Secondary Wholesaler Challenges During Implementation of DSCSA Required Track and Trace Platforms

VRS/Serialization Observation Start Date- 5/1/2018

FDA Pilot Observation Start Date- 5/3/19

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Final Report- 1/20/2020

To illustrate the challenges a small secondary Wholesale Distributor will encounter while implementing the November 27, 2019 DSCSA requirement for Verification Routing Services for Saleable Returns, Distributor has monitored and provided valuable feedback during the FDA Pilot Program. This project has also considered the upcoming Serialization requirements under DSCSA for Wholesale Distributors. The following sections will identify factors that have delayed implementation, caused strain on operational and financial assets, and ultimately made compliance a difficult task to accomplish with limited resources in a niche sector of the drug supply chain. Upon completion of implementation of the VRS Requirement, has accomplished success that most other similarly situated wholesalers have struggled to attain. These challenges should be taken into consideration when assessing the time and resources required for all trading partners to achieve the necessary level of compliance.

Major challenges involved with successful implementation of a functional and compliant VRS Solution include the following:

Challenge Identified No. 1 – NABP's VAWD Accreditation requirements to ensure customer retention and market access for sourcing products have cause financial and operational adjustments to preexisting business model. Without accreditation, sourcing and distribution declines and distributor cannot maintain revenue required to ensure resources can be allocated to platforms and employee resources necessary for DSCSA compliance deadlines. Additional Tech Budget must be allocated to meet higher operations criteria requirements which may cause delays in DSCSA compliance projects.

NABP's VAWD Accreditation has consumed much of the resources (both financial and employee time) in order to update SOPs to align with their criteria. This alignment has taken valuable time that should be spent on the implementation of the original Serialization Solution, and the Alternate VRS Solution. Without allocating the internal resources to the VAWD Accreditation process, which has consumed multiple employees' tasks for the last 2 years, distributor risks losing Manufacturer relationships and customers that account for the fiscal solvency of our company. Accreditation was posited as "voluntary", but our experienced list business showing otherwise. It was more of a requirement for our survival and has inhibited resources from effectively implementing our original Serialization Solution and the new Alternate VRS Solution.

Challenge Identified No. 2 – As a distributor we had to contract multiple VRS Solution providers in order to successfully implement a solution capable of verifying saleable returns electronically. This required financial investment of more than double the previous Tech budget, required hundreds of hours of

attention over a 12+ month time frame, and ultimately was not functional until an Alternate Solution was contracted and customized by our preexisting ERP Solution. If our ERP system did not proactively choose a service provider and build out the connections required to pass information through EDI, distributor would most likely still be without a functioning VRS solution to be compliant with saleable returns verification requirements.

Challenge Identified No. 3 –Inconsistencies in configurations methods between hardware and software manufacturer's requirements, ERP Solution configuration and data transfer requirements, and Alternate VRS Solutions recommendations for information required for integration vary drastically and need to be dictated by the ERP Solution used by a drug distributor.

Challenge Identified No. 4 - Alternate VRS Solution (that does not include Serialization requirements until 2023) decreased the Tech Budget to less than 20% annually and onetime implementation fee is only 5% of annual Tech budget.

Challenge Identified No. 5 – Quantifying and identifying which Drug Manufacturers are not able to provide standard product identifiers has been completed and the list of items that are still in need of this information has been compiled for Alternate VRS Solution provider's assistance.

Assessment of these challenges can be summarized with the following recommendations to decrease the negative impact on a secondary wholesale distributor attempting to comply with the VRS requirements.

Assessing Challenge No. 1 for the industry – While we have gained VAWD Accreditation in the last few months, it is an ongoing issue for all Drug Distributors involved in the Drug Supply Chain. With PBMs requiring certain accreditation in order for dispensers to ensure continued reimbursements for prescriptions filled to patients, most pharmacy err on the side of caution and only purchase from accredited wholesalers. The vast Majority of the accredited distributors include the Big Three (Cardinal, McKesson, and Amerisource Bergen), large specialty distributors, distribution centers for chain retailers, and common 3PLs/repackagers. This limited pool of accredited vendors impacts availability, purchase terms and cost of prescriptions, and likelihood of sustainable trading between anyone functioning outside of the umbrella described in the previous statement. Not only does this effect independent pharmacies, but the wholesale industry that acts a supplemental source for dispensers who cannot solely source from the limited pool mentioned.

Assessing Challenge No. 2 for the industry – Sourcing of a VRS/Serialization Solution, prior to our ERP providers decision to work in conjunction with one specific provider, created various problems. Our proactive approach caused unnecessary delays, expended financial and operational resources, and ultimately the project was cancelled 12 months after integration could not be achieved. Distributors should consult with their ERP provider to identify the VRS Solution best suited for integration and implementation. Although distributor was better prepared to handle the implementation because of the months of failed attempts with another VRS/Serialization Solution provider, the financial and operational expenditures far outweigh any benefits of the failed project.

Assessing Challenge No. 3 for the industry –Master Data files for secondary wholesale distributors are not static. Drug inventory changes regularly based on availability, demand, price, along with other factors that are unforeseeable. Without a static catalogue of inventory items, ERP Solution providers

need to be in control of the fields required for Master Data files to be able to integrate with a VRS Solution. Allowing a VRS Solution providers to dictate requirements causes an increase in customization of distributors Master Data files that is costly to outsource the changes, and time consuming to handle to updates internally. VRS Solution requirements that are inconsistent with existing Master Data within an ERP Solution increases the amount of customization required, which increases costs and time expended.

Assessing Challenge No. 4 for the industry – Financial investments decrease exponentially when a Distributor can obtain their VRS Solution directly through their existing ERP Solution provider. Contracting a VRS Solution that is unfamiliar with ERP Solution requirements for data integration is far too costly and time consuming for small secondary distributors to handle integration internally. ERP Solutions should be required to comply ahead of the distributors in order to ensure seamless implementation and reduce disruptions within the supply chain.

Assessing Challenge No. 5 for the industry –Until Drug Manufacturers have sent complete Master Data files with GTIN data sheets for all of their products to all VRS Solution providers, there is no way for any distributor to quantify the amount the of time and effort required to obtain and maintain the Master Data required for successful VRS saleable return verifications. Distributors will never have access to the Master Data that belongs to each Drug Manufacturer, and manual entry of GTINs upon receipt is a continuous project. Grandfathered and exempt products are still identifiable on short dated inventory and those items are still in the supply chain today. Until those products have expired out of the supply chain, there will be no way to be fully compliant with all aspects of the Saleable Return Verification requirements.