cencora

Drug Supply Chain Security Act

Cencora expectations of FDA "stabilization" period

Dear valued partner,

Cencora applauds the FDAs recent enforcement policy and welcomes this "stabilization" period as an opportunity to keep the DSCSA systems and processes active while allowing time to work out the "bugs" and ensure smooth supply chain operations before the November 27, 2024 enforcement date; this clearly puts patients and product access first.

Cencora appreciates the effort that many of our manufacturer partners have invested over the last nine years, and most recently, to establish live interoperable connections to exchange the required enhanced DSCSA data prior to the November 27, 2023 deadline.

To that end, we acknowledge the recent FDA guidance, published August 30, 2023, allowing for delayed enforcement of the Enhanced Drug Distribution Security (EDDS) requirements. The FDA has already publicly referred to this as "not a delay", but a period of "stabilization". As called out in the EDDS final guidance:

> **This guidance is not intended to provide, and should not be viewed as providing, a justification for delaying efforts by trading partners to implement the enhanced drug distribution security requirements under section 582(g)(1) of the FD&C Act. FDA strongly urges trading partners to continue their efforts to implement necessary measures to satisfy these enhanced drug distribution security requirements.**

The FDA has also publicly communicated that they "expect trading partners to have the systems and processes in place to meet these requirements as of November 27, 2023". This means the industry cannot treat this as a pause and we need to proceed with our initial deadlines. Cencora is committed to moving the supply chain forward in this transformative initiative and will be collaborating with both HDA and FDA during established check-ins to ensure the broader industry continues to progress and does not slow down. We will continue to assist our manufacturer trading partners achieve compliance by providing timely feedback on their respective DSCSA transactions.

It's also important to highlight that until November 27, 2024, the use of the current compliance methods to exchange DSCSA transaction data regarding products, investigate and report or illegitimate products, and handle sellable returns will continue to be required for each shipment between trading partners. Simply put, we expect the current DSCSA data exchanges to continue to be transmitted in an

DSCSA compliant EDI 856 transaction until such time that we can align to cutover to the enhanced EPCIS data exchange.

Cencora Manufacturer Partners Milestones

To ensure compliance with the FDA enforcement guidance, Cencora is establishing the following milestones which allows flexibility for our manufacturer partners who might have non-compliant product (not aggregated) yet continues our commitment to keep moving forward. These expectations are applicable to all Human Health Drug Distribution, MWI Animal Health direct purchase of human drugs, and American Health Packaging:

October 31, 2023: We fully expect **every** trading partner to have their systems and processes in place to exchange EPCIS data as required by the initial November 27, 2023 deadline. This means ensuring Cencora has received a full list of GTINs, manufacturers have successfully tested an EPCIS exchange, and there has been an agreed to production date to start sending enhanced serialized data.

November 27, 2023: Per the guidance from the FDA, we expect every manufacturer partner to have enabled product data exchange for those products that are compliant (i.e. aggregated). **Failure to do so is a compliance violation of the intent of the FDA compliance policy which also puts Cencora at a regulatory risk of non-compliance.**

March 31, 2024: Cencora fully expects 100% of all sales to contain serialized data by the end of March. We need this to ensure the ability to facilitate verification against replicate data and to enable our ability for outbound data exchange. If a manufacturer cannot send 100% of data due to unaggregated inventory, we expect the individual NDC to be communicated, including a date of expected aggregation and a process for how we will manage against this list. If manufacturer partners are not ready by this date, Cencora plans to submit a WEE for these products per our internal requirements.

What is the impact of AmerisourceBergen becoming Cencora?

The Cencora portfolio of companies includes AmerisourceBergen, a leader in pharmaceutical distribution and supply chain operations in the U.S. as well as our various business units, including American Health Packaging.

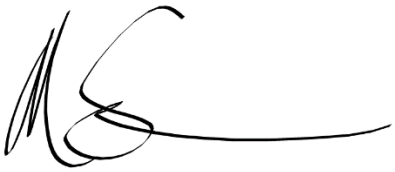
We've received several inquiries about what our name change means to DSCSA. While we have publicly changed our corporate name, the effort to change our operational, transactional, and regulatory systems will take some time.

At this point the following can be said:

1. **Future communications will be sent explaining when we expect trading partners to change their DSCSA TI sold-to to be Cencora Inc. from AmerisourceBergen or its affiliated businesses.**
2. **Cencora's GLN numbers will NOT change, and we've already initiated a legal name change with GS1. All that will change is the name associated with our company prefix. The prefix itself will remain the same.**
3. **Our FDA annual registration will continue to reflect our current licensure until a time we can successfully transfer those state licenses over to the new name.**

Thank you for your partnership and commitment,

Matt Sample



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For additional questions or concerns, please email SecureSupplyChain@AmerisourceBergen.com