Various states have similar barriers. For example, pharmacists have had challenges

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<sup>10</sup> OASH. OASH’s 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>

<sup>11</sup> HHS. Office of the General Counsel. ADVISORY OPINION 20-02. May 19, 2020, available at: <https://www.hhs.gov/sites/default/files/advisory-opinion-20-02-hhs-ogc-prep-act.pdf>

<sup>12</sup> State of California. Important Information for California State Board of Pharmacy Licensees Related to COVID-19 Testing. May 12, 2020 available at: [https://www.dca.ca.gov/licensees/pharmacists\\_covid19\\_tests\\_guidance.pdf](https://www.dca.ca.gov/licensees/pharmacists_covid19_tests_guidance.pdf)

with gaining other licensed practitioner (OLP) status in states where Medicaid covers OLP services. Therefore, as previously mentioned, we urge Congress to pass legislation authorizing pharmacists as recognized Part B providers of testing and vaccination services to enable appropriate payment for these services. Congress should also require CMS to issue guidance clarifying this change to state Medicaid programs.

- Q2: What changes can be made to Public Health Emergency Preparedness and Hospital Preparedness Program to help states prepare and respond more quickly?

As previously mentioned, HHS helped expand the availability of COVID-19 tests on April 8, 2020, when the OASH issued official guidance declaring that licensed pharmacists are authorized under the Public Readiness and Emergency Preparedness (PREP) Act to order and administer FDA-authorized COVID-19 tests.<sup>13</sup> HHS further clarified the ability of pharmacists to respond to the current public health emergency on May 19, 2020, when HHS issued an Advisory Opinion explaining that the PREP Act preempts any state or local requirement that prohibits or effectively prohibits a pharmacist from ordering and administering FDA-authorized tests for COVID-19.<sup>14</sup>

To further help America rapidly recover from the pandemic, Congress should pass legislation to codify this guidance and direct HHS to issue a similar PREP Act Advisory Opinion authorizing pharmacists to provide COVID-19 vaccines and treatments to their patients. Every state allows pharmacists to administer vaccinations to their patients at varying degrees,<sup>15</sup> which is indicative of states' recognition that pharmacists are qualified to safely and effectively administer vaccines.<sup>16</sup> However, many states impose barriers that impede the ability of pharmacists to defeat the pandemic by broadly and rapidly vaccinating their patients when a vaccine become available. For example, some states only allow pharmacists to administer certain specified vaccines. Our national effort to stop the pandemic cannot wait while states go through the lengthy process of amending their laws or rules to list new COVID-19 vaccines. Other states prevent pharmacists (but not other providers) from vaccinating certain age groups, even when vaccines have been included in the ACIP vaccine recommendations and scheduled or FDA approved or authorized.

Widespread vaccination of the populace will be key to defeating the pandemic, so pharmacists should be authorized to vaccinate all age groups with vaccines approved or authorized by the FDA for COVID-19 and future PHEs, consistent with the FDA labeling or other instructions for use for such vaccines. In addition, several states do not allow pharmacists to administer a clinically appropriate vaccination, but instead require a prescription or other permissive authority

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<sup>13</sup> OASH. OASH's 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>

<sup>14</sup> HHS. Office of the General Counsel. ADVISORY OPINION 20-02. May 19, 2020, available at: <https://www.hhs.gov/sites/default/files/advisory-opinion-20-02-hhs-ogc-prep-act.pdf>

<sup>15</sup> Cason D., Schmit, JD, et al., Expanding State Laws and a Growing Role for Pharmacists in Vaccination Services, (published online Aug. 12, 2017), available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5704925/>.

<sup>16</sup> The federal government agrees. For years, pharmacists have served as Medicare “mass immunizers,” administering vaccines to millions of Medicare patients. See Medicare Learning Network, Roster Billing for Mass Immunizers (2019), available at [https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/Mass\\_Immunize\\_Roster\\_Bill\\_factsheet\\_ICN907275.pdf](https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/Mass_Immunize_Roster_Bill_factsheet_ICN907275.pdf).

from another health care provider or granted by the state.<sup>17</sup> No diagnosis is needed for a vaccination, so this barrier to pharmacist vaccinations needlessly requires many patients across the country to work with two health care providers to obtain clinically appropriate vaccinations. Pharmacists are trained and able to follow and implement CDC immunization guidelines.

Congress should not only expressly clarify authority for pharmacists to order and administer tests, treatment, and immunization across the country for COVID-19, but also codify authority for testing, treatment, and immunization across the country to address future pandemics.

### **Who Is on the Flagpole? – Improve Coordination of Federal Agencies During a Public Health Emergency**

- Q5: Have well-intended requirements and directives created too much bureaucracy and slowed federal response?

In summary, while well-intended, CMS’ regulations addressed several aspects of COVID-19 pharmacist testing, there still remains a large gap for pharmacists to provide increased capacity for testing across the U.S. because of the complicated CMS pathways for pharmacist payment for providing testing and pharmacist services. Specifically, CMS could not outline a testing program with direct payment for pharmacists’ services as Medicare providers because of current constraints in the law. To make pharmacist services more accessible, the law must change and pharmacists must be added as providers under section 1861 of the Social Security Act. Accordingly, Congress can fill the gap by authorizing pharmacists as recognized Part B providers of testing and vaccination services to enable appropriate payment for these services.

## **II. Additional Policy Considerations**

APhA submitted a response to the Chairman’s December 11, 2018 request for recommendations to help address America’s rising health care costs urging the HELP Committee to support passing the “*Pharmacy and Medically Underserved Areas Enhancement Act*,” last introduced in the 115<sup>th</sup> Congress as S. 109.<sup>18</sup> The *Pharmacy and Medically Underserved Areas Enhancement Act* would increase beneficiaries’ access to pharmacist-provided patient care services under Medicare Part B. Despite the fact many states and Medicaid programs are turning to pharmacists to improve patients’ health and outcomes and lower medication-related costs,<sup>19</sup> Medicare Part B does not cover pharmacist-provided patient care services even though pharmacists have the most medication-related education and training of any health care professionals.

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<sup>17</sup> Schmidt, Cason and Matthew S. Penn. Expanding State Laws and a Growing Role for Pharmacists in Vaccination Services J Am Pharm Assoc (2003). 2017 Nov-Dec; 57(6): 661–669. Published online 2017 Aug 12, available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5704925/>.

<sup>18</sup> See, American Pharmacists Association, *Recommendations to Help Address America’s Rising Health Care Costs*, February 27, 2019, available at: [https://www.pharmacist.com/sites/default/files/audience/APhA%20Comments%20to%20Senate%20HELP%20Committee%20RE%20Lowering%20Healthcare%20Costs%2002\\_27\\_2019.pdf](https://www.pharmacist.com/sites/default/files/audience/APhA%20Comments%20to%20Senate%20HELP%20Committee%20RE%20Lowering%20Healthcare%20Costs%2002_27_2019.pdf)

<sup>19</sup> CMS/ CMCS Informational Bulletin. State Flexibility to Facilitate Timely Access to Drug Therapy by Expanding the Scope of Pharmacy Practice using Collaborative Practice Agreements, Standing Orders or Other Predetermined Protocols. January 17, 2017. Available at: <https://www.medicaid.gov/federal-policy-guidance/downloads/cib011717.pdf>

As drugs become more expensive, complex, and personalized, the need to optimize their impact also increases. Almost 50% of patients with chronic diseases do not take their medications correctly.<sup>20</sup> In addition, the United States spends a possible \$672 billion annually on medication-related problems and nonoptimized medication therapy, including nonadherence.<sup>21</sup> Given millions of Americans do not have adequate access to health care and nearly 90% of Americans live within five miles of a community pharmacy,<sup>22</sup> APhA believes policies need to utilize pharmacists to stop perpetuating these access issues.

In 2018, 56 Senators signed onto S. 109 and the bill enjoyed the support of many bipartisan members of the HELP Committee. We continue to urge the Committee to include it in any final legislation to address the COVID-19 PHE, drug pricing, and health care costs.

APhA greatly appreciates your consideration of our recommendations and leadership to help our nation prepare and prevent the next pandemic. Together we can help you achieve the goal of optimizing testing and vaccination access by enabling our nation's pharmacists to respond to the mounting and immediate needs of those impacted by the COVID-19 pandemic. Please contact Alicia Kerry J. Mica, Senior Lobbyist, at [AMica@aphanet.org](mailto:AMica@aphanet.org) to arrange a meeting with APhA to discuss steps the Committee could take to recognize pharmacists as providers of COVID-19 testing and vaccination services to ensure access in all communities across the country.

Sincerely,



Ilisa BG Bernstein, PharmD, JD, FAPhA  
Senior Vice President, Pharmacy Practice and Government Affairs

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<sup>20</sup> Sabaté E, editor, ed. Adherence to Long-Term Therapies: Evidence for Action. Geneva, Switzerland: World Health Organization; 2003. Available at: <https://www.cdc.gov/chronicdisease/about/costs/index.htm>

<sup>21</sup> Watanabe, Jonathan H. Et. al. Cost of Prescription Drug-Related Morbidity and Mortality. Annals of Pharmacotherapy. First Published March 26, 2018. Available at: <http://journals.sagepub.com/eprint/ic2iH2maTdI5zfN5iUay/full>

<sup>22</sup> NCPDP Pharmacy File, ArcGIS Census Tract File. NACDS Economics Department.