Implementation Pilot for Two-Dimensional (2D) Vaccine Barcodes

Overview:
National Drug Code (NDC) Usage in EMR Systems

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Facts Recap: National Drug Code (NDC)

The Food and Drug Administration (FDA) issues a 10 digit identification number for each drug product available in the US market.

These numbers are issued to Manufacturers of these products.

There are 3 possible formats of the NDC (from manufacturer)

The 5-4-1 format e.g. 49281-5890-5

(5) (4) (1)

The 5-3-2 format e.g. 49281-589-05

(5) (3) (2)

The 4-4-2 format e.g. 4928-1589-05

(4) (4) (2)

The NDC Data Structure:

- The first segment is the "Labeler Code"
- The second segment is the "Product Code"
- The third segment is the "Package Code"

The NDC encoded in a barcode (1D or 2D) is unformatted (without hyphens).

The NDC printed on the product label is formatted for human readability.

In 2D barcodes, the NDC is embedded in the Global Trade Item Number (GTIN) as shown below.

E.g. if 01003**4928158905**817**131028**10**U4275AA** is the raw 2D

NDC = 4928158905

Expiration Date = 131028

Lot # = U4275AA

Encoded Data

GTIN: (1) (01) 00349281589058
Expiry: (17) 131028 (YYMMDD)
Lot#: (10) U4275AA

How do EMRs currently use NDC?

- EMRs store NDC in a master product database. Some EMRs have the capability to convert NDC into a GTIN and vice versa.
- Typically EMRs do not allow users to "hand-key" NDC at the time of inventory or vaccine administration (there are a few EMRs that allow users to pick NDC from a pick list).
- EMRs typically derive the NDC from the Vaccine Name, Manufacturer. These fields are entered by users at the time of inventory or vaccine administration.
- A 10 digit NDC needs to be converted to a 11 digit NDC for claims submission and reporting to IIS, in a 5-4-2 format. The conversion rule is a "happy accident" and the format was initiated by insurance companies.
- The NDC stored in the EMR product database is a 11 digit NDC. EMRs convert the FDA issued 10 digit NDC to a 11 digit NDC **based on internal formatting rules**. A "0" is appended to the segment that needs to confirm to the 5-4-2 standard. No user action is needed for this conversion. A representative conversion process is shown below.

FDA Issued NDC	Apply Mfg based formatting rules and Convert to	EMR Stores as	EMR Reports as (claims and IIS)
49281-5890-5 (5-4-1)	49281-5890-**0**5 (5-4-2)	4928158900**5**	4928158900**5** Or 49281-5890-**0**5
49281-589-05 (5-3-2)	49281-**0**589-05 (5-4-2)	4928**1**058905	4928**1**058905 Or 49281-**0**589-05
4928-1589-05 (4-4-2)	**0**4928-1589-05 (5-4-2)	**0**4928158905	**0**4928158905 Or **0**4928-1589-05

**For illustration purposes only, individual implementations may vary*

Conversion to MVX or CVX/CPT Codes

- In addition to the product master database, EMRs also maintain MVX, CVX and CPT mapping tables.
  - Several NDC (of the same drug product class) may map to 1 CVX code.
  - A manufacturer maps to 1 MVX code
  - CPT code is derived from the treatment offered to the patient
- EMR vendors regularly update their master tables from commercially available data sources e.g. First Data Bank, National Drug Database etc.

How can EMRs in future use GTIN to derive NDC?

- In the future, the EMRs with GTIN scanning and processing capability will need to
    - Maintain a mapping table of GTIN to a 11 digit NDC
        - Given a GTIN, derive a 11 digit NDC based on a backend mapping table lookup

    And/Or

    - Maintain a mapping of 10 digit NDC to a 11 digit NDC
- Should NOT rely on formatting rules to put "0" in segments for NDC10 to NDC11 conversion, as this is prone to error
- The GTIN-NDC lookup and conversion process may look like below. All other internal EMR implementation details, including MVX/CVX/CPT conversions can remain same.

Scan GTIN	Lookup and Convert to 11 digit NDC as	Store 11 digit NDC as	Reports as (claims and IIS)
0034928158905 (GTIN from a 5-4-1 mfg)	49281-5890-05 (5-4-2)	49281589005	49281589005 Or 49281-5890-05
0034928158905 (GTIN from a 5-3-2 mfg)	49281-0589-05 (5-4-2)	49281058905	49281058905 Or 49281-0589-05
0034928158905 (GTIN from a 4-4-2 mfg)	04928-1589-05 (5-4-2)	04928158905	04928158905 Or 04928-1589-05

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