January 18, 2022

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244

Re: Intervention needed for antiviral dispensing program viability

Dear Administrator Brooks-LaSure:

The National Community Pharmacists Association (NCPA) is imploring that the Centers for Medicare and Medicaid Services (CMS) immediately intervene to ensure robust access and appropriate use of COVID-19 oral antiviral therapies.

NCPA represents America’s community pharmacists, including 19,400 independent community pharmacies. Almost half of all community pharmacies provide long-term care services and play a critical role in ensuring patients have immediate access to medications in both community and long-term care (LTC) settings. Together, our members represent a $67 billion healthcare marketplace, employ 215,000 individuals, and provide an expanding set of healthcare services to millions of patients every day. Our members are small business owners who are among America’s most accessible healthcare providers.

Community pharmacies are on the front line of helping Americans prevent SARS-CoV-2 infections by administering hundreds of millions of vaccines and preventing hospitalizations by administering and dispensing COVID-19 therapeutics. States are relying on pharmacies to extend the access to therapeutics in rural areas and areas with high social vulnerability.

Now, at the end of just the first distribution cycle, pharmacy owners that are going above and beyond during this eye-popping surge of Omicron variant find themselves blinking in disbelief at the dispensing fees that are supposed to cover the costs involved in dispensing U.S. government procured PAXLOVID and molnupiravir. **NCPA asks for immediate intervention before these pharmacies are forced to stop dispensing the oral antiviral drugs because they can’t justify the cost to their business.**

CMS urged Medicare Part D plan sponsors to pay “dispensing fees for USG-procured EUA oral antiviral drugs during the COVID-19 PHE sufficient to ensure eligible patients can readily access these drugs at available pharmacies. CMS encourages sponsors to consider paying a dispensing fee for these drugs that may be higher than a sponsor’s usual negotiated dispensing fees** given the unique circumstances during the PHE.”
While the reimbursement rates that NCPA members have reported may be higher than the usual negotiated dispensing fees, they are still far below these pharmacies’ cost to dispense. **As of January 14, 2022, the highest enhanced dispensing fee reported is $10.50 with the low end being $1 by BlueCross Blue Shield’s PBM Prime Therapeutics.** These fees are lower than the Professional Dispensing Fee in most state Medicaid programs. Even the $10.50 dispensing fee fails to cover the additional costs required to optimize beneficiary safety and effectiveness for these breakthrough treatments. This is astounding and extremely disappointing considering the U.S. government has paid over $700 per course of therapy for molnupiravir and over $500 per course of therapy for PAXLOVID.

NCPA has spoken with numerous independent pharmacists who have been allocated product and are actively dispensing these prescriptions. The attached list is of additional tasks involved with dispensing oral COVID-19 antivirals that would not be considered part of the usual dispensing process – including a time factor for each. **The pharmacies in the first distribution cycle estimate the additional time involved with dispensing the oral antivirals requires a dispensing fee consistent with the COVID-19 vaccine administration fee of $40.** This reflects additional steps such as the non-standard ordering and receiving of the physical product, on-boarding new patients, and participating in the prescriber decision making process (working with prescribers to prioritize limited available doses, accurate data on e-prescriptions, transitioning patients from monoclonal antibodies to oral therapy).

Administrator Brooks-LaSure, it is unconscionable that Medicare Part D plan sponsors and/or their pharmacy benefit managers (PBMs) are reimbursing pharmacies at these dismal rates, especially when these therapies can avoid costly hospitalizations. **NCPA is asking for immediate intervention to ensure continued access to oral antivirals for COVID-19, and that CMS use your full authority to provide Medicare and Medicaid coverage of the additional pharmacists’ costs to dispense these vital therapies.**

Sincerely,

[Signature]

B. Douglas Hoey, R.Ph., M.B.A.
NCPA Chief Executive Officer
The list below is of additional tasks involved with dispensing oral COVID-19 antivirals that would not be considered part of the usual dispensing process – including a time factor for each.

1. Non-standard ordering (most pharmacies have automated replenishment ordering; this is a manual process) *(0.067 hour) 4 minutes*
2. Non-standard receiving (pharmacies securing this inventory differently) *(0.017 hour) 1 minute*
3. Greater involvement in prescriber decision making process (working with prescribers to prioritize limited available doses, accurate data on electronic prescription, transitioning patients from monoclonal antibodies to oral therapy). Prescribers are not up-to-speed on all the interactions, co-morbidity issues, dose adjustment for renal impairment, etc. RPh are having to interact with the prescribers on every Rx for every potential PAXLOVID patient. They can't just get an electronic prescription and dispense it. *(0.25 hour) 15 minutes*
4. Gathering Rx and medical history and payer info for new patients, which many of these are and RPh are likely to never see them again. *(0.083 hour) 5 minutes*
5. Tracking pick-up date to ensure therapy initiated within EUA instructions for use. *(0.033 hour) 2 minutes*
6. Scheduling delivery or other arrangements to minimize exposure to confirmed positive case and related PPE. Pharmacy calling patient to inform about pickup either in drive thru if available or curbside to avoid potential exposure in store. *(0.067 hour) 4 minutes*
7. Enhanced patient counseling. RPh is avoiding costly complications that could result from a patient getting PAXLOVID that shouldn't get it or should get the lower dose. Enhanced drug-drug interaction screening. This is taking much more time than a traditional prescription. *(0.133 hour) 8 minutes*
8. Ongoing monitoring after patient receives prescription. *(0.05 hour) 3 minutes*
9. Trying to get a paid claim and dealing with PBMs which are rejecting claims as Non-Part D covered drug as one example. *(0.067 hour) 4 minutes*
10. Reporting inventory and sales. *(0.033 hour) 2 minutes*

Other considerations:
- Participating in federal, state and county phone calls, webinars, etc. to remain the expert in antivirals.
- Managing call volume. Pharmacies that have access to PAXLOVID are listed on the county website precipitating calls from patients and prescribers for prescription information, etc.
- Triaging multitudes of e-prescribed Rx’s to qualify patients, many for patients who do not qualify based on risk factors or timing of Rx. This is before getting into other clinical issues.
- Prioritizing unvaccinated patients. Time is necessary to determine/confirm vaccination status.
- Reporting usage and inventory movement to state and/or federal entity on a daily or weekly basis. Logging into special website with special passwords (and usually a slow process).
- Pharmacists providing testing services. When a patient tests positive, pharmacists are triaging them for potential eligibility for PAXLOVID. Screening risk factors that would qualify them for a PAXLOVID Rx. Then working with patient's doctor on a potential prescription.
• Pharmacists have agreed to offer this service and take on the overhead costs (patient education, Rx education, phone call volume, testing) on top of everything else they are doing to keep patients well during a pandemic.

Additional anecdotes:

• Additionally, we can’t just add these prescriptions to our will call (filled prescriptions waiting to be picked up). Once they’re checked, we’ve been leaving them in a bin beside the front counter pharmacist. *Rationale for this: b/c there’s such a tight treatment window, if someone doesn't show up by end of day, pharmacists look at the first day of symptoms. If they will still be within the treatment window the next business day, they call or text the patient that they will need to pick up the next day or their medication will be returned to stock. If the patient is outside the treatment window on the next business day, the med is reversed and returned to stock BEFORE we leave for the day. Otherwise reporting to CDC, the next morning will be inaccurate. (We typically report to the registry every morning for this reason)*
• I think the biggest thing in the beginning is lack of product; so, we are in the same position as we were with vaccines. We need to police who can and can’t get it. We need to prioritize other patient groups over others. Or only work with certain prescribers. While not part of the actual dispensing time, our staff will spend the bulk of the time on the phone with prescribers and patients asking if we have the product and how we can get it. It’s already started, we have so many calls asking if they can get a RX to have if needed or prescribers asking how they can write a RX for it.
• And lastly PPE involved in delivering curbside. For our testing we do curbside, we have new mask, shields, gloves, etc. This is COVID positive patient, and we need to make sure to protect our staff for any potential exposure.