

Updated Guidance for Documenting Vaccine National Drug Codes (NDCs) and Lot Numbers in IISs and EHRs

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Purpose

This updated guidance for documenting National Drug Codes (NDCs) and lot numbers for administered vaccines is for both immunization providers and city/state immunization information system (IIS) staff. Please use this guidance when documenting NDCs and lot numbers in either an electronic health record (EHR) or immunization information system (IIS).

Background

Over the last few years, vaccine manufacturers have made changes in vaccine labeling that impact patient safety and vaccine inventory management. These labeling changes have resulted in unit of sale (UoS) packages that have different NDCs and lot numbers from those of unit of use (UoU) vials/syringes (for all NDC presentations and a subset of lot number presentations). A December 2016 survey of vaccine manufacturers who participate in the VFC program showed that for six private and public vaccine products (8% of VFC vaccine doses), lot numbers on the UoU and UoS were similar, but typically differed by one or two additional characters on the UoS item. In early 2021, four of those products' UoS and UoU lot numbers were reconciled to match, resolving this issue. The remaining vaccines with different UoS and UoU lot numbers include:

- ActHIB
- Menveo
- Pentacel

Immunization Provider Guidance for Recording NDCs

- When recording the NDC for an administered vaccine, a provider may capture the NDC on the UoU **OR** UoS, depending on the established clinical workflow.
 - This information should be transmitted or reported (messaged) to the IIS. Typically, this is a function of the EHR and is transmitted in the 5-4-2 format (including the hyphens).
- When documenting administered vaccines that require reconstitution, providers who choose to record the information on the UoU (vial/syringe) should record the NDC from the lyophilized vaccine.
 - This recommendation applies to all reconstituted vaccines, including those with an antigen-containing diluent (such as Menveo and Pentacel).
 - For a list of reconstituted vaccines, see the "[Vaccine with Diluents: How to Use Them](#)" table from the Immunization Action Coalition.
- When documenting administered vaccines that have been repackaged by third-party vendors into kits with gloves and alcohol wipes, providers should capture and message the vaccine manufacturer's NDC.
 - These salable kits contain an NDC from the third-party vendor, as well as an NDC from the vaccine manufacturer.
- **For vaccines purchased with public funds**, providers are required to order new vaccines, report inventory, and submit returns per the UoS (package).

IIS Manager Guidance for Recording NDCs

- IISs should be capable of recording either the UoU NDC or UoS NDC to offer maximum flexibility in accommodating provider clinical workflow.

- IISs should be capable of storing UoS NDCs and converting UoU NDCs submitted by providers to UoS NDCs.
 - For reconstituted vaccines, there will be one UoS NDC with two UoU NDCs; both UoU NDC codes will map to the UoS NDC.
 - Some vaccines have two (or more) UoS NDCs with one UoU NDC. This occurs when there are several vaccine packaging options (e.g., a package of 1 or a package of 10). For example:

BEXSERO Product Presentations

Presentation	UoS NDC Number	Components - UoU
Prefilled syringe (package of 1 syringe per carton)	58160-976-06	0.5 mL single-dose prefilled syringe [NDC 58160-976-02]
Prefilled syringe (package of 10 syringes per carton)	58160-976-20	0.5 mL single-dose prefilled syringe [NDC 58160-976-02]

Both UoS NDC numbers will map to the same [CVX](#) codes. If the intent of the IIS is to capture the specific NDC, an IIS could access the provider’s order (VTrckS ExIS shipment data) to identify the ordered vaccine presentation. Typically, a provider will only order one presentation.

Alternatively, the unique UoU lot number in the IIS could be used to derive the appropriate UoS NDC (except for that of any of the three previously mentioned vaccines that have different lot numbers on the UoU and the UoS). See the [IIS Manager Guidance for Recording Lot Numbers](#).

- The IIS should also be capable of translating UoU NDCs and UoS NDCs into internal representations of vaccines and manufacturers to support existing functions such as forecasting and query, where needed.
 - One possible way to translate UoU and UoS NDCs is to convert NDCs into CVX and manufacturer ([MVX](#)) codes and use existing functionality to link them to the appropriate vaccine and manufacturer records in the IIS. CDC maintains [NDC and CVX Crosswalk Tables](#). These Crosswalk Tables show the relationship between the UoU and UoS NDCs and also allow CVX codes to be derived from NDCs.

Immunization Provider Guidance for Recording Lot Numbers

- Providers may record the lot number from the UoU **OR** UoS, depending on the established clinical workflow.
 - This information should be transmitted or reported to the IIS. Typically, this is a function of the EHR.
 - The National Childhood Vaccine Injury Act mandates that health care providers document lot number information in the patient’s permanent medical record.
 - The lot number entered into the health information system should be case-sensitive and exact.
 - The lot number should not include any additional information (e.g., a prefix or suffix of “P” to indicate a publicly funded lot).
- When documenting administered vaccines that require reconstitution, providers who choose to record information from the UoU should record the lot number from the lyophilized vaccine.
 - This recommendation applies to all reconstituted vaccines, including those with an antigen-containing diluent (Menveo and Pentacel).
 - Manufacturers can derive the lot numbers of antigen-containing diluent from the lot number of the associated lyophilized vaccine. For a list of reconstituted vaccines, see the “[Vaccine with Diluents: How to Use Them](#)” table from the Immunization Action Coalition.

IIS Manager Guidance for Recording Lot Numbers

- IIS functionality should include the ability to capture lot number information.

- The IIS should be prepared for providers to send either the UoS or UoU lot numbers for the following three vaccines:
 - ActHIB
 - Menveo
 - Pentacel
- More information about these three vaccine products, including UoS/UoU lot number patterns, is being compiled by CDC and the American Immunization Registry Association.
- Discrepancies between UoU and UoS lot numbers for these vaccines can be resolved during the reconciliation process. Additionally, IIS managers may consider using their knowledge of a provider's inventory to identify a spectrum of possible matches between UoU and UoS lot numbers based on lot number patterns (see [MIROW Lot Number Validation Best Practices](#)).

Considerations:

- Some city/state immunization programs' operations require UoS NDCs (e.g., for orders, inventory reporting, returns, and shipping data). However, some providers, depending on established clinical workflow and implemented technology solutions (e.g., for recording NDCs and lot numbers by scanning 2D barcodes on vaccine vials/syringes), may capture and send UoU NDCs and lot numbers to the IIS.
- Based on the provider's clinical workflow, it may be more appropriate and effective for the provider to capture and submit the UoU NDC and lot number to the immunization program. For example, some ambulatory EHRs can capture NDC, lot number, and expiration date data by scanning the 2D barcode on the vaccine vial or syringe; can verify that the ordered vaccine is consistent with the vaccine being prepared to be administered; and can check the expiration date to ensure that the vaccine is still active.
- Currently, most EHR systems, electronic data exchange solutions, and IISs support only one field for lot number and one field for NDC for each administered vaccine dose being tracked.
- Reconstituted vaccine products have more than one UoU component (for lyophilized vaccine powder and for liquid diluent), each with different NDCs and different lot numbers. For example, Pentacel has one NDC for the lyophilized (freeze-dried powder) component and a different NDC for the diluent. For reconstituted vaccine products, the UoS lot number matches the UoU lot number for the lyophilized vaccine powder product (with the exceptions of ActHIB and Menveo).

Recall Event

- In the event of a vaccine recall, the vaccine manufacturers will be able to identify and provide the UoS and the UoU of the NDCs and lot numbers. Based on this information, providers (and IIS staff, as needed) will need to search for the identified numbers and conduct recall activities.

Additional Resources

- Mapping Crosswalk Tables – www2a.cdc.gov/vaccines/iis/iisstandards/ndc_crosswalk.asp
- Vaccines with Diluents: How to Use Them – <http://www.immunize.org/catg.d/p3040.pdf>
- MIROW Lot Number Validation Best Practices – http://www.immregistries.org/resources/AIRA-MIROW_Lot_Numbers_Validation_best_practices_micro-guide_05-08-2014.pdf.