Manufacturers, Relabelers and NDCs

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 the September 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 September

- Our guidance has been that RXA-17 should represent the manufacturer of the vaccine and not the labeler or distributer
- 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?