The intent of the Drug Supply Chain Security Act (DSCSA) is to identify and trace certain prescription drugs as they move through the U.S. supply chain. One of the provisions addresses product identification: "Manufacturers and repackagers to put a unique product identifier on certain prescription drug packages, for example, using a bar code that can be easily read electronically." Product identification is scheduled to be implemented in November 2017, however some vaccine manufacturers have begun to encode this information on the salable boxes or packages (unit of sale) using 2D barcodes.

In addition, over the past five years many vaccine manufactures have affixed 2D barcodes onto vaccine vials and syringes (unit of use) in order to improve the data capture of information at the point of vaccine administration. The three data elements included on these vaccine products and encoded with 2D barcodes are:

1. Global Trade Item Number (GTIN) – 14 characters, contains the National Drug Code (NDC)
2. Expiration Date – 6 characters in YYMMDD format
3. Lot Number – up to 10 characters

Example of Vial/Syringe 2D Barcoded Vaccine Data String

0100312345678906171310281 0U4275AA

- GTIN: 00312345678906
- Expiration Date: 131028 (YYMMDD)
- Lot Number: U4275AA
- GS1 Application Identifiers: 01,17 and 10

Note: GS1 is the standards development organization for barcodes. Here is the address for the US affiliate: https://www.gs1us.org/ and the address of the implementation guide developed by GS1 US and the American Academy of Pediatrics (AAP): https://www.gs1us.org/DesktopModules/Bring2mind/DMX/Download.aspx?command=core_download&entryid=628&language=en-US&PortalId=0&TabId=134.

The product identifier as specified by the DSCSA includes the above data items as well as a field for Serial Number. When combined with the GTIN, the Serial Number uniquely identifies an individual package. This provides a level of tracking more granular than the Lot Number. However, at present there is not a strong use case for the collection of serial number information, although there is speculation that package serial numbers could allow for more granular recalls. This assumes vaccine manufacturers can identify recalls by serial number.

Example of New (Unit of Sale) 2D Barcoded Vaccine Data String

0100312345678906211000088935971713102810U4275AA

- GTIN: 00312345678906

- Serial Number: 100008893597
- Expiration Date: 131028 (YYMMDD)
- Lot Number: U4275AA
- GS1 Application Identifiers: 01, 21 ,17 and 10

Software developers and users should be aware of these changes to the 2D barcode. While the original data items, GTIN, Expiration Date and Lot Number, are still present in the new barcodes, the addition of the Serial Number may present problems for applications that currently support barcode scanning and subsequent application database population. While it may not be necessary for the software application to capture/use/display the Serial Number, any scanning enable application will need to account for the inclusion of the Serial Number when parsing the data from the scanned barcode and ensure that currently supported data elements remain accurately identified.

At this point in time, AIRA's Standards and Interoperability Steering Committee (SISC) in conjunction with the CDC have not identified use cases which would benefit from the capture and exchange of the Unit of Sale Serial Numbers. As such, we have no plans at this time to recommend the Serial Number as a core data element for either IIS or EHR systems. Nor do we have plans to enhance the national interoperability standard to include the exchange of the Serial Number. However, we are taking this opportunity to solicit feedback from the community regarding use cases for capturing and exchanging this data. If you have thoughts on potential uses for the Serial Number that would warrant a recommendation to capture and exchange this data, please share these use cases with us. Please email Craig Newman, SISC Co-Chair, at yuo9@cdc.gov, Mary Woinarowicz, SISC Co-Chair, at mary.woinarowicz@nd.gov, or Mary Beth Kurilo, AIRA staff, at mbkurilo@immregistries.org with any comments or questions.