November 17, 2022

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Dockets Management Staff (HFA–305)
Food and Drug Administration
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

Dear Sir or Madam,

The National Council for Prescription Drug Programs (NCPDP) is a not-for-profit American National Standards Institute (ANSI) accredited Standards Developer (ASD) consisting of more than 1,500 members who represent drug manufacturers, chain and independent pharmacies, drug wholesalers, insurers, mail order prescription drug companies, claims processors, pharmacy benefit managers, physician services organizations, prescription drug providers, software vendors, telecommunication vendors, service organizations, government agencies and other parties interested in electronic standardization within the pharmacy services sector of the health care industry. NCPDP provides a forum wherein our diverse membership can develop business solutions, including ANSI-accredited standards and guidance for promoting information exchanges related to medications, supplies and services within the healthcare system.

For over 40 years NCPDP has been committed to furthering the electronic exchange of information between healthcare stakeholders. The NCPDP Telecommunication Standard is the standard used for eligibility, claims processing, reporting and other functions in the pharmacy services industry as named in the Health Insurance Portability and Accountability Act (HIPAA). The NCPDP SCRIPT Standard, Telecommunication Standard and the Formulary and Benefit Standard are the standards in use in electronic prescribing as named in the Medicare Modernization Act (MMA).

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

Summary:

1) The costs of expanding the labeler field from five to six digits, thereby, expanding the FDA National Drug Code (NDC) to 12 digits, are significantly underestimated by the FDA.
2) NCPDP anticipates no significant benefits in terms of quality control or identifier confusion as identified in the NPRM for this proposed solution of expanding the labeler field to six digits or from the consequent expansion of the FDA NDC to 12 digits.
3) NCPDP believes a safer, less costly and less disruptive option exists. The FDA could achieve its goal of having a lengthy reserve of labeler codes, with lighter industry impact, by making the existing five-digit

labeler code alphanumeric. This option would preserve the FDA's existing ten-position NDC format and the HIPAA mandated NDC 11-position format. Therefore, NCPDP is proposing the FDA adopts 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.

NCPDP realizes the proposal in item three above is a substantive change from our previous comments on solving the issue of the finite number of remaining new labeler codes. The justification for the change in our position is detailed below.

FDA: Summary of the Major Provisions of the Proposed Rule
Federal Register page 44039 and 44040
"On the effective date of the final rule, FDA would begin assigning new NDCs in the uniform, 12-digit format, and existing 10-digit NDCs assigned by FDA prior to the effective date would be required to convert to the new, uniform, 12-digit NDC format. As a result, all stakeholders that use FDA-assigned NDCs would need to have systems capable of handling the new, uniform, 12-digit NDC on the effective date of the final rule. Therefore, FDA is proposing to delay the effective date of the final rule for a period of 5 years following its publication to allow stakeholders time to develop and implement such systems.

Additionally, FDA is proposing to allow for a 3-year transition period following the effective date of the final rule. During this proposed 3-year transition period, firms that use 10-digit NDCs assigned prior to the effective date on product labeling should begin updating their labeling to replace the 10-digit NDCs with the new 12-digit NDCs by adding leading zeros to the labeler code, product code, and/or package code segments as needed, as soon as possible. However, to aid with the transition, FDA does not intend to object to continued use of such 10-digit NDCs on the labeling of products remaining in interstate commerce after the effective date during the 3-year transition period."

NCPDP Comment: NCPDP is requesting further clarification on the period to transition after the five years following its publication effective date. Is there an additional three-year transition following the five-year period for a total of eight years before the rule is fully implemented?

NCPDP requests all historical ten-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 would be least disruptive to existing systems and processes while preserving historical records as well as reducing change management costs.

FDA: Costs and Benefits
Federal Register page 44040
"One expected benefit of the proposed rule, if finalized, is that the proposed standardized format would facilitate the adoption of a single NDC format by all stakeholders. Such an adoption would eliminate the need to convert NDCs from one of FDA's prescribed formats to a different standardized format used by other sectors of the healthcare industry (e.g., healthcare providers and payors). Eliminating the need to convert NDCs should reduce potential errors caused by converting from the FDA-assigned NDC format to a different format used by other sectors of the healthcare industry. Standardization and adoption of a single format would also eliminate the need for additional quality control and validation by certain stakeholders, such as payors and prescribers, to ensure a drug product and its respective NDC are accurate; this is particularly important for insurance coverage and reimbursement claims. Another benefit of the proposed rule would be to avoid any potential risks to the public health from potential reductions in medication errors and risk of confusion. We do not have data to quantify these potential benefits and request comments.

The costs to industry of converting current NDC codes to the proposed format would include one-time costs of updating software systems, new training for employees, coordinating labeling updates, and reading and understanding the proposed rule. Industry, however, can incorporate any changes to existing labeling due to this proposed rule into their recurring labeling updates and avoid any relabeling costs. Some software and training costs would occur even without the proposed rule because FDA will begin issuing 6-digit labeler codes, and the current 10-digit NDC formats are not capable of accommodating 6-digit labeler codes. Our estimates, therefore, are conservative. We estimate annualized costs would be about $12.4 million ranging from $6.1 million to $19.4 million using a 7-percent discount rate over a 10-year horizon. Similarly, we estimate annualized costs would be about $10.2 million ranging from $5.1 million to $16.0 million using a 3- percent discount rate over a 10-year horizon. The present-value of the estimated costs would be $87.1 million ranging from $43.1 million to $136.3 million at both the 7-percent and 3- percent discount rates."

NCPDP Comment: The FDA used a RAND Corporation report, about the ICD-9 to ICD-10 transition, from 2004 to estimate the costs of expanding the NDC. The FDA estimates the NDC expansion would have ten percent of the impact of the ICD expansion. NCPDP believes the costs of the currently proposed FDA solution are highly underestimated due to the expansion of the stakeholders involved and the pervasive nature of the NDC versus the ICD-10 codes. For instance, unlike NDCs, the ICD codes are not printed and applied to every object in the supply chain that is then tracked and monitored as it is exchanged between parties. Since there are so many more specific tasks in which NDCs are used compared to diagnosis codes, it would be better to estimate system impact not at ten percent of the cost of the ICD-10 transition but three to ten times greater than the cost of the ICD-10 transition.

The NDC is mandatory in every aspect throughout the drug supply chain. This includes the manufacturing and packaging of the drug, delivery of drugs to the patient and post-dispensing analytics.

Therefore, NCPDP recommends the use of an alphanumeric, five-character labeler code rather than expanding to a six-digit labeler code resulting in a 12-digit NDC because of the pervasive use of the current NCPDP formatted 11-digit NDC in the healthcare industry.

Impacted Stakeholders

NCPDP is unable to comment on specific costs to individual member organizations or the healthcare industry as a whole but will comment on the increase in the number of stakeholders involved.

FDA expects expanding the NDC would impact pharmaceutical companies, insurers, hospitals, medical offices, nursing facilities, pharmacies, dentist offices, residential facilities, home healthcare, outpatient care centers medical/diagnostic offices, medical equipment retailers and other healthcare practitioners.

NCPDP agrees the FDA's list of stakeholders is accurate; however, it is not comprehensive. Additional healthcare stakeholders significantly impacted by expanding the NDC include, but are not limited to:

- State Prescription Drug Monitoring Programs
- State Medicaid Agencies
- Drug data vendors (compendia)
- Drug distributors
- Pharmacy benefit managers
- Pharmacy claims processors
- Payers other than insurers (e.g., employers health plans, claim sponsors, labor unions and the government)

- Rebate processors
- Software vendors
- Auditors
- Intermediaries and clearinghouses
- Data aggregators and analytics entities
- Additional governmental entities (e.g., NLM, FDA, DEA)
- Health Information Exchanges
- Additional Standards organizations (e.g., X12 for administrative and supply chain transactions and GS1 which issues GTIN for barcodes)
- Regulatory agencies

These costs, regardless of the solution, would be burdensome to the wide set of stakeholders who today work with medications in the United States. These costs would be passed along to patients, and at the same time, could delay development of critical patient care initiatives.

Since many entities already store and communicate NDCs as alphanumeric (e.g., string, text) fields, the impact and cost of transition would be substantially decreased compared to a change in the format of the NDC.

Major impacts could still affect the cost to entities that do store the NDC number as numeric. In discussions with some of the NCPDP member entities, they confirm the cost and impact would be less to transition to an alphanumeric format than to increase the length, change the format and retain as a numeric field.

FDA: Current Regulatory Framework and the Need for the Regulation
Federal Register page 44041

"*The NDC for each listed drug marketed in the United States is a unique 10-digit,2 3-segment number (§ 207.33(b) (21 CFR 207.33(b)). The 3 segments of the NDC include the labeler code, product code, and package code (id.). The first segment, the labeler code, is a unique 4-, 5-, or (in the future) 6- digit number assigned by FDA that identifies the manufacturer, repacker, relabeler, or private label distributor of the drug (id.). The second segment, the product code, is a 3- or 4-digit number that identifies a specific active ingredient, strength, and dosage form of a drug manufactured, repackaged, relabeled, or distributed by the labeler (id.; § 207.35(b) (21 CFR 207.35(b))). The third segment, the package code, is a 1- or 2-digit number that identifies package sizes and types (§ 207.33(b)). Different package codes differentiate between different quantitative and qualitative attributes of the product packaging (§ 207.35). Both the product and package codes are proposed by persons submitting drug listing information (see § 207.33(d)(1)). The Agency will assign a proposed NDC if it has not been used previously, is not currently in use, and has not been reserved for future assignment to a different drug (§ 207.33(d)(2))".*

NCPDP Comment: NCPDP requests the FDA supply the total number of NDCs that have been assigned and how many of these NDCs are in use. Additionally, NCPDP requests the FDA supply the total number of reserved labeler codes and the purpose for reserving these labeler codes for future assignment.

NCPDP requests the FDA confirm labeler codes of repeating numbers (i.e., 00000, 11111, 22222, etc.) will not be assigned as it may impact existing industry use of these values.

NCPDP recommends the use of a five-character alphanumeric labeler code because it is less impactful to the industry and less disruptive to patient care than FDA's proposed changes. If the FDA requires a single format we recommend the current HIPAA mandated 11-position format which is 5-4-2.

FDA: The Effect on Other Non-FDA NDC Formats

Federal Register page 44044

"*Recognizing that new data standard(s) may be necessary to encode the new, uniform, 12-digit NDC into a data carrier, we propose to revise § 201.25© to allow the use of linear or nonlinear barcodes that meet specified standards. FDA is considering whether to further revise § 201.25(c) to accommodate potential advances in technologies and standards development by allowing the use of unspecified automatic identification and data capture formats other than linear or nonlinear barcodes in the future without the need to revise the regulation again. Therefore, we are asking stakeholders to provide comments on whether to include such flexibility".*

NCPDP Comment: NCPDP recommends the following to help ensure with the change to the NDC format, pharmacies can continue to rely on barcode scanning for product validation and to provide further information as the FDA considers revision of 21 CFR 201.25(c):

Barcode scanning as a product validation step is used throughout day-to-day operations in the drug supply chain, from manufacturer to the delivery of medication to the patient. Product validation ensures the selected physical product matches the intended product for a particular task or step along the supply chain. Additionally, barcode types used at each step can vary depending on their intended use.

Based on the final FDA decision for the NDC format, and the pervasive use of multiple barcode types, NCPDP offers the following general comments:

- Any change in the NDC format, whether alphanumeric or expanded numeric, will require changes to the product identification and, therefore, barcode.
- These proposed changes to the NDC format will require modifications on how this information is encoded within barcodes and should remain consistent with Drug Supply Chain Security Act (DSCSA) requirements for products regulated under 21 CFR 201.25(c).

Summary of Costs and Benefits

Federal Register page 44045

"One expected benefit of the proposed rule, if finalized, is that the proposed standardized format would facilitate the adoption of a single NDC format by all stakeholders. Such an adoption would eliminate the need to convert NDCs from one of the FDA-prescribed formats to a different standardized format used by other sectors of the healthcare industry (e.g., healthcare providers and payors). Eliminating the need to convert NDCs should reduce potential errors caused by converting from the FDA- assigned NDC format to a different format used by other sectors of the healthcare industry. Standardization and adoption of a single format would also eliminate the need for additional quality control and validation by certain stakeholders, such as payors and prescribers, to ensure a drug product and its respective NDC are accurate; this is particularly important for insurance coverage and reimbursement claims. Another benefit of the proposed rule would be to avoid any potential risks to the public health from potential reductions in medication errors and risk of confusion. We do not have data to quantify these potential benefits and request comments."

NCPDP Comment: Conversions today are executed by drug data vendors known as compendia, who publish the standardized NCPDP 11-digit Product Identifier NDC. Because most stakeholders use a compendium-published NCPDP 11-digit Product Identifier formatted NDC, there is little concern about conversion quality control.

FDA also expects medication errors may occur when there is confusion between NDCs and other numbers such as batch, model or order number that may use an overlapping three-segment format with fewer than 12 digits. NCPDP is not aware of errors occurring because of identifiers confused across domains. Since active NDCs account

for approximately 100,000 of the ten billion NDC values possible today (ten to the tenth power), the likelihood of taking 11 digits from another domain and randomly happening upon an active NDC is one in 100,000. Expanding from 10 digits to 12 digits would not provide a statistically relevant reduction to the existing minimal risk in this context.

The addition of random alpha characters (four-character suffix) to biological products was implemented by the FDA in an effort to avoid confusion amongst biosimilar products. If the addition of the random four-letter suffix can support FDA in avoiding confusion at a clinical ingredient level, there should be no confusion in using letters at the NDC's Labeler Code level.

Since the NDC is already stored and communicated as an alphanumeric field by many stakeholders, NCPDP anticipates the following benefits:

- The risk to patient safety would be reduced. The alphanumeric NDC solution would require minimal, if any, conversions in many circumstances. All existing NDCs would remain the same, eliminating potential issues in incorrectly or inconsistently converting the various NDC formats (4-4-2, 5-3-2, 5-4-1) to a 6-4-2 format. Any mistake in this conversion by any entity along the supply chain could end with an adverse event with catastrophic results or death. By reducing the number of conversions required, this issue could be minimized.
- The timeline to full implementation and transition could be accelerated. Having fewer entities that have major conversions to perform, and the less costly nature of those that do have conversions necessary, would positively impact the speed to compliance.

Additional benefits noted by NCPDP:

- The industry would not have to wait on a change of HIPAA Regulations to change the named NDC-11 to an alphanumeric labeler code.
- The middle digits of the NDC, known as product code identifiers, are the most important part of the NDC safety check process and will not be impacted by an alphanumeric labeler code.
- Keeping the FDA NDC with a length of ten characters would also accelerate the date at which FDA could assign labelers after exhausting the five-digit labeler code.
- NCPDP standards already allow for the Product Service ID to be formatted as alphanumeric characters. Any healthcare stakeholder whose code treats the Product Service ID as numeric today would misread NDC values which start with zero; it is our understanding that most systems read this field as text. Alphanumeric labeler codes should have comparatively light impact on the industry when compared to expanding the labeler code size.
- Preserving the FDA NDC as ten characters would also avoid impact to other identifiers (e.g., UPC, etc.) that are currently reformatted into a NCPDP 11-digit Product Identifier NDC for usage in the pharmacy industry.
- NCPDP standards allow for the use of other identifiers such as HCPCS or CPT codes. The NCPDP Telecommunication Standard and related standards support a qualifier field to distinguish between the unique code sets, such as NDC, HCPCS or CPT.
- Since there is currently no statute of limitations surrounding the Medicaid Drug Rebate invoicing or disputing, the proposal to add only the alpha code on new labelers going forward and the implementation of an alphanumeric 5-character labeler code should be easier for state Medicaid agencies and their vendors to invoice and dispute claims. The FDA proposal would be a huge burden on the states specific to all the historical claims from 1991 to today.

Risks:

- In responding to one prior comment, the NPRM states that assigning an alphanumeric labeler may lead to errors because of letters being confused with numbers. That problem could be mitigated by assigning labelers without confusable letters such as (B, D, I, O and Q). Using the remaining 21 letters in addition to digits 0-9 would extend the labeler domain from its current 10^5 (100,000) possible labeler values to 31^5 (>26 million) possible labeler values.

NCPDP Conclusion:

- NCPDP standards already require the Product Service ID be formatted with characters, not numbers. Therefore, alphanumeric labeler codes should have comparatively light impact on the industry in comparison to an expanded labeler code.
- Leaving the FDA NDC with a length of ten characters would also avoid potential impacts to other identifiers that are currently transformed into an 11-digit NCPDP formatted NDC for usage in the pharmacy industry.
- If the FDA moves forward with expanding the format to a 12-digit NDC, the system coding, conversions and coordination in the industry would create greater costs and patient safety risks than the alphanumeric recommendation. Strategic transition planning and additional time will be required to mitigate these risks.
- NCPDP requests the FDA change course and plan to make the labeler alphanumeric while retaining the current length of both the labeler and the NDC.

NCPDP would like to thank the FDA for the opportunity to submit comments on FDA–2021–N–1351 *Revising the National Drug Code Format and Drug Label Barcode Requirements*. NCPDP and its members are not averse to changing the NDC format and recognize it is inevitable. NCPDP looks forward to working with the FDA to resolve the NDC challenge and to ensure the healthcare industry is minimally impacted and able to move forward.

For direct inquiries or questions related to this letter, please contact:

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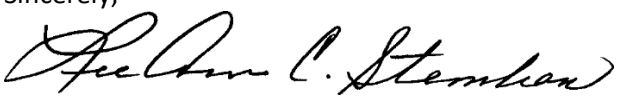
Sincerely,



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