March 9, 2022

Submitted electronically via email

Paul Loebach, Director, Drug Registration and Listing Staff
Jeffrey Shuren, M.D., J.D., Director, Center for Devices and Radiological Health
Food and Drug Administration
10903 New Hampshire Ave.
Silver Spring, MD 20903

Dear Mr. Loebach and Dr. Shuren:

RE: Six-Digit Labeler Codes and National Drug Code (NDC) Changes

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 is writing today to reiterate concerns expressed in our February 23, 2015, letter regarding the FDA's intent to increase the labeler code length from five digits to six digits that was published in the 21 CFR 207.35 (b)(2)(i) on December 6, 2007. In the 2015 letter, NCPDP recommended the following:

- A minimum advance notice of 10 years to the healthcare industry prior to the FDA's first issuance of a six-digit labeler code for use within the NDC, which takes us to 2026.
- Formal notification to the entire healthcare industry when only 10,000 of the five-digit labeler codes remain available.
- When the last available five-digit labeler code is assigned, the FDA would begin assignment of six-digit labeler code starting with "100000" or greater.
- With the assignment of the first six-digit labeler code starting with "100000" or greater, all existing NDCs of five-digit labeler code be amended to include a leading zero to make a six-digit labeler code.
- Additionally, because 21 CFR 207.35 (b)(2)(ii) makes no provision for the format of the remaining digits of the NDC once the labeler code increases to six-digits, NCPDP strongly recommends the current NCPDP formatting according to the NCPDP Product Identifier Standard be maintained:
    - The use of the existing 5-3-2 labeler-product-package code configuration (e.g., xxxxx-0xxx-xx) or 5-4-1 labeler-product-package code configuration (e.g., xxxxx-xxxx-0x)

remains the same for six-digit labeler code. For the six-digit labeler code the format would be 0xxxxx-0xxx-xx or 0xxxxx-xxxx-0x to preserve the existing labeler code and reformatted identifiers already in use in the industry.

It is our understanding the Notice of Proposed Rulemaking (NPRM) will be issued in March 2022, finalized in 2023 and effective in 2026. It is also our understanding the implementation will be after the Drug Supply Chain Security Act (DSCSA) is completed. The labeler code change impacts more than NDCs. In our letter dated June 4, 2021, we reiterated concerns expressed in our letter dated April 4, 2016, regarding changes to the Unique Device Identifier (UDI). In the 2021 letter we also recommended the timeline published in Docket No. FDA–2016–D–0199 for ''Enforcement Policy on National Health Related Item Code and National Drug Code Numbers Assigned to Devices" be extended. Granting additional time is essential for stakeholders to make changes to ensure medical device reimbursement, supply chain and procurement systems and processes using the UDI can be implemented successfully.

NCPDP anticipates HHS/CMS will issue an NPRM in the next few months naming a new version of the NCPDP Telecommunication Standard. This new version will be mandated under the HIPAA Transaction and Code Set Rules and its implementation may also be required in 2026. The expected version to be named includes the expansion of the product identifier field length to support up to 40 characters. Assuming HHS/CMS issues the NPRM as reflected in the latest Unified Agenda of Regulatory and Deregulatory Actions, NCPDP requests the FDA delay enforcement until after the new HIPAA rule is fully implemented. This gives the industry the time necessary to coordinate system enhancements, perform internal and external electronic data exchange testing, and implement this new standard to support the use of the applicable product identifiers to ensure patient safety.

Thank you for your consideration of our input. NCPDP welcomes the opportunity to meet with FDA representatives to discuss our concerns in greater detail and, at the appropriate time, work together to create a mutually agreeable implementation strategy and timeline.

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

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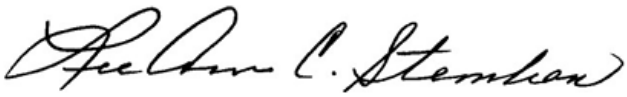
Sincerely,



Lee Ann C. Stember
President & CEO
National Council for Prescription Drug Programs (NCPDP)

cc:
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