

Understanding the FDA's Plans for NDCs



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BACKGROUND

Years before COVID-19 was a household word, the Food and Drug Administration (FDA) was considering how to change the National Drug Code (NDC) structure to manage the projected depletion of five-digit labeler codes. In 2018, the FDA held the first public hearing to allow stakeholders to present assessments of four potential FDA options and present alternative solutions. The FDA, having been correctly focused on the COVID public health emergency for the past two and a half years, is now refocusing attention on the NDC shortage.

Due to the complexity of changing the NDC structure and the FDA's multiyear plan for full implementation, this will be the first in a series of installments about this topic. Here we will focus on the FDA's proposed solution, an explanation of the stepped, multiyear approach, and key projected dates for the multiphase implementation. In future columns we will discuss any changes to the FDA's proposal regarding system requirements as each deadline approaches.

PROPOSED NDC STRUCTURE

On July 22, 2022, the FDA issued an NPRM (notice of proposed rulemaking), which describes the FDA's plans for NDC modification and provides guidance on how to submit comments and concerns on the proposed solution. To address the issue of running out of 10-digit NDCs, the proposal describes the FDA's intended solution to adopt a single, uniform 12-digit format for FDA-assigned NDCs. The FDA is proposing to change the NDC to 12 digits in length, with three distinct and consistent segments and one uniform format. Additionally, the FDA is proposing to revise the drug product barcode label requirements. Comments may be submitted per the instructions contained in the NPRM, with the comment period ending on Nov. 22, 2022. The full proposal can be found on the FDA website at "Proposed Rule on Revising the National Drug Code Format."

CURRENT NDC STRUCTURE AS DEFINED BY THE FDA

NDCs currently issued are 10-digit codes constructed in one of three formats: 4-4-2, 5-3-2 or 5-4-1. In the examples on the next page, the first table illustrates an NDC in the 5-4-1 format. Systems throughout the industry convert the 10-digit code into an 11-digit 5-4-2 format. In part, this has led to a nonuniform approach to labeling and the creation of various crosswalk functionalities built into processes to "standardize" the NDC into an 11-digit value. The FDA proposal creates a single format for the NDC with the same separate and distinct segments, 6-4-2.

The impact on retail pharmacy and all associated business partners cannot be overstated. The 6-4-2 format, being the most reasonable approach, still requires a massive industry-wide overhaul to accommodate the new format. Changes to the NDC will impact all participants in healthcare that use drug data. This includes human and animal drug manufacturers, insurers, payers, wholesale distributors, compendia and clinical decision information databases, pharmacies, hospitals, clinics and healthcare practitioners, dentist offices, prisons, nursing care facilities, importers, federal agencies using the NDC, state and local governments, and other supply chain stakeholders that use FDA-assigned NDCs.

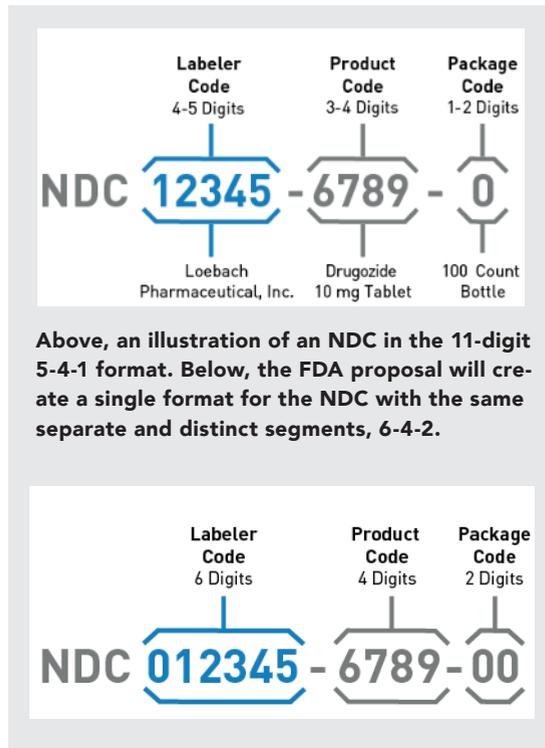
Some organizations have taken the initiative during the COVID pause to update their systems to accept a 12-digit NDC in anticipation of the expansion. The American Society for Automation in Pharmacy (ASAP) prescription drug monitoring program reporting standard has increased the length of the NDC field to accommodate a 12-digit NDC. Similarly, the National Council for Prescription Drug Programs (NCPDP) product service ID currently accepts 19 characters, and the next telecommunication version is expected to accept 40

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characters to accommodate other IDs besides the NDC.

RETAIL PHARMACY PREPARATION BEGINS NOW

In the immediate short term, retail pharmacy should become educated on the new NDC format, understand the proposed timelines, and submit concerns and suggestions to the FDA by Nov. 22, 2022, following the comment guidelines as stated in the NPRM. Plans for the development of system enhancements, testing, and implementation should be initiated. A significant portion of the planning must include transparency and coordination with business partners whose transactions include an NDC exchange. A typical retail pharmacy will need to



Above, an illustration of an NDC in the 11-digit 5-4-1 format. Below, the FDA proposal will create a single format for the NDC with the same separate and distinct segments, 6-4-2.

engage with wholesalers, pharmaceutical partners, procurement vendors, third-party adjudication entities, finan-

cial reporting vendors, and any other partner who uses NDC data. Internally, retail pharmacies will need to investigate changes that may be required in upstream and downstream systems that use the NDC. One approach is to establish a quarterly or biannual update meeting with vendors on their development activities to address the NDC changes.

As the FDA receives and responds to comments, an effective date announcement should be forthcoming in early 2023. Once released, the clock starts ticking toward implementation dates! **CT**

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The FDA's Projected Multiphase Implementation Schedule

2023 (Expected date but dependent on the FDA's responses to public comment).

- Effective date of initial 12-digit assignments is announced.
- Begin year one of the five-year period to implementation date:
 - NDC-utilizing systems have five years to:
 - Modify software and databases to accommodate 12-digit NDCs.
 - Build processes that take existing 10-digit NDCs and convert them to the new 12-digit 6-4-2 format.

2028–2029

- Effective date arrives.
- Critical date for all systems to accept and process 12-digit NDCs.
- The FDA begins to assign new 12-digit NDCs in the 6-4-2 format.

- All drug-listing files submitted on or after this date must use a 12-digit format.

2031–2032

- Three-year transition period begins for 10-digit NDC-run-out for manufacturers.
 - Designed to allow products labeled with 10-digit NDCs prior to the effective date to still move through the supply chain.
 - Assumes that at the end of three years, these products will have been consumed or be expired.
- By the end of the transition period, all product in the supply chain will be labeled with 12-digit NDCs.
- Current 10-digit NDC labeling will have to be converted to 12-digit labeling during the transition period.