March 3, 2023

The Honorable Xavier Becerra
Secretary
U.S. Dept. of Health & Human Services
200 Independence Ave. SW
Washington, D.C. 20201

Dr. Ashish Jha
The White House
1600 Pennsylvania Ave. NW
Washington, DC 20500

Dear Secretary Becerra and Dr. Jha,

On behalf of our over 300,000 pharmacists, student pharmacists, pharmacy interns, and pharmacy technician members, we are writing to request the Administration take immediate action to ensure continued access to certain critical patient care services delivered by pharmacists under the COVID-19 public health emergency (PHE).

Throughout the pandemic, our members have been critical providers of infectious disease testing, vaccination, and administration of COVID-19 treatments, including monoclonal antibody therapeutics, in pharmacies as well as hospitals and health systems. They have also played an essential role in maintaining patient access to chronic disease care and other non-COVID-related services.

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. As we transition into a post-PHE world, below we have highlighted some of the key threats to the continued engagement of pharmacists, pharmacy technicians, and pharmacy students in both COVID-19 treatment and vital patient care services.

- **Reimbursement for Testing, Vaccination, and Treatment of Uninsured Patients**: Federal funds covering testing, vaccination, and treatment of uninsured patients across all sites of care have run out. The provider contract agreement between U.S. Department of Health & Human Services (HHS) and pharmacies for COVID-19 services requires pharmacists to provide COVID-19 products (vaccination, treatments, etc.) free of charge "regardless of the vaccine recipient's ability to pay." However, since April 5, 2022, pharmacies are expected to provide these services without the ability to file claims for uninsured patients, which is fiscally 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 will 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 funding and to reallocate available federal resources to ensure continued patient access to these vital services and avoid major care gaps and community vulnerability for future public health events.

- **Maintaining and Reimbursing Pharmacist-Provided Services Under the PREP Act:** Pharmacists, as the nation's most accessible healthcare 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 federal authority for pharmacists and pharmacy technicians to order and perform infectious disease testing, administer vaccines, and administer certain COVID-19 therapeutics depends on HHS's amendments to the COVID-19 Prep Act Declarations. Unless the Administration takes steps to make these authorities permanent, patient access to these pharmacist services will end on October 1, 2024, taking critical public health infrastructure away from our nation's patients. To ensure that the nation remains prepared for future COVID-19 surges as well as emerging viral threats, as a permanent part of our nation's public health infrastructure, pharmacists must maintain the authority to provide these services outside of a PHE. Our organizations are advocating for the passage of federal legislation that would ensure patient access to these services during any future PHE. During the pandemic, many states expanded their state scope of practice to ensure pharmacists, pharmacy interns, and pharmacy technicians could provide these services – to avoid creating a patchwork of coverage, we strongly urge the Administration to explore all avenues to ensure these services continue to be supported at the federal level.

- **Permanently Maintain and Enhance Telehealth Flexibility**: We recommend that the Centers for Medicare & Medicaid Services (CMS) make telehealth flexibilities permanent, including allowing all Medicare beneficiaries access to telehealth services and loosening the telehealth origination site requirements. Although we recognize that the Consolidated Appropriations Act of 2023 extended these flexibilities beyond the PHE's end, it is critical that CMS make them permanent through rulemaking. The growth of telehealth services during the pandemic 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 assure the broadest possible patient access and the highest quality services, we further recommend that CMS take the following steps:

    - *Permanently Allow Direct Supervision To Be Provided Virtually*: During the PHE, in order to accommodate the provision of telehealth services, CMS has relaxed its rule requiring physicians to provide "direct supervision" of auxiliary personnel. Pursuant to the temporary regulatory flexibility, physicians may provide "virtual supervision" of auxiliary personnel. Physicians should be empowered to supervise clinical staff virtually, at their discretion, regardless of whether there is a declared PHE.

      Allowing physicians and auxiliary personnel to provide services from two separate locations supports the expansion of telehealth services and protects frontline workers in periods of high viral spread, which will likely continue to be an issue even post-PHE. Therefore, we ask that CMS provide permanent authority for direct supervision to be provided virtually in order to meet the growing demand for telehealth services.

- **Protecting Access to Treatment for Opioid Use Disorder:** Our organizations appreciate the Administration's efforts to improve access to medications for opioid use disorder (MOUD). During the pandemic, the Substance Abuse and Mental Health Services Administration (SAMHSA) and Drug Enforcement Administration (DEA) provided flexibilities allowing initiation of buprenorphine treatment via telephonic visit and providing opioid treatment programs with authority to dispense take-home doses of methadone to patients rather than requiring daily

visits to receive medication. As demand for MOUD treatment continues to far outstrip patient access to these services, we strongly support SAMHSA and DEA proposals to make these flexibilities permanent, maximizing the use of pharmacists, and urge the agencies to finalize these proposals as soon as possible.

- **Maintaining Hospital-at-Home Programs:** We recognize that the Hospital-at-Home (HAH) program is supported by waivers related to the PHE and that Congress has extended those waivers for an additional two years, but we encourage the Administration to take all possible regulatory steps to make the program permanent immediately. Specifically, should CMS not possess sufficient regulatory authority to continue the program as is, we urge the agency to consider alternative options, such as funding it as a Centers for Medicaid and Medicare Innovation (CMMI) program until Congress provides statutory authority. Although the HAH program was rolled out broadly during the PHE to expand hospital resources, studies show that even under normal conditions the HAH model can improve outcomes while decreasing systemic costs.[1] Given the resources invested in creating HAH programs, failing to maintain them post-PHE would be a missed opportunity for our healthcare system.

We respectfully request that HHS clarify all of the above in a writing, perhaps similar to what CMS did in its policy paper: *Medicare Advantage and Part D Plans: CMS Flexibilities to Fight COVID-19*.[2] Our organizations would welcome the opportunity to meet with you to discuss the key role pharmacists, pharmacy personnel, and pharmacies play in patient access during the COVID-19 response and in future public health emergencies. We have worked closely with your office in the past, sharing information from the front lines and flagging looming public health threats, and we look forward to continuing that collaboration as we work together to address COVID-19 and other public health challenges.

Sincerely,

American Association of Colleges of Pharmacy

American Association of Psychiatric Pharmacists

American College of Clinical Pharmacy

Academy of Managed Care Pharmacy

American Society of Consultant Pharmacists

American Society of Health-System Pharmacists

Hematology/Oncology Pharmacy Association

National Alliance of State Pharmacy Associations

National Community Pharmacists Association

Society of Infectious Diseases Pharmacists

[1] *See, e.g.,* Geneviève Arsenault-Lapierre, PhD; Mary Henein, MSc; Dina Gaid, PhD; Mélanie Le Berre, MSc; Genevieve Gore, MLIS; Isabelle Vedel, MD, PhD, "Hospital-at-Home Interventions Versus In-Hospital Stay for Patients with Chronic Disease Who Report to the Emergency Department," HEALTH POLICY (June 8, 2021), *available at* https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2780783.

[2] Available at: Medicare Advantage and Part D Plans: CMS Flexibilities to Fight COVID-19,

CC: Dr. Thomas Tsai, Senior Policy Advisor for the COVID-19 Response, Testing and Treatment Coordinator White House COVID-19 Response Team

The Honorable Dawn O'Connell, JD, Assistant Secretary for Preparedness and Response (ASPR)

The Honorable Chiquita Brooks-LaSure, Administrator, CMS