The Systems House, Inc.

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DSCSA Quick Update for 2020

What is a VRS and Do I Need to get one?

Updated 9/1/2020 – djf

Much like you must do today, as of November 2020 you are supposed to verify any product that is returned prior to selling it again. What has changed is that you now need to do this down to the serial number level , whereas before the lot number on the pedigree document (t3 info) and the pedigree itself were enough to verify this item was the one you sold.

One solution being offered is a **VRS - `Verification Router Service.`**

Below is a quick overview of how a VRS will work, it does not in any way require you to connect directly as most partners will have a web portal as well.

The manufacturers in theory must provide the information. However, should you wish to connect directly to the VRS so you do not have to retype or scan your serial numbers you can do so.

This would be treated like any other EDI transaction even If the format is slightly different. And is typically real time.

MDS-Nx supports the lightweight message standard for real time verification of the products. However currently (September 2020) – The responses are not standardized so you may need to review still manually what the status returned really means.

https://www.gs1.org/docs/standards/gs1_lightweight_verification_messaging_standard_v_1_0_2.pdf

The current best practice is to use the web portal to scan in your barcodes and verify them. Again, as VRS becomes more mainstream we will likely add them as EDI partners and Integrate the different providers, much like we do for EDI 856 documents today (electronic t3 info)

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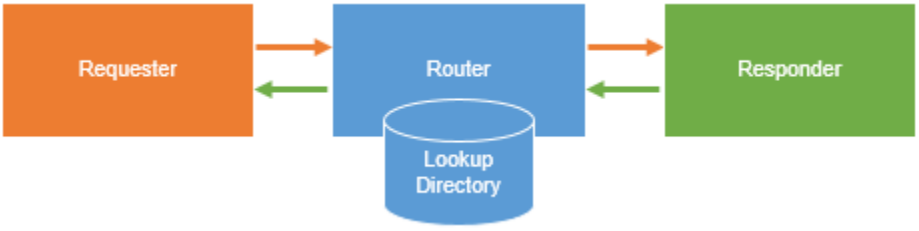
A Verification Router Service connects manufacturers and wholesalers

each one has a separate setup, and it would be a new EDI transaction for the verification etc.



The VRS model provides three basic service components:

Wholesalers use the requester service to create and submit a verification request and receive the response.

The router service uses its lookup directory to locate the product information and route the request to the correct source.

Manufacturers use the responder service to receive the verification request and respond to the requester.

Verification of Product Identifiers for pharmaceuticals Under the Drug Supply Chain Security Act (DSCSA) § 582(c)(4)(D), beginning November 27, 2019,

wholesaler distributors are required to verify the product identifier including Standardized Numerical 149 Identifier (SNI) of products returned to them before the returned products can be placed into inventory for resale. DSCSA defines verification as the process of "determining whether the product identifier affixed to or imprinted upon a package or homogeneous case corresponds to the [SNI] … assigned to the product by the manufacturer or the repackager…." [§ 581(28)]

"Verification" or "verify" means "determining whether the product identifier affixed to or imprinted upon on a package or homogeneous case corresponds to the [SNI] … assigned to the product by the manufacturer or the repackager…." [§ 581(28)]. A manufacturer who receives a verification request 156 from a repackager, wholesale distributor, or dispenser must respond to that request within 24 hours (or such other time the Food and Drug Administration (FDA) establishes) [§ 582(b)(4)(C)]. A repackager also has 24 hours to respond [§ 582(e)(4)(C)].

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For MDS-Nx Clients to simplify a vrs is just an electronic way of verifying the serial numbers are real.

Technically as part of dcsca - when you get a product in currently you are supposed to get a t3 doc (pedigree) - with the lot# on it. you are then supposed to verify the product is real with the manufacturer who is listed on the document. in november of this year (2019) they added the serial number to requirement, so you now must verify the serial number.

For Saleable Returns they have also required that all the items you get back as returned from your pharmacy/customers are verified.

Since you sold them - MDS would not allow you to take the return normally if the lot# does not match. And when you resell it - you can decide if you want to show the customer it was touched by another pharmacy who could have potentially swapped it for an older or different product. The T3 (pedigree) doc in MDS has the information you can choose what parameters you want and decide if this information shows to the next customer in your supply chain.

Having said that the VRS is not part of the law - it is just designed to make it easier and of course it will likely cost money on both sides. Most of the times much like the t3 info - the manufacturer picks up the cost and you just get the info delivered to you.

Current Solutions for Saleable Returns (Verification Router Service)

For saleable returns we can also verify using including EPICS (see lightweight messaging standard link above), VRS, Email/Phone, EPICS & VRS. If you prefer more manual approach, you can communicate directly with the manufacturer, provide the applicable information and once the verification is requested, the manufacturer is required to respond to these requests within 24 hours, again the web portal is likely the most common interaction. This should be like downloading a pedigree or t3 document today.

The issue of being able *to "verify"* a returned product using only the data stored in a distributor's system was discussed at a recent HDA Meeting and although it was not 100% confirmed legally, the consensus to be able to use stored data to verify a returned product was the following:

- Product MUST be purchased directly from the manufacturer/repackager
- Product elements "GTIN, Lot#, Serial #, Expiration Date" MUST be received electronically into the system, NO secondary service provider information is acceptable

What this would imply is only those distributors that are buying directly from the manufacturer/repackager can verify any returns using the data they are storing in their systems. Having said that this was a discussion, and no government entity has established this rule. However, we are providing as informational and Industry best practices.

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Grandfathered Product

There are currently non-serialized and serialized products in the market. And many of the product that are returns will have not have serialization as of November 2020. As a result of products with very long expiration dates, that were packaged prior to the November 2018 deadline, the FDA has implemented "Grandfathering" of such products.

However should you have a product that doesn't have a 2D barcode accompanied by the 4 data elements, this product will not meet the requirement by the DSCSA and after the November 2020 deadline, will no longer be able to be sold or received unless the product has been deemed as "Grandfathered". As it appears there will be many of these products still in the supply chain in November 2020. Again, there was no clear answer on what is considered a grandfathered product and as such your best course of action is to check with the FDA (The enforcement agency) for guidance.

Product Identification at the "Smallest Saleable Unit"

The DSCSA required that as of November 2018, Manufacturers and Repackagers apply serial numbers to what they deem to be the "smallest saleable unit". For some distributors, the smallest saleable unit is often the individual units within a case that are sold separately and may no longer be sold at this individual unit level.

Our best practice recommendation is that if you are a distributor that has in the past purchased by the case and sold individual units from that case to your clients, you must ensure that each unit level of product you are selling will have a serialized number in November 2020 . If not, you may have to re-think how you are going to sell this product. Or get permission from the manufacturer to relabel the product and or have them repackage on your behalf.

Alternately you can look at the MDS Manufacturing model for Drug Repackagers that will allow you to create a compliant drug repackaging operation.

As a reminder if you do not have the latest updates you will likely not have all these features so please make sure to update your MDS system as soon as possible to remain in compliance.