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CardinalHealth

April 14, 2020

Dear Valued Supplier,

The Drug Supply Chain Security Act (DSCSA)[1] outlines steps to build an electronic, interoperable system to identify and trace prescription drugs as they are distributed in the United States. It is designed to protect consumers from drugs that may be counterfeit, stolen, contaminated, or otherwise harmful. Cardinal Health remains committed to working with you to comply with the requirements of the law. Given the FDA's decision to grant enforcement discretion, we are providing an update on expectations for EPCIS serialized data exchange and saleable returns verification, so you can plan accordingly.

Saleable Returns Verification

Before re-distributing a saleable returned product, a wholesale distributor must verify the product identifier on each package or sealed homogeneous case. Cardinal Health supports the following automated 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 by May 1, 2020.
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.

EPCIS Serialized Data Exchange

Cardinal Health can receive serialized data via EPCIS now. The Cardinal Health EPCIS Onboarding Guide for DSCSA provides our requirements and outlines the process for engaging our EPCIS Support team to on-board and establish connections. We encourage manufacturers to begin onboarding as soon as possible so that we can build up an ample database and minimize investigations with you.

EPCIS Conformance Testing

Cardinal Health is committed to working with manufacturers to ensure the highest quality regulatory data. To that end we have partnered with Gateway Checker, a GS1 certified Conformance Testing company, to provide select manufacturers with a fixed number of complimentary EPCIS uploads in order to achieve Gateway Checker EPCIS certification. The Gateway Checker testing system evaluates

[1] The full text of the law, including requirements for manufacturers of pharmaceutical products, can be found on the FDA website.

the form, structure, data content, and conformance of submitted EPCIS documents to GS1 standards. Should Cardinal Health recommend a manufacturer pursue conformance certification, this certification should be achieved prior to any further EPCIS testing/onboarding. If manufacturers have achieved EPCIS certification from another conformance testing provider or have achieved the GS1 "Trust Mark", we will honor those certifications pending initial testing with Cardinal Health. Please note: If manufacturers require additional testing above and beyond our complimentary offering, they must incur the incremental testing costs with Gateway Checker. Please contact EPCISsupport@cardinalhealth.com for more information.

GTINs

DSCSA requires the use of standards for identifying products and exchanging data to ensure an interoperable system. For pharmaceuticals, the GTIN-14 is the approved standard identifier that links the product barcode on the unit of sale 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 items, we ask that you send it to us by May 31, 2020, as this is required for EPCIS onboarding. If they are not received by this date, your product may experience service level issues. Please contact drugtracing@cardinalhealth.com for more information.

Verification Router Service

Cardinal Health has selected the Chronicled MediLedger PVS solution as our VRS provider. We are currently working with other VRS solution providers through Chronicled MediLedger to establish the appropriate connections and directory synchronization. We expect VRS solution providers will adhere to the *GS1 Lightweight Messaging Standard* and the *GS1 Healthcare US® Implementation Guideline - Applying the GS1 Lightweight Messaging Standard for DSCSA Verification of Returned Product Identifiers*. Cardinal Health does not expect to test connections with each manufacturer, rather we will use the connection tests between VRS systems.

Because the FDA granted wholesale distributors a one-year delay in enforcement of the requirement to verify a saleable return, Cardinal Health did not activate the saleable returns verification process in November 2019. We are participating in the HDA facilitated VRS Taskforce to determine an industry wide approach to testing as we continue to monitor VRS progress. The timing of when we will start sending verification requests through the VRS is still to be determined but we are currently targeting late summer.

Non-Compliance

We cannot operationally support manual verifications. If you cannot support one of the two automated options (sending EPCIS serialized data or using a VRS), 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% of sales). In its discretion, Cardinal Health may assess a fee 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 and initiate a suspect product investigation. It's important that we have your company's DSCSA Exceptions contact name and email address to research and resolve any saleable returns verification issues. We appreciate that many of you have already shared this information with Cardinal Health. If you haven't yet, please send it to drugtracing@cardinalhealth.com.

We are creating a portal to document any negative verifications responses received through the VRS and anticipate sending an e-mail to the manufacturer with the relevant information including GTIN, serial number, lot and expiration date and plan to also include a picture of the 2D barcode and human readable from the package. We'll ask for confirmation as to whether the product is illegitimate or if the negative response was possibly due to a barcode scan, data transmission or other issue. If illegitimate, we will work with you to determine the appropriate filing of Form 3911. We have also created new GMB DSCSAVerifications@cardinalhealth.com that manufacturers can use as a contact for follow up with Cardinal Health on Saleable Returns Verifications.

Receiving Serialized Product

- As of November 27, 2019, Cardinal Health checks for product identifiers at receipt.
- The 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 will use your transaction statement as an indication that any non-serialized product received is grandfathered. No additional documentation is expected.
- If the FDA has granted a Waiver, Exception or Exemption for any of your product, please notify us at drugtracing@cardinalhealth.com**.**

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. **While enforcement discretion offers a slight reprieve, it's critical that we all continue with planned efforts to be ready for saleable returns verification in November 2020.**

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

Sincerely,

Dianne Pfahl
Vice President
Global Sourcing