July 9, 2021

Submitted electronically via email

Deborah Bryant
Director, Division of Consumer Advocacy and Assister Support
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

RE: Reference to 8-digit NDC in Transparency in Coverage Final Rule (CMS-9915-F)

Dear Ms. Bryant,

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 1,700 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.

NCPDP is writing today to express our concern regarding guidance issued in the Transparency in Coverage Final Rule (CMS-9915-F) that appears to support the use of an 8-digit NDC (i.e., NDC-8) in the GitHub specification[1] rather than an NCPDP formatted 11-digit NDC (i.e., NDC-11).

Since a HIPAA compliant NCPDP standardized format is an 11-digit NDC, (Labeler – 5 digits, Product – 4 digits, package size – 2 digits), referring to an 8-digit NDC is at first concerning and becomes even more so when one researches the available information on CMS sites.

In the Final Guidance (page 235), it specifies that any billing code be an 11-digit (or zero-removed 10-digit) NDC. Please note, it does not say anything about the use of NDC-8, redundancy, or whether EVERY NDC must be provided when the prices are actually the same. It does state,

> "…a National Drug Code (NDC) (The final rules define the NDC code as a unique 10- digit or 11-digit 3-segment number assigned by the Food and Drug Administration (FDA), which provides a universal product identifier for drugs in the United States),…"

[1] https://github.com/CMSgov/price-transparency-guide/tree/master/schemas/prescription-drugs

In the footnote on page 235 of the same document, it states, "in the preamble to the HIPAA regulations and the Department of Health and Human Services (HHS) stated that it was adopting a uniform 11-digit format to conform to customary practice used in computer systems (65 FR 50314, 50329; Aug. 17, 2000). The HIPAA 11-digit NDC format is standardized such that the labeler code is always 5 digits, the product code is always 4 digits and the package code always 2 digits. To convert a 10-digit NDC to an 11-digit HIPAA standard NDC, a leading zero is added to the appropriate segment to create the 11-digit configuration as defined above. See 83 FR 38666 (Aug. 7, 2018)."

The GitHub specification for prescription drugs contains a serious misunderstanding which should be corrected. It states,: "Data reporting will be on the **first 8 digits** of the full 10-digit or 11-digit NDCs. The last 2 digits of the full 10-digit or 11-digit NDC specify quantity and do not have an impact on the negotiated rate or historic net price." This is incorrect. The last 2 digits of the NDC can include part of the "product segment" of the NDC if the FDA has assigned a 10-digit NDC in the 5-4-1 structure.

The example[2] below uses an 8-digit NDC (which violates the Final Guidance requiring the complete NDC) but really represents an "assumed" NDC with the "0" inserted in the 6th position – an assumption that cannot always be made.

```
"drugs":
[{
                "drug_name": "Simvastatin",
                "drug_type": "generic",
                "ndc": "16729-004",
```

An analysis of one manufacturer's NDCs shows that while the NDC-8s are all the same, they represent entirely different products. Each of the following products are active within the same NDC-8, all made by the same manufacturer, but all are completely different entities with extremely different pricing.

NDC 8	NDC 11	DRUG NAME
63187081	63187081350	SILDENAFIL 20 MG TABLET
63187081	63187081690	RAMIPRIL 10 MG CAPSULE
63187081	63187081430	LOVASTATIN 10 MG TABLET
63187081	63187081130	GLIPIZIDE 10 MG TABLET
63187081	63187081030	GABAPENTIN 300 MG CAPSULE
63187081	63187081730	ESZOPICLONE 1 MG TABLET
63187081	63187081820	DOXYCYCLINE HYCLATE 100 MG CAP
63187081	63187081221	CYCLOBENZAPRINE 10 MG TABLET
63187081	63187081930	BUPROPION HCL XL 300 MG TABLET
63187081	63187081515	ACETAMINOPHEN-COD #3 TABLET

[2] https://github.com/CMSgov/price-transparency-guide/blob/master/examples/prescription-drugs/prescription-drugs.json

This difference will be magnified with over-the-counter products (OTCs). OTCs are most likely Universal Product Codes (UPCs) that are 10-digit identifiers in a 5-5 format which are converted to the NCPDP 11-digit format by inserting a "0" in position 6 (between the two sets of 5 digits). As an example:

UPC 8	UPC 11	Product Name
11917001	11917001339	Nicotine Dis 21mg/24H
11917001	11917001343	Nicotine Dis 14mg/24H

Further, as CMS correctly stated in the Final Rule response to the comment recommending the use of the RxCUI as an alternative to NDC or HCPCS, "the accuracy of pricing information requires precise and specific product information, including package size and manufacturer."[3] By removing the part of the NDC that allows the package size to be conveyed, the specific product information is jeopardized and corrupts the accuracy of the pricing information the Prescription Drug File is intended to provide.

NCPDP believes this guidance and the schema provided for the Prescription Drug File will lead to more confusion and obfuscation rather than clarity and transparency. Moreover, the HIPAA statements all clearly point to the use of an NCPDP formatted identifier. Coupled with the desire and directive to facilitate interoperability and clarity, NCPDP respectfully requests that CMS issue further guidance recommending the NCPDP formatted NDC-11 as the appropriate drug identifier to use and a corresponding change to the schema.

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

Sandra Garnand
Standards Specialist, Standards Development
NCPDP
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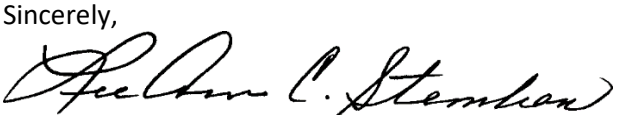
Sincerely,



Lee Ann C. Stember
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[3] Page 240, CMS Transparency in Coverage-9915F