

HL7 Immunization User Group

MONTHLY MEETING

SEPTEMBER 21, 2017

2:00 PM ET

Agenda

- Welcome
- Updates
 - Co-chair Update
 - SISC Update
 - HL7 Work Group Meeting Update
- Discussion Topic:
Manufacturers, Labelers, and NDC's
 - IIS Perspective Presentation
 - EHR Perspective Presentations

Co-Chair Update

New co-chair:

- Danny Wise from Allscripts has volunteered to serve as co-chair
- We are working to get approval from the AIRA board

Current co-chairs:

- Kim Salisbury-Keith
- Nathan Bunker
- Kevin Snow
- Danny Wise

SISC Update

STANDARDS AND INTEROPERABILITY STEERING
COMMITTEE (CRAIG NEWMAN)

HL7 Work Group Meeting

NATHAN BUNKER

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HL7 Work Group Meeting

31st Annual Plenary & Working Group Meeting

- San Diego CA
- September 9 – 15, 2017

Immunization Activities:

- Conformance Tooling Demonstration
 - AEGIS demonstrated their WildFHIR Server and Touchstone
 - NIST showed progress on testing tools, now more integrated: IGAMT, TCAMT, GVT
- Conformance within Immunization Space
 - Craig Newman gave update on HL7 v.2.8.2 ballot comment reconcillation
 - Floyd Eisenberg and Lori Fourquet gave an update on the EHR Certification
 - Working with 4 vendors, looking to get ONC reciprocity, program is free to participants

HL7 Work Group Meeting

Next meetings:

- January 2018 – New Orleans Louisiana
- May 2018 – Cologne Germany
- Sept 2018 – Baltimore Maryland
- Jan 2019 – San Antonio Texas

Discussion Topic

MANUFACTURERS, LABELERS, AND NDC'S
(CRAIG NEWMAN)

The Problem

- Inventory management and other IIS functions rely heavily on knowing what vaccine was administered, including who produced the product
- There is some question regarding what to send in a few edge cases because vaccines can be repackaged or redistributed
- The use of NDCs and the introduction of barcode scanning workflows will impact the capture and exchange of data

Definitions

- Manufacturer – the company who manufactured the vaccine
- Labeler – some products are relabeled for sale by another company
- National Drug Code – vaccine product identifier required by MU3
 - <labeler> - <product> - <package>
 - The labeler part of the NDC is assigned by the FDA, but the other two components are defined by the labeler
- Unit of Sale – the NDC on the outer container (package, kit, carton)
- Unit of Use – the NDC on the inner container (vial, syringe, etc)



Fringe Cases

- Relabeling
 - Grifolis purchases Td vaccine from Mass Biologics and sells it
 - 13533-0131-01 (Grifolis) versus 14362-0111-04 (Mass Biologics)
- Value Added Products
 - EZ Flu kits include not only the vaccine, but also gloves and other products needed to give an administration
 - The source of vaccine varies
- Mergers and Acquisitions
 - Novartis sold its vaccine unit to GlaxoSmithKline
 - bioCSL and Novartis joined to create Seqirus
 - Wyeth is a subsidiary of Pfizer

HL7

- RXA-17 is the Substance Manufacturer
 - Definition: This field contains the manufacturer of the medical substance administered.
 - This field is Required for new administrations and Optional for historical reports
- When RXA-5 (Vaccine Code) uses a CVX code, RXA-17 may be need to identify a specific product, but an NDC is unique for a product
- Because the NDC contains a “labeler”, there is a possibility for discrepancies between the NDC labeler and the RXA-17 manufacturer



On Today's Call

- Hear from EHR vendors about how their users collect and record the NDC and manufacturer when documenting an administration
 - Is it the manufacturer or the labeler that is captured?
 - Is it the Unit of Use or Unit of Sale that is captured?
 - How will barcodes affect data collection?
- Hear from IIS about how the data they receive RXA-5 and RXA-17 is stored/used
 - What information is received by the purchasing process?
 - How does the Unit of Use versus Unit of Sale received impact the use of the data?
 - What data is needed for inventory management?
- Hear from anyone else with thoughts or concerns on the topic



Questions for Today

- Our guidance has been that RXA-17 should represent the manufacturer of the vaccine and not the labeler or distributor
- But is this consistent with data capture work flows and will it support IIS functionality in areas such as inventory management?
- With the use of NDCs, how is the use of RXA-17 impacted?
- How does a barcoding scanning workflow impact data capture?
- How are lots of vaccines purchased and documented?
- What data does the inventory management system use when decrementing inventory?

IIS Perspective



September
2017

Supporting NDC in RXA-5 (Administered Code) and MVX in RXA-17 (Substance Manufacturer Name)

Kevin Snow
Envision Technology Partners, Inc.

Overview

RXA-5 (Administered Code)

RXA-17 (Substance Manufacturer Name)

Registry Changes

Resources

RXA-5 (Administered Code) – Possible cases

CVX only

- Verify is a known CVX

NDC only

- Verify is a known NDC
- You might receive the NDC Unit of Use or the NDC Unit of Sale

CVX and NDC are be passed in

- Verify the CVX and the associated CVX to the NDC matches
- Could be in either order (CVX could be in the identifier or the alternative identifier)

The NDC may be incorrectly formatted

- 11 digits is required (you can't always get from 10 digits to 11)
- 11 digits with dashes is standard format but you should still be able to load 11 digits with-out dashes

RXA-17 (Substance Manufacturer Name) - Validation

17	Substance Manufacturer Name	CE	C(R/O)	[0..1]		If the first occurrence of RXA-9.1 is valued "00" and RXA-20 is valued "CP" or "PA"	MVX
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It's tricky to validate anything more than MVX is known and conditionally required for a new immunization.

- On an older Immunization the MVX might be have been active at that point in time
- One drug company acquires another

MVX

Definition

The MVX is an alphabetic string, which represents the manufacturer of a vaccine. It reflects the manufacturer of the specific instance of the vaccine. For example, Pfizer (MVX = PFR) acquired Wyeth (MVX = WAL). Prevnar is a vaccine that was manufactured by Wyeth. Immunizations of Prevnar that were manufactured by Wyeth continue to use the MVX of WAL. Prevnar that is now manufactured by Pfizer will have an MVX of PFR. Existing records will not be changed.

- Source: <https://www.cdc.gov/vaccines/programs/iis/downloads/business-rules.pdf>

RXA-17 (Substance Manufacturer Name) - Use Case

You receive a valid NDC in RXA-5 but nothing or an invalid value in RXA-17.

You could still store the associated CVX and MVX code by using the NDC crosswalk table. Assuming CVX is required in your database model you would have to at least have to do that.

Depending how you store inventory also having access to the MVX could help with matching for electronic inventory decrementing.

Developer Note: We found we ended up needing to place a low weight on Manufacturer in regards to matching for electronic inventory decrementing.

Registry Changes

Add the ability to map Unit of Use or Unit of Sale to a CVX (and MVX)

<https://www2a.cdc.gov/vaccines/iis/iisstandards/vaccines.asp?rpt=ndc>

IIS: NDC Lookup Crosswalk



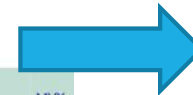
This webpage is designed as a lookup table where the Unit of Use and Unit of Sale NDC are mapped to each other. Global Trade Identification Numbers (GTIN) are provided for vaccines that are 2D barcoded. Note that a few vaccines are packaged with two component vaccines. Each component vaccine of a multiple component vaccine will have a unique NDC which also differs from the NDC of the unit of sale. Pentacel is an example. This means that there will be two rows linking the unit of use to unit of sale.



Sort Table by Column: Simply click on the column heading to sort the table accordingly.

The columns are defined after the table.

Sale NDC11	Sale Proprietary Name	Sale Labeler	Start Date	End Date	Sale GTIN	Sale Last Update	Use NDC11	No Use NDC	Use GTIN	Use Last Update	CVX Code	CVX Description	MVX Code
49281-0415-10	FLUZONE QUADRIVALENT PF	SANOFI PASTEUR				9/22/2015	49281-0415-58	False	00349281415586	9/22/2015	150	influenza, injectable, quadrivalent, preservative free	PMC
33332-0115-10	AFLURIA	CSL Limited				9/22/2015	33332-0115-11	False		9/22/2015	141	Influenza, seasonal, injectable	CSL



vaccination_code_id	sale_ndc	use_ndc
162	00005-0100-02	00005-0100-01
162	00005-0100-05	00005-0100-01
162	00005-0100-10	00005-0100-01
100	00005-1970-50	00005-1970-49
133	00005-1971-02	00005-1971-01
133	00005-1971-04	00005-1971-01
133	00005-1971-05	00005-1971-01
62	00006-4045-00	00006-4045-01
62	00006-4045-41	00006-4045-01
116	00006-4047-20	00006-4047-01
116	00006-4047-41	00006-4047-01

Developer Note: Often you can get from the Unit of Sale to the Unit of Use code by just ignoring the packaging id component (last 2 digits) but this isn't always true so you really need the crosswalk table.

You need to monitor the table for changes

Sale NDC11	Sale Proprietary Name	Sale Labeler	Start Date	End Date	Sale GTIN	Sale Last Update ↓	Use NDC11	No Use NDC	Use GTIN	Use Last Update ↓	CVX Code	CVX Description	MVX Code
49281-0913-01	STAMARIL	Sanofi Pasteur Inc.				8/23/2017	49281-0913-58	False		8/23/2017	183	Yellow fever vaccine - alt	PMC
70461-0120-02	Fluvirin	Seqirus				8/11/2017	70461-0120-12	False		8/11/2017	140	Influenza, seasonal, injectable, preservative free	SEQ
49281-0517-25	Fluzone Quadrivalent, pediatric	Sanofi				8/11/2017	49281-0517-00	False		8/11/2017	161	Influenza, injectable, quadrivalent, preservative free, pediatric	PMC
49281-0417-10	Fluzone quadrivalent	Sanofi				8/11/2017	49281-0417-58	False		8/11/2017	150	influenza, injectable, quadrivalent, preservative free	PMC

You need to keep your crosswalk table as up to date and possible and monitor your HL7 Logs for unknown NDC errors and verify if it's a case of needing to update your crosswalk.

Developer Note: This would be a good use case for the CDC Vocabulary service or a restful API with query parameter support to make it easier to import these values

Resources

<https://www.cdc.gov/vaccines/programs/iis/code-sets.html>

Immunization Information Systems (IIS)

[IIS Home](#) | [About IIS](#) | [Functional Standards](#) | [Core Data Elements](#) | **Code Sets** | [CVX](#) | [CVX Mapped to Vaccine Groups](#) | [CVX Mapped to VIS](#) | [MVX](#) | [Product Name Mapped to CVX/MVX](#) | [NDC Crosswalk Tables](#) | [VIS Barcode Lookup Table](#) | [VIS URL Table](#)

[CDC](#) > [IIS Home](#)

Code Sets

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CVX	NDC CROSSWALK TABLES
CVX MAPPED TO VACCINE GROUPS	VIS BARCODE LOOKUP TABLE
CVX MAPPED TO VIS	VIS TO CURRENT URL TABLE
MVX	CPT MAPPED TO CVX
PRODUCT NAME MAPPED TO CVX/MVX	2015 EDITION VERSIONED CODES

EHR Perspective

EHR Perspective

Epic – Greg Faber

Allscripts – Danny Wise

Next Meeting

THURSDAY, OCTOBER 12TH

2:00 PM ET / 11:00 AM PT

More Information

Web Links

- Subscribe to immunization group
<http://www.hl7.org/participate/UserGroups.cfm?UserGroup=Immunization>
- Public User Group Wiki
<http://www.hl7.org/special/committees/iug/index.cfm>
- Private User Group Wiki
<http://iugwiki.hl7.org/>
- HL7 Press Release
<http://www.hl7.org/documentcenter/public temp F760602A-1C23-BA17-0C0D326E635471F9/pressreleases/HL7 PRESS 20140402.pdf>
- AIRA Press Release
<http://www.immregistries.org/events/2014/04/10/hl7-immunization-user-group>

Contact Information

If you have any questions or comments:

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- Nathan Bunker nbunker@immregistries.org
- Kevin Snow ksnow@envisiontechnology.com
- Danny Wise Danny.Wise@allscripts.com

Thank you!