Date April 4, 2016

UDI Regulatory Policy Support
Center for Devices and Radiological Health
Food and Drug Administration
GUDIDSupport@fda.hhs.gov

RE: Docket No. FDA–2016–D–0199 for ''Enforcement Policy on National Health Related Item Code and National Drug Code Numbers Assigned to Devices''

Dear UDI Regulatory Policy Support:

The National Council for Prescription Drug Programs (NCPDP) is a not-for-profit American National Standards Institute (ANSI)-accredited Standards Development Organization (SDO) consisting of nearly 1600 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, industry professional societies, service organizations, government agencies, and other parties interested in electronic standardization within the pharmacy services sector of the healthcare industry.

NCPDP's recommendation and comments are a result of a multi-stakeholder meeting convened to address UDI adoption for medical devices sold by retail pharmacies and the NCPDP UDI task group. Each sector, pharmacy, payer, manufacturer and compendium, provided comments and input regarding the impact of the prohibition against providing National Health Related Item Code (NHRIC) or National Drug Code (NDC) numbers on device labels and device packages. The comments submitted by each sector are attached.

In reviewing the comments, several themes emerged among the stakeholders:

1. Pharmacy, payer, manufacturer and compendium systems rely on an 11-digit identifier for medical devices along with 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, expensive development costs, and coordination with trading partners.
2. Additional time is needed to properly implement introduction of UDI-DI without jeopardizing patient safety while still adhering to current laws and regulations.
3. There is a risk of disruption of patient access until the UDI-DI is recognized as the device identifier in all systems.
4. The key is all industry sectors and SDO standards require interoperability to have successful patient outcomes.
5. New versions of NCPDP standards and code set (UDI) would need to be adopted under HIPAA.

Based on the multi-stakeholder input, there is a significant national effort required to coordinate the implementation of and the transition to the UDI. In the interest of patient safety, NCPDP recommends a 10-year enforcement delay.

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.

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

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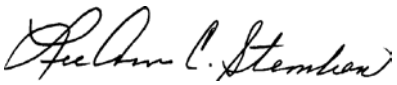
Sincerely,



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cc: NCPDP Board of Trustees

Attachments:
Compendia Stakeholder Impact
Manufacturer Stakeholder Impact
Pharmacy Benefit Managers (PBM) Stakeholder Impact
Pharmacy Stakeholder Impact