August 19, 2022

Robert Fenton, White House National Monkeypox Response Coordinator Demetre Daskalakis, MD, White House National Monkeypox Response Deputy Coordinator U.S. Department of Health and Human Services 200 Independence Ave., Washington, DC 20201

RE: Request to amend the declaration of a monkeypox Public Health Emergency to identify pharmacists, pharmacy students and pharmacy technicians as qualified persons covered under the PREP Act

Dear Mr. Fenton and Dr. Daskalakis.

In the two weeks since HHS Secretary Xavier Becerra announced the Biden Administration declaration of a public health emergency (PHE) for the monkeypox outbreak (Clade one (I) and Clade two (II) strains), the case count nationwide has more than doubled—to more than 14,115 cases and growing. To ensure timely access to testing, vaccines and therapeutics for monkeypox, our organizations, who represent the majority of the nation's 300,000 pharmacists in all sites of care, strongly recommend that HHS issue a Public Readiness and Emergency Preparedness (PREP) Act declaration that pharmacists, pharmacy students and pharmacy technicians, as appropriate, can order and administer FDA authorized or approved monkeypox vaccines, testing and therapeutics.

Pharmacists continue to stand ready and able to help prevent the spread of monkeypox. While many states allow pharmacists the authority to administer the monkeypox vaccines, 12 states and the District of Columbia lack clear authority or have barriers for pharmacists to administer the monkeypox vaccines.

As you know, pharmacists are the most accessible health care providers with close to 90% of the U.S. population living within 5 miles of a pharmacy, and patients do not typically require an appointment to see their pharmacist. This strategic position allowed pharmacists to safely and effectively administer more than 260 million doses of the COVID-19 vaccine as of August 4th, 2022. In doing so, pharmacists have been able to serve as patient educators and vaccination promoters; procure and use proper personal protective equipment (PPE); and competently administer vaccines to patients in a variety of traditional and nontraditional settings. When patients seek to access care from a pharmacist, requiring the pharmacist to direct them to another provider for testing, immunization or treatment creates unnecessary delays in care that can adversely impact the effectiveness of therapy. To ensure pharmacists are able to expand patient access as monkeypox testing, vaccine and therapeutic supplies increase, we urge you to proactively authorize pharmacists to order and administer monkeypox testing, vaccines and therapeutics.

We look forward to receiving specific authorization from HHS that pharmacists, pharmacy students and pharmacy technicians, as appropriate, can order and administer FDA authorized or approved monkeypox vaccines, testing and therapeutics under the PREP Act. Our organizations also urge HHS to proactively coordinate with payers, including Medicare and Medicaid, to ensure adequate reimbursement is available to support access to these services when provided by pharmacists.

Sincerely,

American Pharmacists Association (APhA)

American Association of Colleges of Pharmacy (AACP)

American Association of Psychiatric Pharmacists (AAPP)

American College of Apothecaries (ACA)

American College of Clinical Pharmacy (ACCP)

Academy of Managed Care Pharmacy (AMCP)

American Society of Consultant Pharmacists (ASCP)

American Society of Health-System Pharmacists (ASHP)

FMI – The Food Industry Association

Hematology/Oncology Pharmacy Association (HOPA)

Society of Infectious Diseases Pharmacists (SIDP)

National Alliance of State Pharmacy Associations (NASPA)

National Association of Specialty Pharmacy (NASP)

National Community Pharmacists Association (NCPA)

cc: David Boucher, PhD, Director, Infectious Disease Preparedness and Response, ASPR Peter Marks, MD, PhD., Director, Center for Biologics Evaluation and Research (CBER), FDA

Hilary Marston, MD Chief Medical Officer, FDA

Katherine Alvarez, Chief of Staff, ASPR

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

The Honorable Xavier Becerra, Secretary, HHS