

April 19 2022

Dr. Ashish Jha
COVID-19 Response Coordinator
The White House Coronavirus Task Force

Dear Dr. Jha,

On behalf of our over 300,000 pharmacist, student pharmacist, and pharmacy technician members, we congratulate you on your appointment as the nation's new COVID-19 czar. Throughout the pandemic, our members have been critical providers of infectious disease testing, vaccination, and administration of COVID-19 monoclonal antibody treatments in pharmacies, hospitals and health systems, and long-term care and assisted living facilities. Despite the clear benefit of these pharmacist-provided services to patients and public health, challenges remain to maintaining them, both through the next phase of the pandemic and for future public health emergencies (PHEs). Below we have highlighted some the key threats to the continued engagement of pharmacist and pharmacy technicians in COVID-19 response.

- **Limited Ability to Engage in “Test to Treat” due to FDA Limitations:** As noted above, pharmacists have played a key role in COVID-19 testing and the subsequent dispensing of monoclonal antibody treatments. Most states authorize pharmacists to order medications, either independently or through collaborative practice with other providers, similar to what you may have observed at the Providence VA Medical Center. In September 2021, Secretary Becerra took an important step to expand patient access by authorizing pharmacists in all 50 states to order oral treatments for COVID-19 under the 9th Amendment to the Public Readiness and Emergency Preparedness Act (PREP) declaration. Unfortunately, the FDA specifically excluded pharmacist prescribers from the Emergency Use Authorizations (EUAs) for COVID-19 oral antivirals. This limitation is inconsistent with FDA's normally provider-neutral prescriber directives in approval and EUA decisions. In practice, the EUA limitation means that only pharmacies with an in-house physician, physician assistant or nurse practitioner can provide antiviral therapies – preventing many pharmacies from offering treatment. The agency provided no justification for preventing patients from accessing these drugs from their pharmacists. Absent a change to the EUA wording, pharmacists will be unable to provide timely access to antiviral medications, significantly limiting patient access and potentially resulting in treatment delays that reduce or eliminate antivirals' therapeutic benefit. Of note, other countries are engaging their pharmacists in COVID-19 treatment - pharmacists in Quebec are now authorized to prescribe the oral antiviral drug Paxlovid to symptomatic patients with COVID-19 who are at risk of developing complications and test positive for the virus.
- **Reimbursement for Testing, Vaccination, and Treatment of Uninsured Patients:** Federal funds covering testing, vaccination, and treatment of uninsured patients across all sites of care are running out. The provider contract agreement between HHS and pharmacies for COVID-19 services requires pharmacists to provide COVID-19 products (vaccination, testing, treatments, etc.) free of charge “regardless of the vaccine recipient's ability to pay.” However, since April 5, 2022, pharmacies are now expected to provide these services without the ability to file claims for services to uninsured patients, which is unsustainable. In a perfect world, reimbursement would not be a consideration. However, given the financial pressures pharmacies already face, particularly in rural and underserved areas, and the need to further stretch already overburdened staff to provide these services, it may be financially infeasible for many pharmacies to continue to offer these services without a clear reimbursement mechanism. While we recognize that Congress has authority over funding for uninsured patients, we urge you to advocate for congressional funding and want you to be aware

this situation jeopardizes patient access just as we begin providing the next round of COVID-19 booster doses, and potentially pediatric and annual vaccinations. The CDC needs to modify the provider agreement for COVID-19 services following HRSA's announcement on ending reimbursement or pharmacists will be severely challenged to continue to provide equitable access to COVID-19 vaccinations and services to one of our nation's most vulnerable patient populations, the uninsured.

- **Maintaining and Reimbursing PREP Act Services Provided by Pharmacists:** Pharmacists, as the nation's most accessible provider, are uniquely situated to offer vaccinations, as well as efficient testing and immediate initiation of time-sensitive, outpatient medication for COVID-19 and other viruses (e.g., influenza, RSV). The authority for pharmacists and pharmacy technicians to provide infectious disease testing, vaccination, and administration of COVID-19 therapeutics depends on HHS's use of the PREP Act. Unless the administration takes steps to make these authorities permanent, patient access to these pharmacist services will stop on the earlier of the final day the Declaration of Emergency or October 1, 2024, taking critical public health infrastructure away from our nation's patients. To ensure that the United States remains prepared for future COVID-19 surges as well as emerging viral threats, pharmacists must maintain the authority to provide these services outside of a PHE. Our organizations are advocating for the passage of federal legislation, the Equitable Community Access to Pharmacy Services Act (ECAPS), which would ensure patient access to these services during any future PHE. In the meantime, the HHS Secretary could clarify (or otherwise amend or extend) that the temporary pharmacist authorities under PREP Act declarations will remain in place until at least October 2024 and not be impacted by the lifting of the COVID-19 PHE.

Congratulations again on your appointment. Our organizations would welcome the opportunity to meet with you to discuss the key role pharmacists and pharmacies play in patient access during the COVID-19 response and in future PHEs. We have worked closely with your office in the past, sharing information from the front lines and flagging looming threats, and we look forward to continuing that collaboration as we work together to defeat COVID-19.

Sincerely,

American Society of Health-System Pharmacists (ASHP)
Academy of Managed Care Pharmacy (AMCP)
American Association of Colleges of Pharmacy (AACP)
American College of Apothecaries (ACA)
American College of Clinical Pharmacy (ACCP)
American Pharmacists Association (APhA)
College of Psychiatric and Neurologic Pharmacists (CPNP)
American Society of Consultant Pharmacists (ASCP)
National Alliance of State Pharmacy Associations (NASPA)
National Association of Specialty Pharmacy (NASP)
National Community Pharmacists Association (NCPA)
National Pharmaceutical Association (NPhA)
Society of Infectious Diseases Pharmacists (SIDP)