From: Paul Wilson
Sent: Thursday, January 19, 2023 10:38 AM
To: Siobhan.Perdue@pfizer.com
Cc: Lauren.Levine@Pfizer.com
Subject: Preparation for U.S. Food and Drug Administration (FDA) Approval of COVID-19 Oral Antivirals

Dear Ms. Perdue:

The National Council for Prescription Drug Programs (NCPDP) is a not-for-profit American National Standards Institute (ANSI) accredited Standards Developer (ASD) consisting of more than 1,500 members representing entities including, but not limited to, claims processors, data management and analysis vendors, federal and state government agencies, insurers, intermediaries, pharmaceutical manufacturers, pharmacies, pharmacy benefit managers, professional services organizations, software and system vendors and other parties interested in electronic standardization within the pharmacy services sector of the healthcare industry. NCPDP provides a forum wherein our diverse membership can develop business solutions, including ANSI-accredited standards and guidance for promoting information exchanges related to medications, supplies and services within the healthcare system.

On November 4, 2022, The Centers for Medicare and Medicaid Services (CMS) released a memo titled, "Part D Coverage of Oral Antivirals for COVID-19." The memo (see email attachment) provides guidance and information to Medicare Part D sponsors in advance of oral antiviral drugs for COVID-19 receiving FDA approval.

CMS specifically addresses the potential scenarios involving COVID-19 oral antivirals currently available only under an Emergency Use Authorization (EUA) that remain in circulation at the time the FDA grants full approval and/or the United States Government (USG) procures the FDA approved products. These scenarios require unique National Drug Codes (NDCs) to distinguish among (a) a USG procured EUA product, (b) a USG procured FDA approved product and (c) an FDA approved product not procured by the USG.

For Medicare Part D, CMS currently allows flexibilities for USG-procured oral antivirals to be billed for dispensing fees only with unique Prescription Drug Event (PDE) submissions. In the memo, CMS advises the same unique PDE submission method would continue if the USG procured the FDA approved product. If the FDA approved product was not procured by the USG, CMS expects normal PDE submissions with both drug costs and dispensing fees. To differentiate what type of PDE submission is needed, the industry needs three (3) separate unique NDCs to ensure claim billing and reporting are compliant with CMS' expectations.

Without unique NDCs, payers rely solely on the pharmacy to submit the appropriate costs with the appropriate product being submitted within a pharmacy claim transaction. This would introduce challenges for a payer being able to audit and ensure appropriate billing practices. For purposes of inventory control, billing and remittance of payment, unique NDCs are required.

If the NDC for the EUA product, the NDC for the FDA approved commercially available product purchased by the government and the NDC for the commercially available product purchased by the pharmacy are the same, it is impossible for the pharmacy to differentiate between free products and purchased products.

From a pharmacy perspective, some states are closely monitoring USG-procured inventory and requesting specific reporting on those free products. Without unique NDCs, states will be challenged to ensure appropriate reporting as well as dispensing and inventory control when there could be three sources of the same medication on the pharmacy shelf at one time.

Having unique NDCs for the EUA product, the commercially available FDA approved product purchased by the pharmacy and the commercially available FDA approved product purchased by USG will decrease the confusion at the time of ordering and dispensing. NCPDP is proposing adding "EUA" in the compendia drug name description to assist in product identification.

NCPDP is also requesting the FDA provide advance guidance to the industry regarding status of EUA products in circulation when the Public Health Emergency (PHE) ends. For example, address whether EUA products can continue to be dispensed once the PHE ends.

NCPDP appreciates the support of our industry partners to ensure proper practices occur and accurately reflect the fast-paced changes the COVID-19 PHE creates. Ensuring we have three unique NDCs will reduce the potential for fraud, waste and abuse that may occur along with allowing accurate billing and inventory practices.

For direct inquiries or questions related to this letter, please contact:

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Respectfully,

Lee Ann C. Stember
President & CEO
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Thanks,

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Work Group Meetings | August 2-4, 2023 | The Davenport Grand | Spokane, WA
Work Group Meetings | November 1-3, 2023 | Grand Hyatt | San Antonio, TX