October 28, 2021

[Sent electronically] Xavier Becerra Secretary U.S. Department of Health and Human Services 200 Independence Ave., S.W. Washington, D.C. 20201

RE: Employing the PREP Act to Improve Patient Access to Time-Sensitive Influenza Therapies

Dear Secretary Becerra:

On behalf of our more than 200,000 pharmacy, pharmacist, student pharmacist, and pharmacy technician members, we applaud the U.S. Department of Health & Human Services' (HHS) use of the Public Readiness and Emergency Preparedness (PREP) Act to increase patient access though order and administration of infectious disease testing, vaccination, and COVID-19 therapeutics by pharmacies and pharmacists. Throughout the COVID-19 pandemic, pharmacists have been a vital point of patient access to and provider of these critical services. With the SARS-CoV-2 virus still circulating as we approach peak influenza season, we urge the HHS to protect public health by utilizing the PREP Act to allow pharmacists to provide patients with rapid access to time-sensitive testing and antiviral therapies for influenza.

Public health experts across the United States have been expressing increased concern that a resurgence of COVID-19 and influenza could create an urgent need for influenza antiviral therapy during the coming winter months. Last year, influenza levels decreased dramatically, largely due to COVID-19 mitigation measures such as handwashing, masking and social distancing. Relaxation of those measures this summer resulted in an unusually high number of viral respiratory illnesses, including influenza and respiratory syncytial virus (RSV). With more activities moving indoors during the winter months, the potential for continued co-circulation of influenza and the SARS-CoV-2 virus remains high.

Co-circulation of influenza and SARS-CoV-2 this fall and winter is likely to necessitate a substantial increase in access to testing and time-sensitive antiviral therapies. According to the U.S. Centers for Disease Control and Prevention (CDC) 2021 recommendations, during periods of community cocirculation of influenza viruses and SARS-CoV-2, antiviral treatment of influenza should be initiated as soon as possible for outpatients with severe, complicated, or progressive respiratory illness, and outpatients at higher risk for influenza complications who present with any acute respiratory illness symptoms (with or without fever). CDC also recommends that clinicians consider starting early antiviral treatment of non-high-risk outpatients with suspected influenza within 48 hours of symptom onset or, for those exposed to influenza, within 48 hours of first exposure. In order to ensure patients receive time-sensitive antiviral therapy within this window, HHS should apply the PREP Act to allow pharmacists, as members of the healthcare team, to order and administer antiviral medications indicated for prophylaxis and treatment of influenza, in addition to independently ordering and administering influenza tests and authorizing pharmacy technicians and interns to administer flu tests to further bolster community capacity and access. We also urge HHS to coordinate with payors to ensure that adequate reimbursement is available to support access to these services when provided by pharmacists.

Patients who are ideal candidates for time-sensitive influenza medications often seek out their pharmacist as the first point of care for testing, counseling, and self-care. If patients cannot access time-sensitive therapies from their pharmacist, many of them will not initiate therapy in time for these medications to be effective. To do so, patients must schedule an appointment with another clinician, if they have access to one, request a prescription, and then return to the pharmacy to pick up their medication and initiate therapy. Challenges accessing these patient care services are magnified in rural and underserved communities. In many cases, the time window for optimal therapy may be exceeded while patients struggle to access antiviral medication. This unacceptable outcome could be avoided if patients were allowed ready access to testing and therapy from the pharmacist. Furthermore, with many emergency departments and hospitals running near maximum capacity, allowing pharmacists to test and initiate treatment for influenza can help reduce unnecessary strains on the healthcare system.

Initiation of time-sensitive influenza therapy by a pharmacist is not a substitute for vaccination, and pharmacists remain committed to patient access to vaccines for both COVID-19 and influenza. We look forward to working with HHS and the physician community to ensure well-coordinated care for patients receiving time-sensitive influenza therapies.

Pharmacists, as the nation's most accessible provider, are uniquely situated to offer efficient testing and immediate initiation of time-sensitive, outpatient medications for influenza. Research evaluating pharmacist-led flu testing and initiation of treatment has demonstrated safety and effectiveness with high patient satisfaction. Authorizing such care models to be deployed nationwide at this pivotal time in the COVID-19 pandemic will make an impactful difference on equitable access to influenza care this flu season. Thank you for your consideration of this request.

We greatly appreciate the efforts of the Biden Administration to ensure patient access to care during the pandemic. Please do not hesitate to reach out if we can provide any additional information about the administration of time-sensitive influenza medications.

Sincerely,

Academy of Managed Care Pharmacy (AMCP) American College of Clinical Pharmacy (ACCP) American Pharmacists Association (APhA) American Society of Consultant Pharmacists (ASCP) American Society of Health-System Pharmacists (ASHP) College of Psychiatric and Neurologic Pharmacists (CPNP) Hematology/Oncology Pharmacy Association (HOPA) National Alliance of State Pharmacy Associations (NASPA) National Association of Chain Drug Stores (NACDS) National Community Pharmacists Association (NCPA) Society of Infectious Diseases Pharmacists (SIDP)