

Whitepaper: AmerisourceBergen Pilots Product Exceptions Handling

Planning

In anticipation of the next phase of the Drug Supply Chain Security (DSCSA) requirements, **AmerisourceBergen** and a number of manufacturers examined serialized product exceptions, as well as new possible pain points and potential resolutions. With a focus on the 2023 requirements, we organized a pilot program to address the frequency of exceptions, identify where aggregation could be an issue and looked at resolving exceptions between participants within the pharmaceutical supply chain.

Our Goal

To identify the parameters on serialized exception handling – then pilot a remediation process for each exception, measure the effort and time to collect the required data, or resolve the issue. Our vision is that once these processes are validated, we would look to develop standards and protocols for automated resolution.

The Anticipated 2023 Problem

In 2023, DSCSA heightens the need to link physical product movement to electronic data down to the individual unit level. No matter how advanced or automated packaging and distribution methods may be, manual *human* touchpoints will always be in the process. Not to mention, the most accurate a manual process can be is 3 Sigma¹ or about 93% accurate. Considering AmerisourceBergen's current volumes, this could result in 200,000 errors a day or in terms of patient impact - 200,000 prescription drugs not making it to those in need.

Pilot Scope

AmerisourceBergen partnered with several large and small-scale generic and brand pharmaceutical manufacturers to pilot 50+ SKUs, within the AmerisourceBergen distribution center (DC) network -- including DCs in Dothan AL, Brooks, KY and Columbus OH. The focus was on receiving serialized products and the data from the manufacturer and then shipping serialized products to downstream customers. Dispensers and hospital systems were not included in this pilot.

Pilot Details

To begin the effort, the pilot participants focused on three broad categories of exceptions and agreed on how to measure and test these exceptions:

- Packaging and labeling issues (barcode readability, "00" expiration day in barcode)
- Product with missing data (missing Transaction Information from the manufacturer)
- Data without product (missing product, or too much data from the manufacturer)

We collected two-weeks of data (Transaction Information) prior to the pilot kickoff. Why? We needed to accumulate enough data before scanning products in order to minimize false "product - no data - exceptions" when using products already received prior to executing the pilot. Once we were confident we had a sufficient amount of data, we ran eight weeks of live operations using serialized products.

We specifically wanted to examine receiving serialized data via standard GS1 EPCIS messages as well as to observe the ability to receive serialized product at the DCs. Once we received products from the manufacturer, we then wanted to examine at the process of picking, packing and shipping serialized products to dispensers and hospital systems.

In executing the receipt and shipment serialized products, we focused on five distinct exception scenarios:

¹ Six Sigma describes quantitatively how a process is performing. To achieve Six Sigma, a process must not produce more than 3.4 defects per million opportunities. According to Six Sigma, the lowest defect rate a mature manual process can accomplish is 28,222 defects per million opportunities.

1. We received a shipment from a manufacturer and didn't receive an EPCIS file for the given purchase order (Missing all Transaction Information from the manufacturer).
2. We received a shipment from a manufacturer, but we were missing data, though we received an EPCIS file for some of the shipment (we were missing some Transaction Information from the manufacturer).
3. We scanned a serial number at an each-level to fill a dispenser order and the serial number information **was not** available in the AmerisourceBergen DSCSA solution. (Missing Transaction Information from the manufacturer)
4. We received more serial numbers than physical products, either due to receiving fewer products than anticipated, a missed-shipment, or technical data issue.
5. We could not scan some labels because the label itself was not aligned to HDA guidelines or GS1 standards.

In order to ensure we could test the above exception remediation processes, we also staged a few situations in which we "deleted" data out of the EPCIS file to simulate missing Transactional Information at receipt and subsequently at shipment.

Manufacturers sent over 50 serialized shipments and we exchanged 283 GS1 EPCIS files between the manufacturers and AmerisourceBergen. We scanned approximately 12,000 serialized barcodes at the Pallet, Case or Each levels during receiving. We scanned a total of 224,000 units (mostly at the each level), designated for shipment.

Key Takeaways

Labeling Exceptions:

We experienced issues with homogenous cases not having the 2D barcode. Although the law permits a 1D on the case, wholesalers and dispensers are building their ability to scan and store data to HDA guidelines -- which designate the use of a 2D barcode.

In processing pallets during product receipt, we discovered that stacked boxes with the labels facing the same direction were much faster to scan.



However, on the whole, we had very few instances of non-complaint barcodes and readability issues.

Data Exchange:

As in past pilots, exchanging serialized data continues to be a challenge. This is primarily due to multiple EPCIS versions, solution provider constraints, and general inconsistencies. It regularly takes 2-3 months to test and onboard a single manufacturer on to the serialized, GS1 EPCIS data exchange.

- Specific Issues:
 - Agreement on security standards.
 - Several errors found on GS1 EPCIS data, i.e. (GLN vs. SGLN).
 - Master Data (GTIN, GLNs) errors preventing both GS1 EPCIS data processing and scanning
 - Formatting, such as time stamp, syntax format, etc.
- Recommendations:

- Clear guidelines and management on what is to be exchanged and what data will be passed. I.e. should we send master data in the GS1 EPCIS file (the Transaction Information file) or can we rely on another “source” of truth? Which GS1 EPCIS version should be used for the distinct business purpose?
- Standard, repeatable trading partner EPCIS onboarding process through the product file processing cycle.
- Formalized processes and organizations to handle serialization data issues.
- Frequent internal communications of status and challenges

Exceptions occurring during the receipt of product at the Wholesale Distribution Center:

On a small scale, it was feasible to manually resolve exceptions at receipt, especially when it was due to a missing file. This process typically could be executed within 24 hours with dedicated pilot teams. Looking to 2023, automation will be required in order to make this efficient, seamless, and not delay product movement.

If there was an overage from the manufacturer, there could be delays in receiving due to the manufacturer needing to research the issue. This will delay product movement, result in larger quarantine areas within the DC, or drive larger ordering quantities.

When addressing ““more data than product”” – we developed a report that showed that serial numbers were transmitted to AmerisourceBergen but we never received product. We need to define parameters on when to run and share these reports. It’s likely that if AmerisourceBergen has too much data, then another wholesaler is probably missing data. A report of this issue could prove to be valuable.

Exceptions occurring during the Sale of Product to the Pharmacy or Hospital System:

When scanning an item at the each-level and identifying an exception due to missing data, a stark realization occurred. AmerisourceBergen was only able to provide a product identifier (GTIN, serial number, lot number and expiration) back to the manufacturer for investigation; we didn’t know the original case, or purchase order for the individual unit that was received. Given the process at receiving ensures the transaction information was received for the high-level logistics units, these exceptions will most likely be the result of a packaging or distribution aggregation issue.

Furthermore, in discussing these exceptions with the manufacturers, we found that in most instances it is not possible to associate the product identifier to be sold to the original transaction. That said, AmerisourceBergen attempted to remediate the exception by simply verifying the product identifier with the manufacturer and documenting the occurrence.

AmerisourceBergen’s Recommendations

Missing Transaction Information due to Data or Aggregation Errors:

In the future, we expect these types of product, no data exceptions to happen thousands of times a day and AmerisourceBergen may never be able to get the Transaction Information for these individual units. We propose the following process for those engaging in direct purchase between a wholesaler and manufacturer:

1. Verify the serial number in question.
2. Document this as a deviation to the TI requirement with both AmerisourceBergen and the manufacturer.
3. Investigate this as part of a trading partners corrective and preventative action programs.
4. Distribute the Rx product to the dispenser partners.

If we cannot resolve these types of exceptions -- when a wholesaler buys direct from a manufacturer, we will see a significant amount of products being quarantined and potentially returned; and ultimately this will have an impact on product availability, pricing, and most important patient access.

In looking to an automated process, the HDA Verification router service can automate exception management and real time remediation; this should be considered as a long-term objective of that initiative as we look to 2023.

Approach towards Aggregation

Given the productivity benefits inference provides, from aggregation, we should think of aggregated data as a business transaction like EDI, and not attribute a level of regulatory rigor that would be applied to GMP (Good Manufacturing Practices) data and the subsequent data integrity requirements.

Without aggregation and subsequent use of inferences, manufacturers shipping homogenous cases will be required to open those cases and scan each unit before shipping in order to provide a list of serial numbers within the Transaction Information. A wholesaler will be required to do the same when we sell full cases. If aggregation and inference are not leveraged, this will impact supply chain efficiencies with increased costs, increased inventory, and potentially increased exceptions due to the additional manual touch points.

Let us agree on the use of aggregation and Inference as a business efficiency model, and focus on discussing acceptable methods to resolve exception when they occur. Let's consider the chain of custody of data throughout the supply chain -- the complexity of ensuring every serial number will align perfectly with each product at the time of receipt or shipment may be cumbersome.

We will need a path forward to move safe, viable product to the patient. If we don't, we may be required to quarantine, destroy, or return 0.5+% of all Rx product sold daily.

In addition, the pilot revealed some additional considerations. What does the 2023 cutover look like on November 2023, once we have serialized product without the corresponding Transaction Information? How do we know what was received prior to November 27, 2023? This certainly will require some industry collaboration on how to prevent "false" errors in November 2023.

What about exceptions as the products move downstream? We need to take a risk-based approach to explore similar exceptions and remediation processes as the products continue to move down the supply chain to the patient.

Next Steps

Given the short timeframe of the pilot, we were unable to measure true exception frequency. Many of the product and no data exceptions that occurred were due to using product that was received before we started the pilot, despite our best efforts to remove them from the pilot.