1300 Morris Drive
Chesterbrook, PA 19807
www.amerisourcebergen.com

Preparing for Serialization:
AmerisourceBergen's Updated Position on Preparing for November 2019/2020

2018 Requirements for the Manufacturers:

On November 27, 2018, our manufacturer partners were required to have their prescription pharmaceutical products serialized, at the saleable unit and homogenous case, to be compliant with DSCSA requirements. AmerisourceBergen is auditing serialized product labels to ensure alignment with GS1 standards and HDA guidelines. Starting in 2020, DSCSA labeling assessments will be incorporated into our manufacturer scorecards.

Later this year, AmerisourceBergen will start scanning the 2D GS1 DataMatrix barcodes to verify products during saleable returns processing. It's imperative that these barcodes are scannable, and the data is usable. If a manufacturer is **NOT** following **GS1 standards**, which includes the use of compliant GTINs, or there are any barcode quality issues that prevent successful scans, **we will not be able to transact those items**; they may be subject to quarantine and a request for credit.

Our labeling and barcode requirements can be found under Prescription Drug Packaging section:
https://www.amerisourcebergen.com/manufacturer-operations-and-replenishment#anchor1

What You Can Do:

Make sure your barcodes are GS1 compliant. Contact our team if you have any questions or concerns: securesupplychain@amerisourcebergen.com.

2019 DSCSA Saleable Returns:

AmerisourceBergen is looking to leverage two methods to execute "automatic" verification requests, with our 450+ manufacturer trading partners, to support our estimated 13M+ annual saleable returns.

We are asking manufacturers to…

1) Send serialized data upon shipment to AmerisourceBergen (EPCIS), and/or
2) Leverage the use of a Verification Router Service (VRS) / network

We operationally **cannot** support manual verification requests, or portals, even for exceptions.

For those planning on sending serialized data, which implies that you are aggregating and your 3PL or distribution center can send EPCIS data, AmerisourceBergen is onboarding and testing now – and we must start receiving production data, via EPCIS 1.1 or 1.2 **by May 1, 2020**. 98% of all returns happen within the first six months. Failure to meet this date will result in this method not being viable, and/or product being returned for full credit that can't be verified in November 2020.

If you require the use of a VRS, please consider that AmerisourceBergen will be utilizing SAP Information Collaboration Hub (SAP ICH) as our VRS provider which is part of the MediLedger network. AmerisourceBergen expects all manufacturers or their solution providers to be interoperable with the MediLedger network. Testing and onboarding can start after November 11, 2019; please reach out to schedule testing immediately.

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Enforcement Discretion Approach

The FDA granted the drug wholesalers one year enforcement discretion for verifying wholesale sellable returns. HDA indicated that we, the industry, intend to turn on our systems this year to use to identify and resolve data integrity and technical issues which would have resulted in supply disruption had we not obtained enforcement discretion. With that said, we expect each manufacturer to continue as if we never received enforcement discretion; this is not a time-out. Failure to do so will just shift the same supply risks to November 2020.

To fully test and stabilize the VRS network, AmerisourceBergen plans to do the following:

- Use 2019 and early 2020 to test manufacturer trading partners in a quality environment.
- Starting February, start limited production verification requests and ramp up targeting verifying 100% products by the end of August 2020.
- To phase in products to product, Manufacturers only should load only their products (GTINs), into the VRS lookup directory, when they are ready to receive verification requests.
- We will treat no-response verifications as a technical issues and not as suspect products; we will restock those products for resale.
- We will treat any negative verification responses as potentially suspect and quarantine and investigate per our internal procedures.

What You Can Do NOW:

1) If you have not done so already, please email securesupplychain@amerisourcebergen.com to let us know your solution for saleable returns and get our GTIN/GLN master data template. Please make note that VRS issues should be sent to VRS@amerisourcebergen.com

2) Fill out this short survey providing us your key contacts that we'll need to support the going forward with suspect/illegitimate investigations, master data issues, and VRS technical issues: https://tinyurl.com/ABC-DSCSA-Contacts

3) Ensure appropriate data integrity controls are in place to confirm that all serialized products also have a related product identifier record in your VRS repository. Missing data will result in a false negative verification response and possibly a suspect product investigation n.

Please respond to these requests with the highest priority so we can move forward and stabilize our solutions. As we prepare for November 2020, we want to use the extra year to ensure products continue to move through the supply chain without disruption and to safeguard patient access.

Thank you,

Matt Sample
VP, Manufacturer Operations
October 2019