

Future Format of the National Drug Code

Leyla Rahjou-Esfandiary, PharmD

Drug Registration and Listing
Branch | Office of Compliance
CDER | US FDA

Electronic Drug Registration and Listing (eDRLS) Using CDER Direct – SBIA
2024 Workshop



Learning Objectives



- Define the National Drug Code (NDC)
- Provide an overview of the proposed rule revising the NDC format
- Describe the proposed implementation timeline

Poll Question

Which statement is true about the NDC?

- A. NDC is required to appear on all human prescription drug carton labels
- B. NDC is 11 digits and is used in dispensing and reimbursement transactions
- C. NDC is 10 digits and has various formats
- D. Both A and B

What is the NDC?



- Unique identifiers for drugs in the U.S.
- For most drugs is included on the labeling
- It must be assigned to all drugs in commercial distribution
- Can be part of the UPC



Current NDC segments and formats

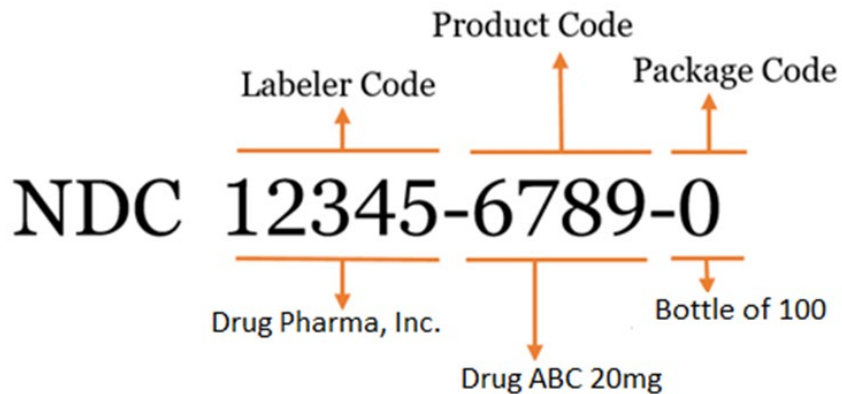
NDC is a 10-digit numerical identifier with:

3 segments

- Labeler code
- Product code
- Package code

3 FDA-assigned formats

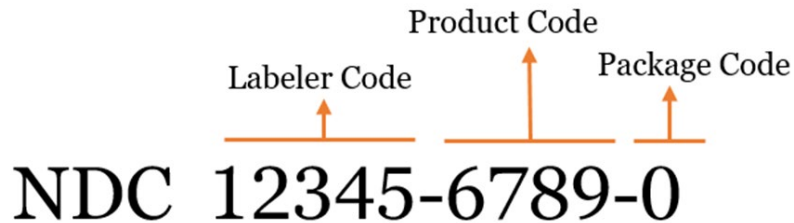
- 4-4-2
- 5-3-2
- 5-4-1



The HIPAA format

- Health Insurance Portability and Accountability Act
 - Adopted a uniform 11-digit NDC format that is required to be used when a HIPAA-covered transaction includes an NDC
 - This 11-digit format is standardized into a 5-4-2 format
 - Created by adding a leading zero to the applicable short segment

Current NDC conversions



Current NDC Formats

FDA 10-Digit NDC Formats		Examples of NDCs Converted into HIPAA 11-Digit Identifier Format (with zero added 0)		
XXXXXX (FDA-assigned labeler code)		Segment Format	With Hyphens	Without Hyphens
Format 1	12345-6789-0	5-4-1	12345-6789-00	12345678900
Format 2	12345-678-90	5-3-2	12345-0678-90	12345067890
Format 3	1234-5678-90	4-4-2	01234-5678-90	01234567890

FDA will run out of 5-digit LCs



- Under current regulations (21 CFR 207.33), once FDA runs out of 5-digit labeler codes, it will start assigning 6-digit labeler codes
- NDCs with 6-digit labeler codes would be 11-digits and would be required to be in one of the following 2 new formats:
 - 6-3-2
 - 6-4-1

Future Scenarios		
FDA 11-Digit NDC Formats		
Without any changes to the existing rule, there would be two additional formats created when 6-digit labeler codes are assigned.		
		Segment Format
Format 4	123456-7890-1	6-4-1
Format 5	123456-789-01	6-3-2

Emerging NDC situation

- Without a change, there would be five NDC formats, 3 in 10-digits and 2 in 11-digits
- An FDA-assigned 11-digit NDC may cause confusion with HIPAA converted, 11-digit NDCs
- The healthcare systems and payors currently convert 10-digit NDCs to 11-digit NDCs, which increases healthcare costs and may be a factor in medication errors

Possible Scenario if the Proposed Rule Is Not Adopted

		Segment Format	With Hyphens	Without Hyphens
Drug A (Format 1)	12345-6789-1	5-4-1 <i>(10 digits)</i>	12345-6789-01	12345678901
Drug B (Format 5)	123456-789-01	6-3-2 <i>(11 digits)</i>	123456-789-01	12345678901



Two distinct FDA-assigned NDCs for different drug products could result in the same HIPAA 11-digit identifier when hyphens are not used.

Proposed rule issued in July 2022

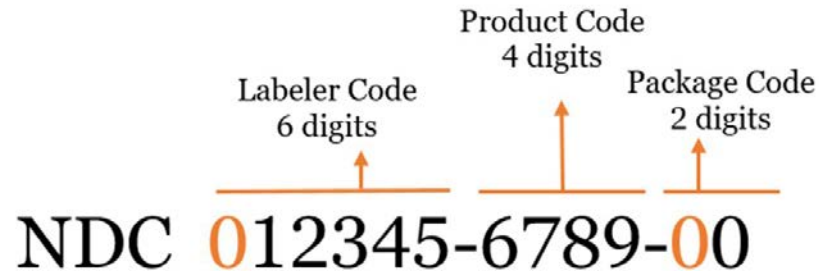


- Intended to minimize the impact of the transition to 6-digit labeler codes
- Intended to eliminates the timing uncertainty and multiple NDC lengths and formats

Proposed rule overview

- Proposed rule would update the length and format of NDCs
- Under the proposed rule, NDCs would expand from 10 digits to 12 digits
- Drug product barcode labeling requirements would be updated

Proposed National Drug Code (NDC) Change

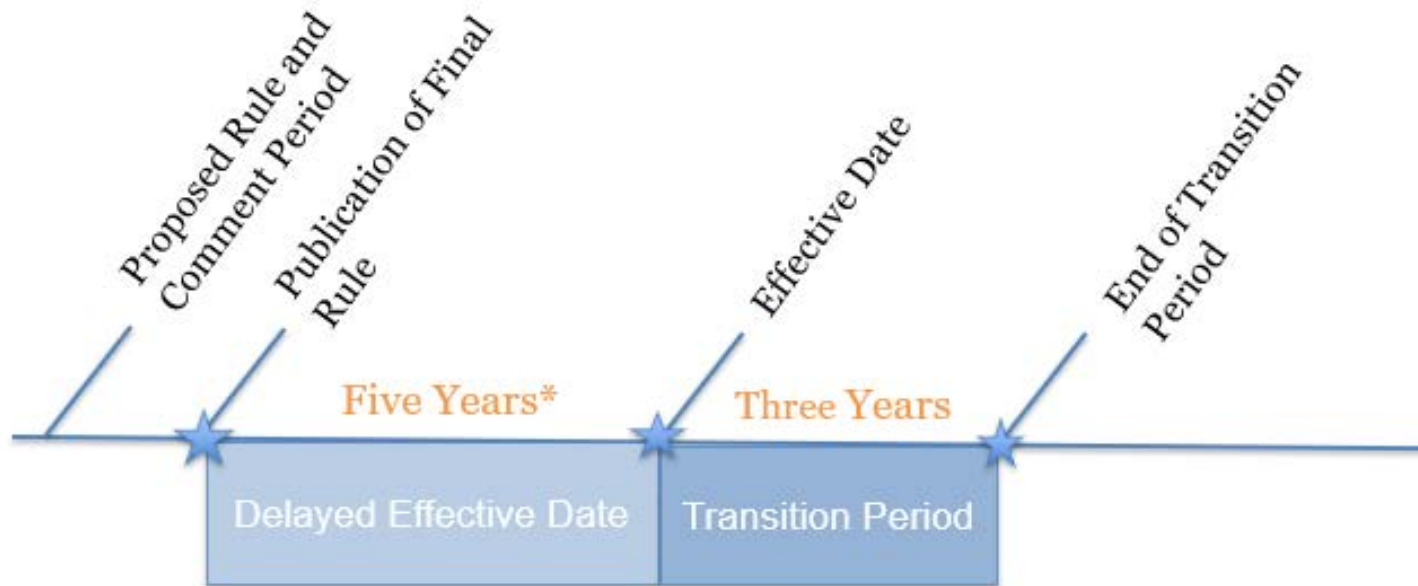


Potential benefits of proposed rule



- Adoption of a single NDC format by all stakeholders
- Minimizing confusion and medication errors
- Certainty with date and planning

Proposed timeline



Proposed timeline

- Final rule would include a delayed effective date
- Provides a 3-year transition period to facilitate a smooth transition
 - Minimizes relabeling costs
 - Decreases risk of drug shortage due to timing of product release
 - Limits timeframe of confusion with coexisting labeling with 2 different lengths of NDC

Effective date



- On the effective date:
 - FDA would convert all NDCs to 12 digits
 - FDA would begin assigning 6-digit labeler codes and NDCs in the new 12-digit format
 - Stakeholders should have systems capable of handling the new, uniform, 12-digit NDC
 - Firms should start labeling drugs that were assigned 10-digit NDCs with new 12-digit NDC format
 - Drug listing submissions would be required to use the new 12-digit NDC format

Transition period

- 3-year transition period following the effective date
 - FDA will publish and maintain both 10- and 12- digit NDCs
 - Drug labeling with both 10 and 12-digit NDCs will be in commercial distribution during the transition period but a map road will be available online
- At the end of transition period:
 - All firms would be required to use a 12-digit NDC in listing files
 - No enforcement discretion for labeling

Stakeholder preparation



- Operating systems compatibility (if rule finalized)
 - Have all systems ready to accommodate 12-digit NDCs in 6-4-2 format
- Labeling
 - Plan labeling updates and annual reports according to the rule's effective date
- Drug Listing
 - Confirm 12-digit NDC format after effective date
 - Provide updated labeling for your drug listing files after the effective date

Challenge Question

Which statement is true?

- A. The proposed rule, if finalized, will require inclusion of NDC on all drug labels and labeling
- B. Once finalized, if remain as proposed, the final rule will be effective right after publication
- C. During transition period, there will be 10-, 11-, and 12-digit NDCs on drug labels
- D. The proposed rule, if finalized, will standardize the length and format of the NDC

Resources



- Federal Register :: Revising the National Drug Code Format and Drug Label Barcode Requirements
 - <https://www.federalregister.gov/documents/2022/07/25/2022-15414/revising-the-national-drug-code-format-and-drug-label-barcode-requirements>

Summary



- With or without a final rule, the NDC format will change in the future.

Stay informed!

Questions?

Leyla.Rahjou-Esfandiary@fda.hhs.gov
eDRLS@fda.hhs.gov

