July 2019

Dear Valued Supplier,

As the pharmaceutical industry crosses the midpoint in the 10-year implementation of the Drug Supply Chain Security Act (DSCSA)[1], Cardinal Health remains committed to working with you to comply with all requirements of the law. With unit level serialization and enhanced verification on the horizon, we would like to share expectations for meeting November 2019 requirements so you can plan accordingly.

DSCSA supplier survey

We are sending out a survey that we expect our manufacturer partners to complete by **July 19, 2019**. The survey will ask questions regarding DSCSA readiness and request points of contact. The link to the survey can be found here.

Communication of GTINs

The DSCSA requires the use of standards for identifying products and exchanging data to ensure an interoperable system. For pharmaceuticals, the GTIN-14 is the identifier that links the product barcode to the master data associated with that product, including the NDC, package size and quantity.

If you have not already provided GTIN Information to Cardinal Health for your existing items, we ask that you send it to us by **September 1, 2019.**

We can accept your GTIN information in two ways:

- Through an electronic repository
- On the Cardinal Health GTIN excel template. Send completed forms to GMB-DUB-SupplierCleansing@cardinalhealth.com.

It is critical that your GTINs are properly loaded in our Master Data when we receive serialized product in November. If we do not have all your GTIN data, it may cause service disruptions. In lieu of using an electronic repository to transmit GTIN updates, we require an HDA Product Form submitted to Cardinal Health for all updates and changes.

Saleable returns verification

Before re-distributing a saleable returned product, a wholesale distributor must verify the product identifier on each package or each sealed homogeneous case. Cardinal Health supports the following options:

1. Manufacturers send aggregated serialized data via EPCIS with each shipment allowing Cardinal Health to verify product identifiers internally.
    - If you choose this option, we ask that you start to send your data to Cardinal Health immediately, in order for us to begin verification in November 2019.
2. Verification Router Service (VRS)
    - Manufacturers maintain their own database of serial numbers and subscribe to the VRS network that routes requests for verification and corresponding manufacturer responses.

If you cannot support one of the two options outlined above product will be a.) quarantined until verified, b.) morgued for full supplier credit or c.) returned to the supplier for full credit. This may result in reduced product availability for customers

(which can account for 2-3 percent of sales). A fee may be assessed to process products that cannot be re-distributed.

Saleable returns exception handling

If Cardinal Health receives a negative response on a saleable return verification, we will immediately quarantine the item(s) and initiate a suspect product investigation. We expect your immediate assistance in researching and resolving these issues. **Manufacturers must provide us with a point of contact to resolve saleable return verification exceptions.** We ask that you do this via the DSCSA supplier survey. If you do not have this information by the due date please send the information to drugtracing@cardinalhealth.com.

Verification Router Service[2]

Cardinal Health has elected to utilize the Chronicled MediLedger solution as our Verification Router Service provider. We anticipate the Chronicled MediLedger solution will be interoperable with other VRS systems and will adhere to current VRS business requirements set forth by the HDA VRS Task Force and GS1 lightweight messaging standards. It is our intent that Cardinal Health will not have to test connections with each manufacturer, rather will leverage the connection tests between VRS systems. In some instances, we may select specific manufacturers to test with if necessary. Further communication regarding VRS deployment will be shared, if necessary.

In order to ensure the Chronicled MediLedger solution is properly connected to all the VRS providers, we are asking that you please indicate how you plan to connect to the VRS network (if applicable for your organization) via our DSCSA supplier survey, which must be completed by July 19, 2019. We understand that a manufacturer may wish to communicate additional details on the verification response to indicate other saleable product conditions. We will accept the optional fields if they are communicated in accordance with the forthcoming GS1 messaging standards.

EPCIS on-boarding & technical guide

Cardinal Health has published an updated **Trading Partner Technical Guide** which provides our requirements for serialized data exchange. It outlines a new streamlined process for engaging our team to on-board and establish connections with Cardinal Health. The guide is posted on our Pharmaceutical Tracing website. Please follow the steps in the guide and complete the pre-requisites to engage with our EPCIS Support Team.

Receiving requirements

- Beginning November 27, 2019, Cardinal Health will check for product identifiers at receipt.
- FDA has clarified that a package is considered grandfathered if it was packaged by the manufacturer before November 27, 2018 and that trading partners may engage in transactions of grandfathered product until expiration date.
- Cardinal Health will accept shipments that include non-serialized product if it was packaged prior to that date.
- We intend to use your transaction statement as an indication that any non-serialized product received after November 27, 2019 is grandfathered. No additional documentation is expected.
- Cardinal Health expects ASN 856 EDI documents to transmit TI TH TS for lot level data.
- If the FDA has granted a Waiver, Exception or Exemption for any of your product, please notify us at drugtracing@cardinalhealth.com.

Product identifiers/barcodes

At the package and case level, our requirement is that manufacturers follow GS1 standards and HDA guidelines for barcodes. For specific requirements and information on barcode placement and size, please refer to the Cardinal Health Manufacturer Reference Manual and follow the guidance in the HDA 2017 Barcoding guidelines. We will be auditing barcode compliance in our distribution centers and will contact you if there are issues. Please contact us at barcodes@cardinalhealth.com if you have questions or would like to test.

The safety and security of our nation's pharmaceutical supply is one of our top priorities. We take this responsibility seriously, as a safe and reliable drug supply is central to our customers' businesses and critical to the health and well-being of patients. As a valued manufacturer partner, we recognize the efforts you are making to implement a traceability solution and we look forward to working together to establish an industry-wide, standards-based approach to comply with the DSCSA.

Please send any questions or requests for additional information to drugtracing@cardinalhealth.com

Sincerely,

Dianne Pfahl
Vice President, Global Sourcing

[1] The full text of the law, including requirements for manufacturers of pharmaceutical products, can be found on the FDA website.
[2] See DSCSA sections 582-for definition of verification including (c)(4)(D): "(D) VERIFICATION OF SALEABLE RETURNED PRODUCT