

November 22, 2022

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

Subject: *Revising the National Drug Code Format and Drug Label Barcode Requirements (FDA-2021-N-1351-0001)*

Dear Dockets Management Staff,

We thank you for the opportunity to submit comments for the proposed rule, Revising the National Drug Code Format and Drug Label Barcode Requirements. NCPA represents America's community pharmacists, including 19,400 independent community pharmacies. Almost half of all community pharmacies provide long-term care services and play a critical role in ensuring patients have immediate access to medications in both community and long-term care (LTC) settings. Together, our members represent a \$78.5 billion healthcare marketplace, employ 240,000 individuals, and provide an expanding set of healthcare services to millions of patients every day. Our members are small business owners who are among America's most accessible healthcare providers.

NCPA submits the following comments in response to Revising the National Drug Code Format and Drug Label Barcode Requirements proposed rule.

Summary:

- I. Costs to expanding labeler fields from 5 to 6 digits, therefore expanding the FDA National Drug Code (NDC) to 12-digits, are significantly underestimated by the FDA.
- II. No significant benefits are likely to accrue in terms of quality control or lessening identifier confusion as identified in the NPRM for this proposed solution of expanding the labeler field to 6-digits or from the consequent expansion of the FDA NDC to 12-digits.
- III. A safer, less costly, and less disruptive option exists. NCPA is concerned with the impact of this proposed rule on independent pharmacies and their workflows. Therefore, the FDA could achieve its goal of having a lengthy reserve of labeler codes, with relatively light industry impact, by making the existing 5-digit labeler code alphanumeric, thereby preserving the FDA's existing 10-digit NDC format and the HIPAA mandated NDC 11-digit format. FDA should adopt a change to allow the existing format(s) to be maintained and allow a limited set of alpha characters to be used in the labeler codes.

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NCPA requests further clarification on the transition period after five years following the Proposed Rule's publication effective date. NCPA also asks FDA to clarify if there is an additional 3-year transition following the 5-year period for a total of 8 years before the rule is fully implemented." NCPA requests that all historical 10-digit identifiers be allowed to remain as they are now with leading zeroes, and only new labelers will obtain a new labeler code format. This will simplify transitions within pharmacy management and inventory systems and reduce costs throughout the pharmacy supply chain.

As FDA is aware, the NDC is used from the manufacturer through the pharmaceutical supply chain and health care product distribution system to the pharmacy. This is used for inventory management, billing to payers, dispensing, prescription drug monitoring programs (PDMPs), and performing clinical functions, among several other functions in a community pharmacy. Changes in NDC will likely take several years, as allotted in the Proposed Rule, to fully transition inventory, pharmacy management systems, and follow Drug Supply Chain Security Act (DSCSA) requirements. Costs of this transition may be underestimated by FDA.

The Proposed Rule cites addressing the shortage of 5-digit labeler codes to expanding to a 6-digit labeler code, and a 12-digit NDC. NCPA believes that **use of an alphanumeric 5-character labeler code instead of a 6-digit labeler code is less disruptive and more easily transitioned into the current marketplace.** NCPA's statement on utilization of the alphanumeric labeler code mirrors comments put forth by the National Council for Prescription Drug Programs (NCPDP). 11-character NDCs are present in every step of the pharmacy supply chain, from manufacturer to patient, and the current format is ubiquitous in the healthcare industry. Several technologies utilized throughout the pharmacy supply chain are capable of reading barcodes as alphanumeric, and disruption in this specific area is anticipated to be limited.

Barcode scanning is a key process in many independent pharmacies, and most pharmacy system vendors are able to support alphanumeric reading, should NDC format move to include that option. NCPA strongly supports maintaining consistency in NDC changes with DSCSA requirements. Independent pharmacies will already face disruption in workflow and inventory pending DSCSA barcode requirement changes and maintaining consistency between proposed NDC revisions and DSCSA is key for ease of implementation.

NCPA Conclusion:

- NCPA endorses comments put forth by NCPDP, including utilization of alphanumeric characters as revision to current NDCs. NCPDP standards already identify 'characters' not 'numbers' in their recommendations. Utilizing an alphanumeric system as opposed to expanded labeler codes creates less impact on stakeholders.

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- Leaving the FDA NDC as 10 digits would also avoid impact to other identifiers which today are transformed into an 11-digit NCPDP formatted NDC for usage in the pharmacy industry.
- There will be significant time and costs associated with transitioning the format of NDCs towards an alphanumeric 11-character format or an expanded 12-digit NDC.

NCPA thanks FDA for the opportunity to provide feedback, and we stand ready to work with FDA to offer possible solutions and ideas.

Should you have any questions or concerns, please feel free to contact me at Jessica.satterfield@Ncpa.org or (703) 838-2669.

Sincerely,

A handwritten signature in cursive script that reads "Jessica Satterfield". The signature is written in black ink on a white background.

Jessica Satterfield
Associate Director, Policy and Pharmacy Affairs