November 22, 2022

Dockets Management Staff (HFA-305)
Food and Drug Administration (FDA)
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

RE: Docket No. FDA-2021-N-1351: Revising the National Drug Code Format and Drug Label Barcode Requirements, Proposed Rule

Submitted via www.regulations.gov for Docket No. FDA-2021-N-1351

Dear FDA staff:

The American Pharmacists Association (APhA) and the National Alliance of State Pharmacy Associations (NASPA) are pleased to submit comments on the FDA's proposed rule titled "Revising the National Drug Code Format and Drug Label Barcode Requirements." Our organizations appreciate FDA's intent to adopt a single, uniform, 12-digit format for FDA assigned national drug codes (NDCs) and revise the drug barcode label requirements to allow the use of either linear or nonlinear barcodes, if the barcode meets the prescribed standards.

We believe these changes to the NDC labeling requirements will have a significant impact on the pharmacy sector, specifically pharmacy operations and transactions involving the sale, distribution, and use of drug. We recommend FDA consider those impacts and the timeline to implement the final rule to avoid medication errors and any disruptions to patient care.

APhA is the only organization advancing the entire pharmacy profession. APhA represents pharmacists, student pharmacists, and pharmacy technicians in all practice settings, including but not limited to community pharmacies, hospitals, long-term care facilities, specialty pharmacies, community health centers, physician offices, ambulatory clinics, managed care organizations, hospice settings, and government facilities. Our members strive to improve medication use, advance patient care, and enhance public health.

NASPA is dedicated to enhancing the success of state pharmacy associations in their efforts to advance the profession of pharmacy. NASPA's membership is comprised of state pharmacy associations and over 70 other stakeholder organizations. NASPA promotes leadership, sharing, learning, and policy exchange among its members and pharmacy leaders nationwide.

Implementation Timeline Concerns

Our organizations have significant concerns with FDA's proposed implementation timeline. We believe the proposed five-year implementation deadline from the date of the final rule, with a three-year transition period, will not be an adequate amount of time for the healthcare industry to comply with this proposal.

This proposed change will impact the entire health care sector, from manufacturers, distributors, health systems, pharmacies, clinics, medical offices, and more. This includes nearly every system touching healthcare where medication use happens. For example, pharmaceutical supply and medical chain operations that use and rely on the NDC includes, but is not limited to: pharmaceutical distribution systems; all item-level databases that drive other health information systems; any drug information or clinical information systems; e-prescribing platforms; pharmacy dispensing/workflow systems and related labeling provided to the consumer; pharmacy inventory systems and shelf placement methods; immunization and other product registries; medication error reporting systems, including FDA and private sector; and returned goods systems. In addition, the healthcare industry will need to convert current NDC codes to the new format, update software systems, train employees, and coordinate labeling updates.

Although we have not seen any data demonstrating how long it will take the health care sector to adopt this change, based on experience in other situations involving significant technological transitions, including related to the Drug Supply Chain Security Act (DSCSA) and electronic health records, we expect this change to be extremely challenging.

Impact of Proposed Changes to the NDC

APhA and NASPA supports FDA's intent to use a consistent, uniform barcode format to eliminate the need to convert NDCs from the FDA's currently codified format to different formats that are used by other sectors of the healthcare industry. However, barcode format modifications will have substantial implications beyond the product packaging and impact reimbursement, billing systems, and verifications at the point of dispensing and/or administration. The change must be implemented in a way that minimizes disruption in patient care and does not impose unnecessary costs on the pharmacies and the technology systems pharmacists use.

Our organizations also appreciate that FDA will not object to the continued use of 10-digit NDCs as the industry transitions to the use of 12-digit NDCs. However, FDA's recommendation to add leading zeros to the labeler code, product code, and/or the package code segments during a transition period could lead to potential medication errors if software systems are not set up in time to read the zeros as part of the drug product labeling code.

This proposed rule will also impact implementation of DSCSA, as the NDC is a central data element of the DSCSA's required product identifier. The systems and processes that dispensers are putting into place to comply with the November 27, 2023 implementation date for DSCSA's

electronic interoperability requirements is monumental and costly. Even with a 10-year lead time for full DSCSA implementation, it has been challenging, particularly for independent pharmacies. Modification of those systems and processes for product tracing, verification, and other DSCSA requirements will necessitate significant lead time. It is also unclear how the 10-digit, 11-digit, and 12-digit NDCs can co-exist in the marketplace without significant confusion and potential product mix-ups. Stakeholders will need the time to ensure that systems, processes, and back-up plans are in place to minimize and mitigate product confusion and errors.

Conclusion

APhA and NASPA recommend FDA consider a longer implementation timeline to ensure all stakeholders affected by this change will be prepared. Additionally, we believe education and outreach will be essential and encourages FDA to invest appropriate agency resources to ensure all stakeholders are informed and prepared. If you have any questions, require additional information, or would like to speak to us, or our work group of pharmacists on this topic, please contact Heather Boyd, Director, Health Policy at hboyd@aphanet.org.

Sincerely,

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