Adopting 2D Barcodes

Information for Vaccine Manufacturers

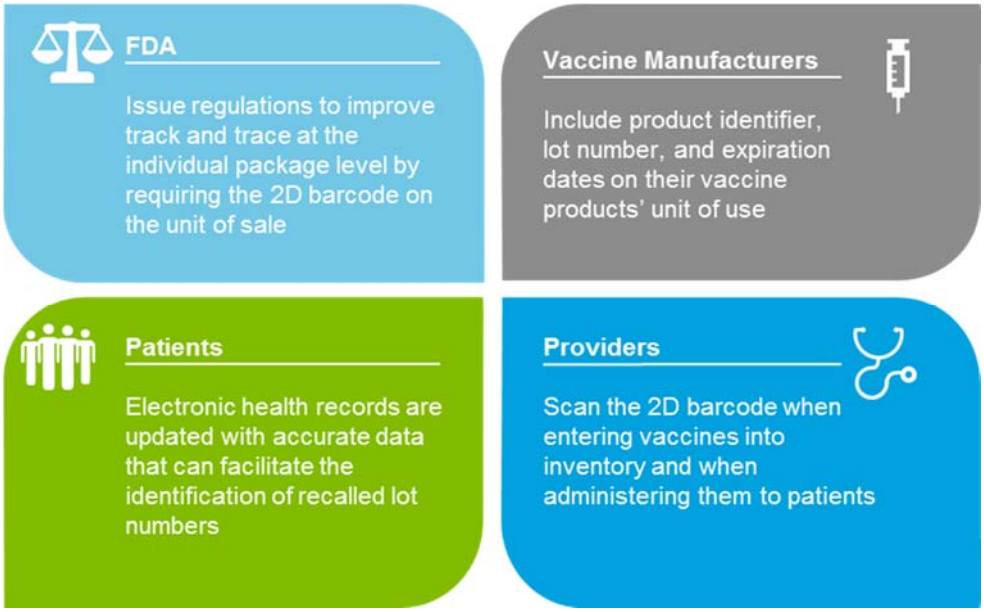
Adopt 2D Barcode Functionality

Two-dimensional (2D) barcodes are an important part of the United States' drug safety infrastructure. They facilitate the accurate tracking of product identifiers (ID) by the Food and Drug Administration (FDA) as well as help healthcare providers capture accurate and complete data about vaccine inventory and administration. Current guidance allows for a product identifier, such as the National Drug Code (NDC), a lot number and an expiration date.

While these same data are present in human readable format on vaccine vial and syringe labels, these data are often captured manually into an electronic medical record (EMR) or Immunization Information System (IIS) by a provider. 2D barcodes capture more data elements and occupy less space than a linear barcode while improving accuracy and completeness when the data within the barcode is captured by scanning.

Industry Investment in 2D Barcoding

For the last several years, stakeholders across government, provider practices, and technology have worked together to promote the use of 2D barcode scanning. In 2011, the FDA issued guidance that opened the door for placing 2D barcodes on vaccine products, allowing manufacturers to replace linear barcodes with alternative symbology that capture product ID, expiration date, and lot number. In 2013, the Drug Supply Chain Security Act (DSCSA) was enacted, which will require all manufacturers to affix 2D barcodes on vaccine unit of sale products in the next couple of years.



Notably, US vaccine manufacturers have led the charge on the adoption of 2D barcodes by beginning to introduce vaccine presentations with 2D barcodes into the supply chain. In addition, an increasing number of health care providers are investing in scanning technology and 2D barcode-compatible EMR systems. Some EMR vendors are integrating 2D barcode functionality by adding additional data fields (e.g. vaccine name, manufacturer name, NDC) captured based on the product ID. These trends are a clear indication that 2D barcodes are becoming more prevalent, and will become an accepted mechanism by which vaccine data are entered into electronic systems.

Benefits

By affixing 2D barcodes on vaccine products vaccine manufacturers are giving healthcare providers a tool to improve patient safety and enhance data quality. First-hand feedback from providers as well as a review of the data collected from scanning of 2D barcodes indicates that 2D barcode scanning was associated with an improvement in the accuracy and completeness of both lot number and expiration date in vaccine administration records. Furthermore, increased adoption of 2D barcodes will allow providers to better protect patients in case of a product recall by enabling them to identify specific lots of recalled vaccines, and the patients to whom they were administered.

Compliance with the Drug Supply Chain Security Act

The FDA's Drug Supply Chain Security Act (DSCSA) will go into effect in the next couple of years. The DSCSA outlines the steps required by the Federal Government to build "an electronic, interoperable system to identify and trace certain prescription drugs as they are distributed in the United States" (Source: FDA). The newly interoperable system will enable the verification of legitimate drug products, enhance detection and notification of counterfeit products, and facilitate more efficient drug recalls. Public health benefits are realized when 2D barcodes are applied at the unit of use, so that individuals receiving vaccines can be identified. The DSCSA's requirement to affix 2D barcodes at the unit of sale is an important step forward in the full adoption of 2D barcodes.

Improve Data Quality and Continue to Provide Public Health Support

Manufacturers can help enhance data quality and improve patient safety, and provide continued support in public health by affixing 2D barcodes on all product units of sale and units of use. A Summary Report is available for reference and provides further detail on potential improvements in data quality. In addition, the following steps will support the continued adoption of 2D barcode scanning amongst all stakeholders.

- Test and subsequently address barcode issues that hinder effective and efficient scanning. Current data suggest that the following items require further examination and have the potential to improve 2D barcode scanning:
  - Enhancing the quality of barcodes by improving the quality and resolution of printing and including high contrast images
  - Altering the barcode style in ways that may aid scanning such as increasing the size of the barcode or using peel-off labels or labels that unfold and can be flattened easily during scanning
- Alert the immunization community of the anticipated dates each vaccine product will include a 2D barcode

Regulatory requirements will fuel increased provider demand for back-end 2D barcode capability in health information technology products. None of this is possible without the availability of 2D barcoded products, and, thus, vaccine manufacturers have a unique opportunity to influence 2D barcode adoption by acting quickly to ensure that their entire vaccine portfolios carry 2D barcodes.

Interested in learning more?

To find out more about how adopting 2D barcode functionality can benefit your organization, please scan the barcode above or visit the CDC's Two-Dimensional Vaccine Barcoding website at:
http://www.cdc.gov/vaccines/programs/iis/2d-vaccine-barcodes/