

December 9, 2020

Dear Ms. Brooks-LaSure and Mr. Gordon:

As our nation continues to struggle with the COVID-19 pandemic and prepare for the largest mass immunization in history, a smooth transition between Presidential Administrations is more critical than ever. To assist the Biden Administration in preparing for day one, we have highlighted our nation's pharmacists' most pressing public health priorities and offered recommendations for addressing them.

Collectively, the undersigned groups represent America's 309,000 licensed, working pharmacists, as well as pharmacy technicians and student pharmacists. Our members are essential frontline workers, providing patient care in a variety of settings, including hospitals, clinics, health centers, community pharmacies, long-term care facilities, and physician offices. Pharmacists are the medication experts on the healthcare team – they now earn clinically-based doctor of pharmacy (Pharm.D.) degrees, and many complete postgraduate residencies and become board-certified in a variety of specialties. They also provide direct patient care services, including immunizations, disease state and medication management, smoking cessation counseling, health and wellness screening, and preventive services. Pharmacists are also the nation's most accessible healthcare professionals, with 90% of Americans living within five miles of a community pharmacy. In short, pharmacists are a linchpin of our nation's public health.

We would welcome the opportunity to meet with the appropriate members of your transition team to share expertise and offer our members' perspective on urgent public health concerns, from COVID-19 to the opioid epidemic. In the interim, we hope our recommendations will be useful during your transition planning. On behalf of our members, we stand ready to assist your team in combatting COVID-19 and improving health access and equity for all Americans.

I. Engage Pharmacists Immediately on Vaccine Distribution Plans

With the good news regarding COVID-19 vaccine efficacy data, the herculean task of distributing the vaccine throughout the country begins. To help prepare for vaccine distribution and administration, our organizations have participated in ongoing federal agency efforts, including 'Operation Warp Speed', HHS, CDC, and FDA discussions, and we have developed our own recommendations to supplement those efforts¹. By necessity, pharmacists will play an outsized role in the COVID-19 immunization process, from ordering and administration to overseeing delivery logistics. While the Trump administration has provided short term regulatory relief to allow pharmacists to administer the COVID-19 vaccine, it is imperative that the Biden administration include pharmacists and pharmacies, including those in rural and underserved communities, in all discussions related to allocation and distribution. As we learned during the initial efforts to roll out COVID-19 testing and to allocate and distribute drugs under Emergency Use Authorizations, these efforts will be extraordinarily detail-focused, and including pharmacists ensures that critical information will not be overlooked, thereby avoiding costly mistakes. We urge the Biden team to ensure that pharmacists from across the continuum of healthcare settings are represented in discussions, including any Advisory Groups, Task Forces, etc., from the outset.

¹ See, e.g., <https://www.ashp.org/-/media/assets/pharmacy-practice/resource-centers/Coronavirus/docs/ASHP-Principles-for-COVID-19-Vaccine.ashx?la=en&hash=8E0E4973769AC1D154C4780EE84DCC6751CE1845>.

II. Remove Barriers for Pharmacists to Fully Engage in Public Health

As highly-trained clinicians, pharmacists have the ability to significantly expand patient access to needed care and contribute to addressing/improving public health. However, major barriers restrict pharmacists from fully utilizing their expertise, such as lack of direct payment for services, including those necessary to support the COVID-19 response, and the inability to provide medication-assisted treatment (MAT) for opioid use disorder.

- Provide Direct Reimbursement for Pharmacists' Services: Despite their central role in the healthcare system, pharmacists are not currently eligible to participate in Medicare. As a result, direct reimbursement for pharmacist services is not available, undermining access to essential services, such as COVID-19 testing, in pharmacies. This lack of direct reimbursement impacts the financial sustainability of pharmacists' services and limits the ability of pharmacists to practice at the top of their license. Further, because the Centers for Medicare & Medicaid Services (CMS) does not directly oversee pharmacists under Medicare, the agency often inadvertently excludes pharmacists during rulemaking. To address this issue, we have crafted legislation, the *Pharmacy and Medically Underserved Areas Enhancement Act*, which would allow pharmacists to deliver care within their scope of practice to patients in federally defined medically underserved communities. This access is particularly vital to meeting patient and community needs during the public health emergency (PHE). We urge the Biden Administration to support the inclusion of this legislation in the next COVID-19 response package.
- Allow Pharmacists to Receive X-Waivers for MAT: One of the most insidious effects of the COVID-19 crisis is its impact on efforts to fight the opioid epidemic. At the same time patients are facing external stressors that can trigger relapse, the PHE has upended existing medication-assisted treatment (MAT) programs, which were already, in many cases, struggling to meet patient need. To expand access to MAT, we urge the Administration to direct its new Health & Human Services (HHS) Secretary to use the authority granted in the Comprehensive Addiction and Recovery Act (CARA) (P.L. 114-198) to revise the "qualifying other practitioner" requirements to allow for pharmacists to receive the requisite waiver (known as an "X- or DATA waiver") necessary to provide MAT services.² In the alternative, we urge the Administration to explore using the Public Readiness and Emergency Preparedness (PREP) Act authority to allow pharmacists who meet certain requirements to provide MAT services during the opioid public health emergency. At present, the exclusion of pharmacists from X-waiver eligibility has robbed patients of access to MAT at a time when demand for care far outstrips capacity.
- Inclusion of Pharmacists in the National Health Service Corps (NHSC): Currently, pharmacists are not eligible to participate in most of the NHSC student loan repayment programs, which are open to primary care clinicians in a Health Resources and Services (HRSA)-approved service site in a Health Professionals Shortage Area. An exception is the Substance Use Disorder Workforce Loan Repayment Program. We recommend that pharmacists be eligible for additional NHSC loan repayment programs.

² Physicians, nurse practitioners, and physician assistants are among the clinicians eligible to receive an X-waiver.

III. Retain the Current Flexibilities Provided During the PHE

During the PHE, to mitigate and prevent COVID-19, HHS and its subagencies instituted a number of regulatory flexibilities for pharmacists and other clinicians. Many of these flexibilities, including test-treat-immunize and telehealth models, should be made permanent, as they have significantly increased patient access without compromising patient care. Given the financial and human resources dedicated to scaling up these service models coupled with their patient access benefits, retaining them is a common sense approach to ensuring our healthcare system is ready for the next viral threat. In addition, payment for these services is imperative in Medicare, Medicaid, and other insurance.

- Permanently Authorize Pharmacists to Test-Treat-Immunize: We urge the Biden administration to use existing authorities and encourage states and Congress to implement or provide new authorities to permanently authorize pharmacists to test, treat, and immunize for COVID-19, influenza, and respiratory syncytial virus (RSV), and to provide pediatric immunizations to children over the age of three. Further, we urge CMS to codify practical reimbursement mechanisms and, where appropriate, exercise enforcement discretion, to ensure that all pharmacists and pharmacies have a sustainable mechanism to offer these services for all patients in all settings, including long-term care settings. Pharmacists are expertly trained healthcare practitioners, but they were previously only authorized to provide these types of services in specific states. CMS's recent guidance regarding COVID-19 testing and immunization and pediatric immunization has provided some consistent application across all states which is critical to public health. Further, this new flexibility allows community and ambulatory care pharmacists to address patient needs during the dangerous intersection of flu season and the current COVID-19 surge, relieving pressure on overwhelmed hospitals and health systems.
- Permanently Authorize Pharmacist Telehealth Flexibilities: The rapid shift to telehealth services during COVID-19 has illustrated the value of telehealth long-term, particularly for patients with mobility issues and those in rural and/or medically underserved areas. In order to accommodate the provision of telehealth services during the PHE, CMS relaxed its rule requiring physicians to provide "direct supervision" of auxiliary personnel, including pharmacists, in situation where direct supervision currently is required by regulation. In these situations, during the PHE, physicians may provide "virtual supervision" of pharmacists. Although pharmacists are fully capable and trained to provide pharmacist patient care services independently or under general supervision, the flexibility provided during the PHE, at the very least, should be made permanent regardless of whether there is a declared PHE. Virtual supervision of pharmacist services, where supervision is required, will help meet the growing demand for telehealth services, which will likely extend beyond the COVID-19 pandemic. Finally, to ensure telehealth services are financially sustainable, physicians and other qualified practitioners must be able to bill for pharmacist-provided telehealth services at a level commensurate with the time and complexity of the services provided when the service meets all applicable billing requirements.
- 1135 Waivers: As COVID-19 continues to surge and we embark on a nationwide mass immunization campaign, every pharmacist will be needed. The flexible workforce and workflow arrangements provided through 1135 waivers have been essential to supporting healthcare teams. These changes have contributed to a more nimble, responsive healthcare system during the PHE and would provide the same benefits when it ends, including flexibility in license portability and remote tasks. We recommend that the Biden administration use existing authorities and encourage states and Congress to implement or provide new authorities to

permanently allow pharmacists and pharmacy technicians with valid licenses to operate across state lines. Additionally, pharmacists and pharmacy staff should be allowed to permanently conduct routine pharmacy tasks remotely as necessary (i.e., prescription data entry and script verification, medication review and reconciliation), including those licensed outside of a state to ensure business continuity.

IV. Ensuring Medication Access and Affordability

Prior to the pandemic, patients were facing a medication affordability crisis. Unfortunately, this will remain an issue after we defeat COVID-19. We urge the Biden Administration to consider solutions that are tailored to reduce both patient out-of-pocket cost and systemic costs, while protecting our supply chain and patient access to medications and services.

- Improve Medication Accessibility: During the PHE, CMS has encouraged insurance plans to practice flexibility around prior authorization protocols, refills, deliveries, and pharmacy audits, which has reduced the administrative burden on clinicians and allowed for more efficient patient care. Specifically, CMS has recommended the removal of prior authorization requirements, waiver of prescription refill limits (e.g., for maintenance medications for well-controlled conditions), relaxation of restrictions on home or mail delivery of prescription drugs, and reprioritization of audit activities and reviews. Given the burden reduction of these flexibilities, we recommend that these flexibilities remain in place long term. Our organizations are concerned with the potential for decreased medication adherence in vulnerable populations, particularly amongst older adults, after the PHE ends, so proactive support for these flexibilities would ensure consistent access to medications in all settings.
- Safeguard the 340B Program: At a time when budgets are stretched thin, the federal 340B drug pricing program helps maximize federal resources while providing access to lifesaving medications and supporting patient services that might otherwise be unavailable. Absent discounts on 340B-purchased drugs, many covered entities and their contract pharmacies may struggle to keep their doors open, as they may be unable to absorb the cost of providing uncompensated care to the most vulnerable patients. CMS cuts to reimbursement for 340B Part B drugs and manufacturer actions to undercut the program, including unilateral cuts to contract pharmacies, threaten the program's stability. We strongly recommend that the Biden Administration take immediate action to safeguard the patient services and benefits enabled by 340B savings, including rescinding the CMS reimbursement cuts and intervening to ensure manufacturers comply with the law regarding contract pharmacies. Given the adverse impact of the pandemic on providers, they need every resource available to continue to care for their vulnerable and underserved communities.
- Lower Prescription Drug Costs: Pharmacies and the patients they serve have long had concerns about the adverse impact of certain pharmacy benefit manager (PBM) practices on prescription drug costs. These practices include the imposition of Medicare Part D pharmacy direct and indirect remuneration (DIR) fees, which are clawed back after the point of sale and lead to artificially high drug costs for seniors. According to the Centers for Medicare & Medicaid Services, the use of DIR fees exploded by 45,000 percent between 2010 and 2017. We believe any DIR fees, if assessed, should be applied only at the point-of-sale to stop inflated out-of-pocket drug costs for our nation's sickest seniors, pushing them into the donut hole at an

accelerated rate. We also believe it is vital to simultaneously standardize pharmacy performance measures in Medicare Part D. We urge your Administration to either support legislation to provide pharmacy DIR fee relief or to address this issue through rulemaking.

Additionally, we support efforts to reduce drug pricing while protecting the safety and security of our drug supply chain. Proposals to implement state importation of drugs from Canada and to tie drug prices to the prices paid by foreign countries remain a serious concern. The new HHS importation program will increase the risks of counterfeit or illegitimate product our system. Further, it will undercut efforts to institute a national drug tracking and tracing system, without any guarantee of significant cost savings. We also have concerns with the current proposal to tie drug prices to those paid by foreign countries includes a mandatory demonstration program that upends drug purchasing models without any precursor small-scale testing. We urge the Biden Administration to focus on solutions that improve pricing transparency and address the root causes of high drug costs.

Across the country, our members are providing essential patient care in community pharmacies, hospitals, health systems, physician offices, long-term care facilities, assisted living facilities, and other healthcare settings spanning the full spectrum of medication use. It is critical that post-COVID policy support the sustainability of accessible healthcare providers and practices that address the health care needs of individuals and communities in times of emergencies and beyond. Our members are on the front lines of the COVID-19 response and they have been a lifeline for patients seeking testing, immunizations, and medications. They are also the leaders in managing fragile drug supply chains on behalf of patients and the healthcare enterprise. We urge you to include their voice and expertise in decisions made by the Biden administration. To that end, we respectfully request a meeting with the Biden transition team to discuss how we can work cooperatively to improve public health and increase the diversity of the clinician workforce. We hope this initial meeting will create the foundation for open lines of communication, including a standing information-sharing meeting with HHS. We look forward to working with the Biden Administration to strengthen our healthcare system and improve patient quality and outcomes.

Sincerely,

**American Society of Health-System Pharmacists
College of Psychiatric and Neurologic Pharmacists
American Society of Consultant Pharmacists
National Alliance of State Pharmacy Associations
Accreditation Council for Pharmacy Education
National Community Pharmacists Association
American Association of Colleges of Pharmacy
American College of Apothecaries
Hematology/Oncology Pharmacy Association
American Pharmacists Association**