

July 11, 2022

The White House 1600 Pennsylvania Avenue, N.W. Washington, DC 20500

RE: Immediate Emergency Action is Necessary to Provide Payment for All Required Pharmacists' Services to Prescribe Paxlovid to Address Health Equity

Dear President Biden:

The American Pharmacists Association (APhA) applauds the Food and Drug Administration's (FDA) recent <u>update</u> to the <u>Emergency Use Authorization</u> (EUA), which authorizes pharmacists to prescribe Paxlovid. The independent action of the FDA supports the bold steps your Administration has already taken to <u>authorize</u> pharmacists to order and dispense oral therapeutics, such as Paxlovid, under the federal Public Readiness and Emergency Preparedness Act (PREP Act). While updating the EUA was a huge step forward, there is no current federal policy providing coverage for all of the associated clinical services required for pharmacist prescribing, such as consultation to determine patient eligibility, assessing renal and hepatic function, obtaining a comprehensive list of medications (prescribed and non-prescribed), and assessing for potential drug interaction services. Absent coverage for the pharmacist's time to conduct patient eligibility and appropriateness, FDA's authorization will be for naught to reduce our nation's health inequities in accessing this lifesaving medication. These services, which take roughly 15-30 minutes per patient, are reimbursed for every other prescriber, but not for pharmacists. It is inequitable, unfair, and unreasonable to think that these services can be provided for free by pharmacists.

Accordingly, we are writing to urge the Administration to take immediate emergency action to provide direct reimbursement for pharmacists—who are now authorized to prescribe Paxlovid. APhA urges the Administration to identify a payment pathway, such as the one the Centers for Medicare and Medicaid Services (CMS) took for COVID-19 vaccination at the beginning of the pandemic through enforcement discretion and interim final rules to provide immediate payment for pharmacists' services.

In setting up a reimbursement pathway, it is important to separate out the clinical "services" for pharmacists to prescribe Paxlovid from the "dispensing fees" for these medications, which most PBMs have ridiculously set at less than \$1.00, based on CMS' <u>current guidance</u>. These

dispensing fees are unacceptable and a disincentive for pharmacies to even stock these medications due to a lack of coverage for the required patient safety checks that can take anywhere from 15-30 minutes of a pharmacist's time, an issue that also must be addressed.

Simply put, the Administration needs to act now—inaction will cost lives and our patients can't wait! Therefore, APhA strongly urges the Administration to continue its strong leadership in combatting COVID-19 and promoting health equity by taking immediate, emergency action to ensure coverage of all of the services required for pharmacist prescribing of Paxlovid. Emergency action is necessary to ensure the government's significant investment in these medications achieves your purpose to save lives rather than allow them to continue to sit on pharmacy shelves.

As stated in the revised EUA, "[t]he FDA recognizes the important role pharmacists have played and continue to play in combatting this pandemic." FDA took action following a new <u>analysis</u> by the Centers for Disease Control and Prevention (CDC), which confirmed APhA's earlier <u>findings</u> of inequitable dispensing of COVID-19 oral antivirals. According to our analysis, as of June 22, 2022, there were over 28,000 community pharmacies located in federally recognized underserved communities, yet only 838 Test to Treat sites had been established in those communities. **Tapping the pharmacies in these areas could increase access to treatments up to 3,200%.** The data shows that the least vulnerable areas nationwide have access to 75% of Test to Treat locations, limiting the most vulnerable communities to only 25% (666) of these locations. However, these areas—which fall in the top 30% of the social vulnerability index—have an estimated 24,000 community pharmacies, most of which are not Test to Treat points of care for oral COVID-19 antiviral medications.

Removing barriers to pharmacist prescribing of oral antivirals has the potential to be a game-changer for addressing health equity and providing timely access to these life-saving treatments in pockets of the country where pharmacists may be the only health care provider for miles—just as they have been available for the administration of COVID-19 vaccines. Pharmacists are educated, trained, and able to assess patients in accordance with clinical guidelines for appropriate use of these more convenient COVID-19 treatment options. We look forward to working with our health care colleagues to improve access to this lifesaving medication.

While we appreciate the opportunity to serve our patients in this capacity, this effort will only be successful and sustainable if CMS and other payers take immediate action to provide adequate, appropriate, and fair payment for pharmacist consultations and services for prescribing Paxlovid.

I welcome the opportunity to discuss with you and others at The White House and HHS/CMS the valuable role that pharmacists can play if payment barriers are removed by using emergency authority to cover the services required for pharmacists' prescribing of Paxlovid. Please contact Michael Baxter, APhA's Senior Director for Regulatory Policy at <a href="mailto:mbaxter@aphanet.org">mbaxter@aphanet.org</a> to arrange a meeting with us.

Sincerely,

Ilisa BG Bernstein, PharmD, JD, FAPhA Interim CEO and Executive Vice President

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cc: The Honorable Xavier Becerra, Secretary, HHS

The Honorable Chiquita Brooks-LaSure, Administrator, CMS

Dr. Meena Seshamani, M.D., Ph.D., Deputy Administrator and Director of Center for Medicare

Dr. B. Cameron Webb, M.D., JD, Senior Policy Advisor for COVID-19 Equity, White House COVID-19 Response Team

Dr. Meg Sullivan, M.D., MPH, Chief Medical Officer, Office of Assistant Secretary for Preparedness and Response