June 04, 2021

Submitted electronically via email

Jeffrey Shuren, M.D., J.D.
Director, Center for Devices and Radiological Health
Food and Drug Administration
5630 Fishers Lane, Rm 1061
Rockville, MD 20852

Re: Enforcement Policy on National Health Related Item Code and National Drug Code Numbers Assigned to Devices

Dear Dr. Shuren,

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 April 4, 2016 letter regarding Docket No. FDA–2016–D–0199 for ‘‘Enforcement Policy on National Health Related Item Code and National Drug Code Numbers Assigned to Devices.” Similar to the recent request from the National Association of Chain Drug Stores (NACDS) dated March 31, 2021, NCPDP encourages the FDA to consider a delay in enforcement to ensure patient safety as technical and operational dependencies are coordinated. While various medical devices are used in the pharmacy industry, diabetic supplies are of critical concern, because comprehensive treatment and risk prevention care is coordinated across providers and payers for 36% of the US population with diabetes.[1]

In the 2016 letter, NCPDP recommended a 10-year enforcement delay based on input from many stakeholders that a significant national effort is required to coordinate the implementation of and the transition to unique device identification (UDI) numbers.

[1] 2020 CDC Diabetes and Pre-Diabetes Census: https://www.cdc.gov/diabetes/pdfs/data/statistics/national-diabetes-statistics-report.pdf

NCPDP appreciates the FDA's intent to permit the continued use of National Health Related Item Code (NHRIC) or National Drug Code (NDC) numbers on device labels and packages of finished devices manufactured and labeled prior to September 24, 2021, by not enforcing the prohibition.

However, an enforcement delay to 2023 is insufficient time to address the patient safety risks that may occur.

There are several issues that must be addressed to successfully transition from NHRIC and NDC numbers to UDI numbers, all of which are very important. These issues include, but are not limited to:

- The Device Identifier portion of the UDI may be longer than current product identifier field length used within the HIPAA named NCPDP Telecommunication Standard for claim billing transactions.
- Pharmacy practice and reimbursement systems may only support the 11-digit product ID format.
- Truncating the GTIN-14 ID used as the device identifier to an 11-digit ID may result in duplication of existing product IDs.
- New 11-digit IDs to replace existing NHRICs lack a standardized naming convention for product packaging. Today, the general term "NDC" is used in product packaging as a descriptor to the existing identifier so the provider can easily identify which product ID type to use for billing. A new term should be created that will identify the new code as the code to be used for billing.
- The two-year enforcement delay is insufficient time to coordinate analysis and standardized processes to address multiple 11-digit identifiers per single product.

Pharmacy, payer, intermediary, vendor, manufacturer and compendium systems rely on an 11-digit identifier for medical devices and drugs for a majority of business functions. The transition from an 11-digit identifier to a more robust and flexible array of identifiers, including the UDI-DI involves at a minimum, complex planning, extensive development costs, testing and coordination with trading partners. This intense level of effort is typically coordinated with the implementation of a new HIPAA named standard.

NCPDP anticipates United States Department of Health and Human Services (HHS) approval and industry implementation of the next HIPAA-named version of the Telecommunication Standard by 01/01/2026. This version includes the expansion of the product identifier length to support up to 40 characters. If HHS approves the new HIPAA-named version in a timely fashion, delaying enforcement until 01/01/2026 will give the industry the time necessary to coordinate system enhancements, perform internal and external electronic data exchange testing and implement this new billing standard to support the use of the applicable product identifiers and ensure patient safety.

Granting additional time is essential for stakeholders to make changes ensuring medical device reimbursement, supply chain and procurement systems and processes using the UDI can be implemented successfully. NCPDP encourages the FDA to consider supporting an enforcement delay that aligns to the anticipated 2026 timeline.

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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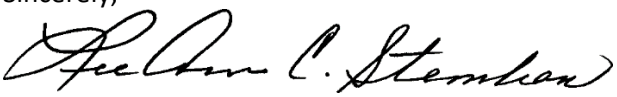
Sincerely,



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