November 20, 2020

Submitted electronically via email

Paul Loebach
Director, Drug Registration and Listing Staff
Office of Program and Regulatory Operations
Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20993-0002

Re: Emergency Use Approved Coronavirus tests transition to commercial use approval

Dear Mr. Loebach:

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 1,700 members who represent drug manufacturers, chain and independent pharmacies, drug wholesalers, insurers, mail order prescription drug companies, claims processors, pharmacy benefit managers, physician services organizations, prescription drug providers, software vendors, telecommunication vendors, service organizations, government agencies and other parties interested in electronic standardization within the pharmacy services sector of the health care 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.

NCPDP would like to bring to your attention the need to require manufacturers of COVID-19 Emergency Use Approved (EUA) tests to assign new product NDCs for commercial products when approved for commercial use in the US. Currently, these EUA COVID-19 tests are administered free of charge to the patient by pharmacies under authorization of a Clinical Laboratory Improvement Amendments lab waiver. This is dependent upon the payment of directly invoiced subsidies (administration fees) from the Federal government for the administration of tests received from the Federal stockpile. The drug data vendors list these product identifiers (Unique Device Identifiers (UDI)) as an EUA test product with no associated cost. EUA COVID-19 tests are still considered unapproved products, or more specifically, unapproved tests.

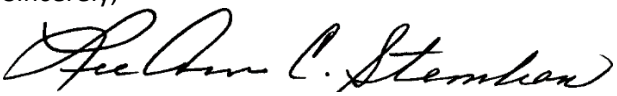
If these tests receive approval by the FDA for administration in a pharmacy in non-emergency circumstances, the possibility exists of confusing free goods vs. commercial product. This would be true especially if one state lifts all COVID-19 restrictions and a neighboring state does not. The existence of both free and commercial goods in the marketplace represented by a single UDI will negatively impact patient care by possibly delaying or denying the administration of the test in the pharmacy setting. It will also impact accurate recordkeeping and potential program payments if the pharmacy servicing the patient and administering the test (or specimen collection) cannot distinguish between the two. The product code and/or package size identifiers should change in a way that clearly distinguishes between the unapproved (free) and approved (commercial) product(s). This will also help to track inventory of unapproved products that will likely be in the channel before and after an FDA approval of the commercial product(s).

Therefore, NCPDP respectively requests the FDA require the manufacturers of tests used in a pharmacy to assign a new UDI if their current EUA product receives a 510K or other FDA approval.

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

Terry Fortin
Assistant Senior Manager, Standards Development
NCPDP
standards@ncpdp.org

Sincerely,



Lee Ann C. Stember
President & CEO
National Council for Prescription Drug Programs (NCPDP)
9240 E. Raintree Drive
Scottsdale, AZ 85260

cc: NCPDP Board of Trustees