

## Preparing for Serialization - AmerisourceBergen's Position on Processing Serialized Products

### 2018 Requirements for the Manufacturers:

By this November, our manufacturer partners must have their pharmaceutical products serialized to be compliant with the next phase of the DSCSA requirements. To assist with this regulatory obligation, we will continue to audit serialized product labels to ensure alignment to GS1 standards and HDA Guidelines as well as incorporate a DSCSA labeling assessment into our manufacturer operational scorecards by 2019.

#### What You Can Do:

Please continue to email labels to AmerisourceBergen for review at:  
[securesupplychain@amerisourcebergen.com](mailto:securesupplychain@amerisourcebergen.com).

### 2019 Requirements for the Wholesalers:

Under the DSCSA requirement, Wholesale Distributors cannot engage in non-serialized product transactions. That said, there is an expectation that non-serialized product will continue to be present in the supply chain and as such, that product will be covered by the FDA Grandfathering Guidance. In order to continue to receive non-serialized products, AmerisourceBergen will treat any product that is not serialized after November 2019 as Grandfathered. We will reference the Transaction Statement (TS) as evidence that a manufacturer is complying with all provisions of the law, including the Grandfathering provision.

#### What You Can Do:

Nothing! Please do not modify the TS that you are currently sending to AmerisourceBergen. Any changes would require retesting.

### 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 either 1) send serialized data upon shipment to AmerisourceBergen, or 2) leverage a Verification Router Service (VRS).

If you will be 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 would like to start collecting production data, via EPCIS 1.1 or EPCIS 1.2, no later than February 2019.

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. We also support the use of the MediLedger network, using blockchain technology, as a key enabler of the "lookup" component of our VRS for those not using SAP ICH. To that end, we expect all manufacturers or their solution providers, to be interoperable with the MediLedger network and aligned with the VRS Business Requirements developed by the HDA VRS taskforce.

AmerisourceBergen reserves the right to return products, or prevent customer returns for products, that cannot be verified due to reoccurring, external, technical or data maintenance issues.

**What You Can Do:**

Email [securesupplychain@amerisourcebergen.com](mailto:securesupplychain@amerisourcebergen.com) with questions regarding saleable returns or to find out how many returned units we process for you yearly.

Complete our Saleable Returns Survey with your plans for automated 2019 verification requests to support saleable returns and let us know when you can start testing (sending data or utilizing VRS): <http://tinyurl.com/ABC2019/>

**Master Data:**

Because AmerisourceBergen has over 60,000 GTINs to collect, from 450+ manufacturers, we will need the manufacturers historical GTINs data (GTIN number, NDC, Description, Unit of Measure, Quantity, etc.) by January 2019 to ensure we have the appropriate data to verify products and meet 2019 regulatory requirements for saleable returns. Given the volume of data we must collect, we are looking to use electronic solutions to gather this data, such as HDA Origin or GS1 GDSN.

It's expected that for any new product launches, GTIN data will be provided using the above master data solutions or be provided on the HDA New Product form.

**What You Can Do:**

Email [securesupplychain@amerisourcebergen.com](mailto:securesupplychain@amerisourcebergen.com) and let us know how you intend to share your historical GTIN data.