2D Barcoded Vaccine Use in Pandemic Events

Prepared for

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1 Overview

1.1 Purpose

This document provides information to aid organizations considering the use of 2D scanning to record vaccination encounters during pandemic events. We highlight glossary terms in bold, blue text at first occurrence in this report.

1.2 Pandemic Vaccination Encounters

Pandemic events often present vaccine encounter documentation and inventory accountability challenges that are not common in non-pandemic situations. Pandemic situations can impose difficulties on standard vaccination operations, such as limited quantities of vaccines, emergency use authorization (EUA) vaccines, adjuvant use, and multi-dose vaccinations of transient populations. Vaccination administration, often conducted in non-traditional settings, sometimes by non-traditional provider types, compounds these challenges. Additionally, pandemic events normally require smaller, more frequent entries of vaccines into inventory due to receiving apportioned deliveries as vaccine supply becomes available.

Pandemic response operations and after-event processing rely on accurate documentation and accounting of the product identifier, lot number, and quantities of vaccines administered to inform future response planning. Inaccurate vaccination data have the potential to misinform response efforts, endanger vaccine recipients and introduce inefficiencies into pandemic operations and the vaccine supply chain.

To date, pandemic events have relied heavily upon manual data entry to document the product identifier, lot number and expiration date of vaccines administered in vaccination encounters. The opportunities for inaccurate data entry when manually entering this data are significant and often inflated by the chaotic nature of pandemic events. Character transposition, omission and incorrect entry all contribute to data inaccuracies. The application of two-dimensional (2D) barcodes onto vaccines offers a solution that shows promise to help address the data entry challenges inherent to manual data entry of this information.

1.3 2D Barcodes on Vaccines

In August 2011, the FDA modified the barcode label requirements to allow alternative symbology on vaccine vials and syringes. 2D barcodes on vaccines encode the lot number, expiration date, and unique product identifier of the vaccine. The availability of these data elements in an encoded, machine-readable format provides the opportunity to use scanning rather than manual entry to document these key data elements during a vaccination encounter. 2D barcodes also provide a significant improvement over the linear barcodes that manufacturers have historically applied to vaccine products in that linear barcodes only encode the product National Drug Code (NDC). The product identifier encoded in 2D barcodes on vaccines includes the NDC along with other information.

Over the past three years, the application of 2D barcodes onto vaccine products has increased significantly, from two vaccine presentations in November 2011 to 52 vaccine presentations in September 2014. Sanofi Pasteur, GlaxoSmithKline (GSK) and Merck have all proactively applied 2D barcodes at the primary packaging (vial/syringe) level for several of their vaccine products and each continues to apply 2D barcodes to vaccines in their portfolios.
To date, 2D barcode application on vaccines has predominantly been at the primary packaging level. At present, GSK offers the only 2D barcoded vaccines that have 2D barcodes applied at both the primary packaging and secondary packaging (carton) levels. Novartis has applied a 2D barcode onto the secondary packaging of their Fluvirin vaccine.

NDCs differ on the secondary and primary packaging of most vaccines. The difference presents a need for Health Information Systems (HIS) to maintain NDC relationships to accurately account for vaccine inventory administered. Ordering of vaccines occurs using the NDC located on the vaccine secondary packaging; vaccination documentation occurs using the NDC located on the primary packaging. To facilitate the ability for HIS to consider NDC packaging relationships, the CDC maintains crosswalk tables on their public facing site to show the relationships of vaccine primary and secondary packaging NDCs.

A recently passed federal law¹ promises to drive adoption of 2D barcodes at the secondary packaging level. Title II of the Drug Quality and Security Act (DQSA)—also referred to as the Drug Supply Chain Security Act (DSCSA)—set November 2017 as the deadline for vaccine manufacturers to apply 2D barcodes on the saleable unit (i.e., secondary packaging) of pharmaceutical products. This deadline includes the requirement that vaccine manufacturers encode a standardized numerical identifier (SNI) which introduces a serialized data element to the 2D barcode applied to pharmaceutical secondary packaging. Serialized 2D barcodes enable product verification, which helps to identify potentially compromised vaccine products (i.e., recalled, contaminated, or counterfeit product) within the supply chain.

DSCSA also introduces a pharmaceutical traceability requirement, which requires pharmaceutical manufacturers to have the ability to send Transaction Information (TI), Transaction History (TH), and Transaction Statements (TS) in a paper or electronic format by January 2015. In this same timeframe, pharmaceutical distributors are required to have the ability to send and receive TI, TH, and TS in a paper or electronic format. The requirement then shifts to the provider space (vaccinators). Providers are required to receive TI, TH, and TS in paper or electronic format by July 2015.

### 1.4 2D Barcoded Vaccine Scanning Benefits

A recent CDC project² comparing 2D barcoded vaccine scanning to traditional vaccination encounter recording methods indicated positive improvements in the completeness and accuracy of vaccine lot numbers recorded into electronic medical records when using 2D barcode scanning. Scanning of a vaccine prior to its administration provides an opportunity to realize patient safety benefits through product verification, vaccination schedule validation and contraindication and allergy checking. Additionally, in a subcomponent of the CDC project,³ interviews with health care and supply chain practitioners revealed that 2D barcode scanning shows promise to expedite inventory entry and vaccination administration processes.

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Most HIS use the lot number as the primary identifier to differentiate vaccine products; that is, they use the lot number paired with the product identifier as a primary key of an instance of the vaccine in the data. The improved completeness and accuracy of vaccine lot numbers offered by 2D scanning helps to improve multiple aspects of vaccination documentation and accounting.

The benefits of scanning 2D barcoded vaccines to record vaccine information occur in both standard and pandemic scenarios and fall into two major categories: vaccination encounter documentation, and inventory management. Table 1 provides a summary of these benefits. “Observed”, indicates a prior determination validated through analyses\(^4\). “Proposed” indicates expected benefits.

Table 1. 2D Barcoded Vaccine Scanning Benefits

<table>
<thead>
<tr>
<th>Category</th>
<th>Benefit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vaccination Encounter</td>
<td><strong>Observed</strong></td>
</tr>
<tr>
<td>Documentation</td>
<td>• Reduction in human-introduced errors</td>
</tr>
<tr>
<td></td>
<td><strong>Proposed</strong></td>
</tr>
<tr>
<td></td>
<td>• Operational efficiencies (time savings)</td>
</tr>
<tr>
<td>Inventory</td>
<td><strong>Proposed</strong></td>
</tr>
<tr>
<td>Management</td>
<td>• Operational efficiencies (<strong>aggregation</strong>, <strong>inference</strong>)</td>
</tr>
<tr>
<td></td>
<td>• Improved inventory and recall management abilities</td>
</tr>
<tr>
<td></td>
<td>• Enhanced level of tracking and traceability for vaccines</td>
</tr>
<tr>
<td></td>
<td>• Stronger vaccine supply chain security</td>
</tr>
</tbody>
</table>

2 Vaccination Encounters

Vaccination encounters during pandemic events primarily occur in either mass or individual vaccination settings. We consider both settings in the content that follows, highlighting setting-specific requirements and nuances when applicable.

Mass vaccination\(^5\) is the administration of vaccine doses to a large population over a short period of time; while Individual vaccination is the administration of vaccine doses in traditional setting (e.g. a primary care provider practice or a pharmacy) under a routine timeframe.

Key vaccination encounter data to document in a pandemic event are patient identifying information, and the NDC and lot number of vaccine(s) administered. Complete and accurate recordings of these data are important to pandemic operations as they provide a basis for effective outreach to vaccine recipients and inform accounting of pandemic response resources.

The use of paper-based methods to document vaccination encounters is common during pandemic events. Paper-based methods are effective in that they are relatively easy to institute and do not require a computer at the place of vaccination. Paper-based methods are not without their drawbacks. Timely and accurate transcription of paper-based vaccination encounters into an electronic record is sometimes challenging. Files may be lost or damaged. Data entry resources (i.e., personnel) may be overburdened, leading to human error in transposing or potentially misreading characters during data entry.

The use of an HIS to record vaccination encounters during a pandemic event minimizes the challenges of data loss and damage; however, difficulties inherent to manual data entry, transposition and misreading of characters persist. 2D barcode scanning of vaccines provides a solution to help address these data entry issues. Unfortunately, functionality to scan 2D barcoded vaccines is not yet widely implemented in HIS used in outpatient settings.

The absence of 2D scanning capabilities for vaccination encounters is at least partially due to the relatively recent introduction of 2D barcodes onto vaccines. Competing priorities for HIS vendors (e.g. ICD-10, Meaningful Use compliance) may have delayed plans for the development of functionality to scan a 2D barcode when recording vaccination data. An inquiry of Electronic Health Record (EHR) systems solution owners as part of the CDC 2D Barcode Pilot\(^6\) revealed that three vendors had implemented 2D scanning to record vaccinations and several others have this functionality planned in the next three years.

Table 2 lists combinations of patient record and vaccination record methods for vaccination event documentation during a pandemic event. Electronic records indicate the use of an HIS, typically an EHR or Immunization Information System (IIS). Scan opportunities for electronic records exist only when an HIS can accept 2D barcoded vaccine scans and one or more vaccine(s) used have 2D barcodes applied.

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### Table 2. Patient & Vaccination Documentation Combinations

<table>
<thead>
<tr>
<th>Patient Record</th>
<th>Record of Vaccination</th>
<th>Scan Opportunity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Paper</td>
<td>Paper</td>
<td>No</td>
</tr>
<tr>
<td>Paper</td>
<td>Electronic</td>
<td>Yes</td>
</tr>
<tr>
<td>Electronic</td>
<td>Electronic</td>
<td>Yes</td>
</tr>
<tr>
<td>Electronic</td>
<td>Paper</td>
<td>No</td>
</tr>
</tbody>
</table>

**Paper & Electronic Combination**

The opportunity to use 2D barcode scanning for the combination of a paper patient record with an electronic vaccination record occurs when the vaccine(s) in use has a 2D barcoded peel-off label. Peel-off labels provide the same information printed on the vaccine vial or syringe in a removable sticker. Applying the peel-off label to a paper patient record during a vaccination encounter enables the ability to scan the vaccination data into a HIS after the time of vaccination. This approach does not account for the HIS verification of a scanned vaccine prior to the administration of the vaccination.

**Key Considerations for 2D Scanning in a Pandemic Event**

Figure 1 provides an aid to help determine the applicability of 2D scanning of vaccination administration for a pandemic event. Details of decision point logic follow the diagram.

**Mass or Individual Vaccination Setting**

Operating efficiency and the high level of accuracy offered by 2D barcoded vaccine scanning make 2D barcoded vaccines good candidates for consideration when vaccinating during pandemic events. A unique scenario, specific to mass vaccination settings, exists in which 2D scanning may not be a good fit. When administering a single vaccine with the same lot number in a mass vaccination setting, scanning the vaccine to record the vaccination event introduces an unnecessary step in the vaccination process. Conceivably, a user could scan one vaccine barcode and then enter the total number of vaccines administered.
**Single or Multiple Vaccines**
Though less frequent during pandemic events, there are times when multiple vaccinations are administered during a vaccination encounter. In these situations, 2D barcode scanning of a vaccine prior to administration provides an additional validation point that the vaccine in hand is the vaccine prescribed for administration.

**Single or Multiple Active Lots per Vaccine**
When vaccine inventory includes multiple lots of a vaccine of the same brand (manufacturer, type, and presentation), 2D scanning may help practitioners avoid associating incorrect lot numbers during the vaccination encounter. Many HIS differentiate vaccines that are available for use from those that are not (e.g., later expiration, inventory history) by indicating the inventory as active or inactive. HIS with more advanced logic systems can warn a user when they select an inactive lot during the administration process. HIS can apply this same functionality when a 2D barcode is scanned (i.e., entered into inventory).

**2D Barcodes on Each Vaccine**
When administering multiple vaccines, if there is a mix of 2D barcoded and non-2D barcoded vaccines, leveraging 2D scanning may inhibit productivity. A finding from the CDC 2D Barcode Pilot indicated that health care practitioners generally disliked the use of procedures dependent on the type of barcode available to record vaccination information. A root cause of this dislike was that 2D barcode application was in early stages during the pilot and only applied to a small number of vaccine products. Therefore, scanning of 2D barcoded vaccines required a change for practitioners from the traditional vaccine administration documentation to which they were accustomed. If considering 2D barcoded vaccine scanning for a pandemic event, practitioners should factor the overall percentage of vaccinations that are 2D barcoded vaccines. A higher percentage of 2D barcoded vaccines will likely result in more frequent scanning, thereby making scanning more of the norm than the exception.
This section provides a high-level description of options to leverage 2D barcoded vaccine scanning for inventory management during pandemic events. For the purposes of this report, inventory management encompasses components of the vaccine supply chain beginning with the vaccine manufacturer shipment to distribution entities and ending with receipt at the point-of-care location.

An earlier phase of the CDC 2D Vaccine Barcode Pilot developed a report\(^7\) that details the vaccine supply chain impact when leveraging 2D barcodes on vaccine secondary packaging. Though the report does not specifically refer to pandemic events, its findings highlight benefits that are applicable to pandemic circumstances.

Within pandemic events, differing degrees of situational severity necessitate differing vaccine supply chain protocols. As an example, in a situation where the vaccine in use is a EUA vaccine and there is limited availability of the vaccine, federal apportionment is often an element of the vaccine supply chain. Alternatively, pandemic events for which a vaccine with sufficient supply exists may not require apportionment and thereby not necessitate a state or federal stakeholder in the vaccine supply chain.

Additional considerations potentially required in pandemic events are the movement and tracking of adjuvant supply and supporting medical materials (e.g., kits). Though not addressed here, the tracking and administration of these products also derive benefits from 2D barcode use. Our focus is the ongoing adoption of 2D barcode use at the vaccine secondary and primary packaging levels.

It is not unusual for pandemic events to be chaotic, often occurring during times of local, regional, or national duress. Unfortunately, criminal elements sometimes view pandemic events as opportunities for unlawful gain\(^8,9\). The ability to leverage serialized 2D barcodes to verify the authenticity of a vaccine product will work to deter the introduction of illegitimate vaccine products into the vaccine supply chain during pandemic events. An additional benefit is the increased confidence of vaccinators that they have received and are administering the vaccine they ordered.

The vaccine supply chain depicted in Figure 2 provides a representative view of vaccine logistics for a pandemic event. A green circle in the upper right corner of the process step denotes an opportunity to leverage 2D barcode scanning of vaccines. Not shown, but relevant, third party logistics providers (3PL) assume the same 2D barcoded vaccine scanning benefits as Distribution Centers.

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Process Description

1. Vaccine for pandemic use is ready for shipment. The vaccine manufacturer has filled and finished the packing of the vaccine into cases. Cases are placed onto pallets and loaded onto vehicles for shipment.

2. Vaccines arrive at a distribution center. Content of cases are often separated for distribution / deposit of secondary packaging into bins. A 2D scan opportunity exists when inputting secondary packaging into bins.

3. An order placement by a vaccine provider initiates the order approval process, with approval occurring at the Immunization Awardee. The order then goes to the Centers for Disease Control and Prevention (CDC) for final authorization.

4. CDC authorization of the order prompts the Distribution Center to initiate their processing of the order. Part of this processing presents a 2D scanning opportunity of the secondary packaging when pulling orders from bins.

5. Upon receipt of the order at vaccine provider, a final 2D scanning opportunity for this flow exists when the provider scans the 2D barcode on secondary packaging to enter the vaccine into their inventory.

Distribution Centers

Receive Inventory – At the point of receipt, distributors must enter vaccine products into their inventory. Established mechanisms for vaccine entry into Warehouse Management Systems (WMS) including manual entry and Automatic Information Data Capture (AIDC) technologies such as linear barcode scanning or Optical Character Recognition (OCR), and in some cases 2D barcode use for case and above packaging levels, are currently in place.

Once vaccine manufacturers add serialized identifiers to vaccine secondary packaging for DSCSA compliance, opportunities for aggregation and inference use become available. The benefits of group level inference of transactional information provided by aggregation shows promise. This process reduces both the time and effort required for inventory receipt processing. This in turn has the potential to reduce labor costs and marginally reduce overall transportation time for vaccines.
**Pull Orders**

Distributors often break vaccine pallets and cases down to their saleable level for storage. Filling orders involves picking and packaging saleable units into shipping containers. 2D scanning of secondary packaging to automate data entry elements of picking and packaging has the potential to provide reductions in labor requirements by minimizing manual entry and error correction of the vaccine lot, product identifier, and expiration date. This creates operational efficiencies while simultaneously improving data integrity. Increased data integrity translates into improved abilities for distributors to accurately report inventory levels, often a vital requirement during pandemic events.

**Providers**

*Receive Inventory*

Similar to distributors, providers must enter vaccine products into their inventory at the point of receipt. Providers generally use the vaccine secondary packaging, vaccine primary packaging, or purchase order information to input the vaccine product ID (NDC), lot number, expiration date, and product quantity into HIS systems. The process is typically manual, creating the potential for transcription errors. The increased accountability requirements and often, increased frequency of vaccine inventory entry required during pandemic events amplifies the value of the accuracy and time-savings 2D barcode scanning offers to the provider inventory receipt process.

### 3.1 Additional Considerations

**Adjuvants Combined with Vaccines**

Historically, vaccines leveraging adjuvants are manufactured with the adjuvant and vaccine combined as part of the manufacturing process. The emergence of novel H5N1 in 2011 introduced the potential for vaccine adjuvant in a separate primary packaging from its partner vaccine. In this scenario, manual mixing of the vaccine and vaccine adjuvant are required prior to the vaccine administration (i.e., “at bedside” or close to time of the vaccine administration). For similar scenarios in the future it is recommended that if possible, the adjuvant be related to the vaccine in the HIS database. For example, a HIS could provide a capability to establish a rule that when the vaccine is administered and the NDC of the vaccine is captured, the administration data automatically includes the lot number and NDC of the required adjuvant as part of the vaccination event. This type of rule-based approach would require the flexibility to account for the dynamic needs of manually mixed adjuvant use with vaccines.

Additionally, the need for adjuvants can occur after vaccines are in circulation, requiring individual supply logistics and relationships in HIS. Establishing the adjuvant-to-vaccine relationship in the HIS helps to programmatically record the administration of the adjuvant at the time that the vaccine encounter occurs. If a single lot of an adjuvant is active, the HIS can associate data for the administered adjuvant instead of requiring manual recording of the adjuvant's administration. Scanning the adjuvant if multiple lots of an adjuvant are active could help to avoid recording an inaccurate adjuvant-to-vaccine relationship.
Primary and Secondary Packaging NDC Relationships
Many HIS do not currently maintain NDC relationships. A common operational practice employed to augment the absence of this ability is for inventory to be entered using the NDC of the primary packaging. Practitioners open a carton and scan the vaccine vial or syringe then enter a quantity for the item scanned. This enables a one-to-one relationship between the vaccine administration and decrementing the inventory on hand count. This method is effective, but introduces a layer of complexity in that ordering typically uses the NDC located on vaccine secondary packaging. Unless a relationship between the primary and secondary packaging is established, the relationship of inventory on hand to the level required for ordering must be manually determined.

Scan Patient
Many HIS provide patient management capabilities that leverage 2D barcode scanning. 2D barcodes encoded with patient identifying information are generated and leveraged throughout the vaccination encounter process. Some HIS have the ability to leverage identifying data encoded in state-provided 2D barcodes located on drivers licenses. When available, 2D scanning of the patient identifying information has potential to expedite patient validation in a pandemic event. Patient scanning of 2D barcodes leverages the same hardware as vaccine scanning of 2D barcodes.
4 Recommendations

Use 2D barcode scanning for pandemic events only in specific scenarios
The appropriateness of 2D scanning of vaccines during a pandemic event is specific to the situation in which the scanning would occur. The current variability amongst HIS in their ability to process a 2D barcoded vaccine scan combined with a mixed ability of vaccine manufacturers to apply a 2D barcode does not allow a simple recommendation for 2D scanning use. See Figure 1, Key 2D Scanning Considerations for Pandemic Events. We anticipate that continued adoption of 2D barcoded vaccines in the immunization community will eventually enable the majority of pandemic events to leverage 2D barcoded vaccine scanning.

Enable 2D barcode scanning for vaccine administration
Presently (September 2014), the majority of HIS have not implemented functionality to process data encoded in a 2D barcoded vaccine. HIS must incorporate this ability to realize the benefits of 2D barcoded vaccine scanning during a pandemic event.

Apply 2D barcodes onto pandemic use vaccines at the point of manufacture
Application of a 2D barcode as part of the manufacturing process does not introduce a significant lag in the manufacturing process. If a vaccine manufacturing line is outfitted with 2D barcode labeling capabilities, there may be a minimal impact on output when printing 2D barcodes compared to linear barcodes, but not enough to outweigh the benefits 2D scanning afford pandemic operations. Generating and applying a 2D barcode to pandemic-use vaccines outside of the manufacturing and labeling process would introduce a delay that outweighs the 2D scanning benefits for a pandemic event.

Apply 2D barcodes as peel-off labels onto pandemic use vaccines
Some vaccines come with a label designed for removal from the vaccine vial or syringe without damaging the printed vaccine information on the label (peel-off label). The availability of a peel-off label affords the opportunity to enter data from the vaccine encounter into a HIS at a later point in time without retaining the empty vial or syringe. Use of peel-off labels with 2D barcodes in a pandemic makes 2D barcoded vaccine benefits applicable in this scenario.

Enable adjuvant to vaccine relationships in HIS
Functionality to relate an independent adjuvant (not pre-mixed) to a vaccine provides potential to reduce data entry and avoid data entry errors when recording pandemic vaccine encounters. An established adjuvant-to-vaccine relationship would record the product identifier, lot and expiration date of a related adjuvant when recording a vaccination using the associated vaccine.

To provide this capability, HIS would need to provide functionality to establish the adjuvant-to-vaccine relationship as a business rule through a user interface. A rule-based approach in this format provides the flexibility necessary to relate an adjuvant to one or more vaccines without the need for programmatic HIS changes. A caveat for consideration is that if multiple lots of an adjuvant are active, 2D scanning of the adjuvant is required to associate the correct adjuvant lot to the vaccine administered.

Exercise adjuvant use with vaccines for pandemic events
The use of an independent adjuvant for vaccines is relatively new and has not been used in the United States in a pandemic event. Optimal methods for relating adjuvants to pandemic use vaccines, both programmatically in the case a HIS provides this functionality, and operationally in the case the functionality is not available or a paper-based process is effected, should be determined prior to a pandemic event by assessing the available tools and situation.
Glossary

2D Barcode: Machine-readable graphical images that store data in both horizontal and vertical dimensions.

Adjuvant: A substance that is added to a vaccine to increase the body’s immune response to the vaccine.

Aggregation: The process by which manufacturers pack their serialized unit products of drugs into serialized shipping cases.

Apportioned / Apportionment: The allocation of limited quantities of a vaccine made in consideration of situation-based criteria.

Automatic Identification and Data Capture (AIDC): AIDC technology encodes product data into a scannable format for automatic entry into a computer system (e.g., barcodes, RFID).

Electronic Health Record (EHR): Electronic versions of patient medical records; these records store product information for vaccines administered to patients.

Emergency Use Authorization (EAU): Fills the need for timely and practical medical treatment under emergency conditions and authorizes use of the best product available for treatment or prevention when the relevant product has not already been approved or approved for this specific use by the US Food and Drug Administration.

Expiration Date: The last date of effective use for a product, after which point the product must be disposed of.

Health Information Systems (HIS): General term to describe electronic systems that capture patient information (e.g., EHR, Patient management system).

Immunization Information Systems (IIS): Confidential, population-based, computerized databases that record all immunization doses administered by participating providers to persons residing within a given geopolitical area.

Individual vaccination: The administration of vaccine doses in traditional settings (e.g. provider offices and pharmacy) under a routine time-frame.

Inference: The use of aggregated e-pedigrees at a group level in order to infer the same transactional information for individual units contained within the group through a parent-child relationship.

Linear Barcode: One-dimensional barcodes that consist of parallel lines and spaces of various widths that create specific patterns that encode data.

Lot Number: Number assigned to a specific subgrouping of products produced by a common manufacturer.

Mass vaccination: The administration of vaccine doses to a large population over a short period of time.

National Drug Code (NDC): A unique, three-segment number… which serves as a universal product identifier for human drugs.

Optical Character Recognition (OCR): Conversion of print characters into machine-readable text.
Primary Packaging: Packaging component that is or may be in direct contact with the dosage form.

Secondary Packaging: Packaging component that is not and will not be in direct contact with the dosage form.

Serialized: The application of a unique serial number in the form of a standardized numeric Identifier (SNI) to a prescription drug.

Third Party Logistics Provider (3PL): A firm that provides supply chain operations as an outsourced logistical service.

Traceability: The ability to view each stage of ownership of a pharmaceutical product throughout its lifecycle.

Transaction History (TH): A statement in paper or electronic form, including the transaction information for each prior transaction going back to the manufacturer of the product. A DSCSA required artifact.


Warehouse Management System (WMS): Electronic system that aids the control of materials in a storage facility.