



July 12, 2022

Dr. Ashish K. Jha  
COVID-19 Response Coordinator  
The White House  
1600 Pennsylvania Avenue, N.W.  
Washington, DC 20502

The Honorable Robert M. Califf, MD, MACC  
Commissioner  
Food and Drug Administration (FDA)  
10903 New Hampshire Avenue  
Silver Spring, MD 20993-0002

The Honorable Xavier Becerra  
Secretary  
Department of Health and Human Services (HHS)  
200 Independence Avenue, S.W.  
Washington, DC 20201

The Honorable Chiquita Brooks-LaSure  
Administrator  
Centers for Medicare & Medicaid Services (CMS)  
7500 Security Boulevard  
Baltimore, MD 21244

*Submitted via email*

**Re:** Operationalizing Pharmacist Prescribing of Paxlovid to Improve Public Access, Foster Equity

Dear Dr. Jha, Secretary Becerra, Dr. Califf, and Administrator Brooks-LaSure,

The National Association of Chain Drug Stores (NACDS) welcomes FDA’s EUA revision to support pharmacist prescribing of Paxlovid. By deploying the unique accessibility and clinical expertise of the nation’s pharmacies and pharmacists, we look forward to working together to expand public access to this lifesaving therapy. The importance of this issue is underscored given rising rates of COVID-19 fueled by Omicron subvariants. We share your goals to improve care outcomes and foster equity across diverse and vulnerable communities by supporting better access to Paxlovid for certain individuals at high-risk of progression to severe COVID-19.

To feasibly operationalize improved access to Paxlovid and maximize public benefit of this treatment option, **we urge for your partnership in implementing the following critical recommendations:**

- 1. FDA to Support Additional Strategies for Pharmacists to Meet Requirements for “Sufficient Information” on Renal and Hepatic Function:** Limiting pharmacist prescribing of Paxlovid only to individuals with recent laboratory monitoring undercuts the opportunity to improve access for individuals with the greatest need. Requiring pharmacist-informed prescribing to include access to recent labs may drive patients to seek access to Paxlovid from other settings that are not required to reference recent labs. Therefore, this requirement may inadvertently add friction to the patient journey when an individual presents to a pharmacy only to be referred elsewhere due to lack of labs, needlessly impeding safe and appropriate patient access to Paxlovid. To meaningfully realize better access for the public, including the most underserved and vulnerable, we strongly recommend that additional strategies, such as patient report or attestation, are supported for pharmacists to make an informed decision on renal and hepatic function when recent labs are not

readily available and the patient's provider, if they have one, cannot be reached. In particular, NACDS would welcome the opportunity to work with FDA on a set of clinical questions, for example, that could be used by pharmacists during a patient assessment to gather pertinent clinical information to make an informed decision on hepatic and renal function.

- 2. CMS to Implement a Reimbursement Pathway Supporting Pharmacist Assessments That Inform Appropriate Prescribing & Release Guidance Encouraging All Payers to Immediately Recognize Pharmacists as Prescribers of Paxlovid:** To inform appropriate prescribing in alignment with the EUA, various assessments and evaluations will be performed, including a thorough discussion of symptom onset, comorbidities and risk factors for progression to severe COVID-19, and medication history. Importantly, for patients who may use multiple pharmacies or present to the pharmacy as a new patient, pharmacists often spend additional time and resources to ascertain a patient's medical history and current medication list. However, pharmacists and pharmacies have limited ability to implement clinical assessments and interventions that serve Medicare Part B beneficiaries given lack of a payment pathway. To expeditiously address this critical barrier, we strongly recommend CMS implement a reimbursement pathway, such as leveraging pharmacies that are enrolled in Part B as mass immunizers, for example, through CMS demonstration authority, as was done [recently](#) to cover OTC COVID-19 tests at pharmacies to improve access to care for Part B beneficiaries. We applaud CMS for leveraging their demonstration authority to efficiently stand-up creative solutions that support better care for beneficiaries and continue to meet dynamic pandemic needs. This evolving pandemic requires imaginative solutions to best serve the American people. Therefore, we urge CMS to continue testing the efficacy of Medicare covering otherwise non-covered services in order to conduct initiatives that support meaningful improvements in care, including pharmacist prescribing of Paxlovid. We also urge CMS to support similarly needed changes across other payer types, including Medicaid, commercial and the uninsured population.

As many payers do not currently recognize pharmacists as independent prescribers, we urge CMS to strongly encourage payers through formal guidance to immediately adjust their systems to support this recognition. Without payer system updates to reflect the EUA revision for pharmacists as prescribers, prescription claims with pharmacists rightly designated as prescribers will be rejected, delaying timely access for patients to receive this important therapy within the 5-day symptom window.

- 3. FDA to Clarify Recordkeeping Requirements:** While the EUA references some recordkeeping requirements, we request that FDA clarify specific recordkeeping requirements for pharmacist prescribing of Paxlovid.
- 4. Foster Clear Public Education & Set Consumer Expectations on Pharmacist Prescribing of Paxlovid:** Pharmacist prescribing of Paxlovid will take time to implement and operationalize as noted by HHS and FDA in stakeholder calls last week. Therefore, we greatly appreciate your collaboration in appropriate public messaging and setting reasonable consumer expectations about how and when this intervention may be available to them. This may include what steps individuals

can take to optimize their experience (e.g., bring a copy of your kidney and liver function labs, if available, present to the pharmacy as soon as possible upon developing symptoms, come prepared with a full list of your medications), in addition to any available information about what patients can expect from their insurance coverage with respect to pharmacist prescribing of Paxlovid.

Pharmacies are committed to continue serving the American people by meeting their dynamic and evolving pandemic needs, including to improve lifesaving access to Paxlovid. We look forward to working together to feasibly operationalize pharmacist prescribing of Paxlovid in a manner that meaningfully improves access and fosters equity across the country. For questions or further discussion, please contact NACDS' Sara Roszak, Senior Vice President, Health and Wellness Strategy and Policy at [sroszak@nacds.org](mailto:sroszak@nacds.org) or 703-837-4251. **We will follow-up with your teams immediately to schedule a time to discuss these important issues in greater detail.**

Sincerely,



Steven C. Anderson, FASAE, CAE, IOM  
President and Chief Executive Officer  
National Association of Chain Drug Stores

**Cc:**  
Director Walensky, CDC  
Dr. Meg Sullivan, HHS/ASPR  
Dr. Meena Seshamani, CMS  
Will Harris, CMS  
Erin Richardson, CMS  
Dr. Janet Woodcock, FDA  
Lisa Barclay, White House

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NACDS represents traditional drug stores, supermarkets and mass merchants with pharmacies. Chains operate over 40,000 pharmacies, and NACDS' over 80 chain member companies include regional chains, with a minimum of four stores, and national companies. Chains employ nearly 3 million individuals, including 155,000 pharmacists. They fill over 3 billion prescriptions yearly, and help patients use medicines correctly and safely, while offering innovative services that improve patient health and healthcare affordability. NACDS members also include more than 900 supplier partners and over 70 international members representing 21 countries. Please visit [NACDS.org](http://NACDS.org).