In the Works: Major Change to the NDC Number

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IT MAY NOT BE EXCITING

or cutting-edge except to those of us in information technology, but the pharmaceutical supply chain and pharmacy profession's operations are tied to an infrastructure that depends on a 10- or 11-digit number, the National Drug Code, or NDC number. Nearly every step in the pharmaceutical product manufacturing, distribution, and pharmacy operation uses the NDC code. And the Food and Drug Administration (FDA) is running out of NDC numbers, requiring a look at how the code is structured. Nearly every system will be impacted. It is like the Y2K for pharmacy.

Let's take a quick review of what the NDC is, and how it is structured and used. Drug products are identified and reported using this unique, three-segment number NDC, which is a universal product identifier for human drugs. The three segments of the NDC identify the following:

- The labeler
- The product
- The commercial package size

The NDC number's first set of digits identifies the labeler (manufacturer, re-packager, or distributer). The second set of digits is the product code, which identifies the strength, dosage form, and drug formulation for a specific company. The third set of digits is the package code, which identifies package sizes and types. The FDA assigns the labeler code, while the company assigns the product and package codes.

The NDC was designed as 10-digit number that contains the three segments just noted. The NDC will be in one of the following configurations:

- 4-4-2; for example, 1234-5678-90
- 5-3-2; for example, 12345-678-90
- 5-4-1; for example, 12345-6789-0

Since the NDC is limited to 10 digits, a firm with a five-digit labeler code must choose between a three-digit product code and two-digit package code, or a four-digit product code and one-digit package code. Because the number may be in three different formats, it conflicts with the Health Insurance Portability and Accountability Act (HIPAA), which calls for an 11-digit NDC. One of the major goals of HIPAA was to enforce health information standards. As a result, many systems that used NDC numbers would add a leading zero to the shortest code segment, creating a de facto 11-digit NDC number. The FDA notes that since a zero can be a valid digit in the NDC, confusion may result when trying to reconstitute the NDC back to the FDA 10-digit standard format. For example: 12345-0678-09 (11 digits) could be 12345-678-09 or 12345-0678-9, depending on the firm's configuration.

USE OF THE NDC

NDC numbers are used on a widespread basis. Prescribing, dispensing, reimbursement, safety, clinical management, supply chain management, pharmaceutical manufacturing, and labeling, among other systems, are all dependent on the use of the NDC number (see box on next page). No doubt you can think of many more than I have listed here. A significant issue with many legacy systems that predate the NDC number "shortage" issues is that these systems were hard-coded for the 11-digit format — one reason it was the standard chosen in HIPAA. Hard-coding is the software development practice of embedding data directly into the source code of a program or other executable object, as opposed to obtaining the data from external sources or generating it at runtime. Hard-coded data typically can only be modified by editing the source code. Data that is hard-coded usually represents unchanging pieces of information. Well, not in the NDC number's case any longer.

THE NDC SHORTAGE

The FDA has said that within the next 15 years the NDC format will have to be changed to accommodate longer numbers because of the increase in new labelers entering the United States market and the fact that the FDA is running out of five-digit labeler codes. The five-digit labeler code format provides the FDA with 90,000 labeler codes, and the agency anticipates running out in 15 years. In a 2016 notice, the FDA stated when that when this happens it will begin assigning 6-digit labeler codes. As a result, the agency will be adding two 11-digit formats to the NDC arsenal (6-3-2 and 6-4-1). The FDA has acknowledged that some

stakeholders have promoted the idea of a single, standard NDC format during the comment period on that rule. (To view the rule, "Requirements for Foreign and Domestic Establishment Registration and Listing for Human Drugs, Including Drugs That Are Regulated Under a Biologics License Application, and Animal Drugs," see https://www.federalregister.gov/documents/2016/08/31/2016-20471/requirements-for-foreign-and-domestic-establishment-registration-and-listing-for-human-drugs.)

THE FDA IS LISTENING

The FDA is beginning the long process of seeking input on the NDC number's future format. It held a hearing on Nov. 5, 2018. Public comments are being sought through Jan. 5, 2019. The agency published the notice, "Future Format of the National Drug Code; Public Hearing; Request for Comments" in the Aug. 7, 2018, *Federal Register*, which can be accessed at https://www.federalregister.gov/documents/2018/08/07/2018-16807/future-format-of-the-national-drug-code-public-hearing-request-for-comments.

The hearing's purpose is to obtain and discuss stakeholder feedback on the future format of the NDC number. The FDA is seeking feedback on the following topics:

- The impact of transitioning from a five-digit labeler code to a six-digit labeler code, including the business, economic, information technology, and medical/clinical practice impacts, and its impact on the safety and security of drug products.
- Issues associated with the current lack of NDC uniformity in the marketplace.
- What should the FDA consider as it explores any further changes or expansion to the format or length of the NDC?
- How to best transition to a new format for the NDC.

They have focused questions for those who testify and provide comments, including:

- How would you describe your business or area of focus (e.g., payer, hospital, healthcare practitioner, benefit manager or administrator, pharmacy, manufacturer, re-packager, wholesale distributor, third-party logistics provider, drug compendium, standard-setting organization, or government entity)?
- How do you or your members use the NDC?
- What challenges does your organization or do your members face with the current NDC, and how do you overcome these challenges?
- What changes, if any, would you or your members need to make to your systems to accommodate the six-digit labeler code formats?

The areas that use and rely on the NDC:

- NDC assignment to a new drug product and its appearance on the product's label.
- FDA product approval systems and the NDC product directory.
- Pharmaceutical distribution systems.
- All item-level databases that drive other health information systems.
- Any drug information or clinical information system.
- 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.
- Prescription drug monitoring programs.
- Medication error-reporting systems, including the FDA and the private sector.
- Returned-goods systems.

The move toward a different NDC format will impact nearly every system touching healthcare where medication use happens. The enormity of this activity during the next decade and beyond cannot be understated. It may take that much time and longer to update and recode systems to manage the new format. It could indeed be even bigger than the preparation for the Year 2000. I encourage you to think through the implications for your company and the organizations you are integrated with, both up and down the vertical channel **CT**

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