

Addressing DSCSA Compliance Requirements: 2020 and Beyond



DSCSA Timeline of Events, per FDA Guidance



* Projected schedule, subject to change

What's Changing in 2020?

As of Nov 27, 2020, DSCSA implementation requires that health-system pharmacies, (dispensers) meet two new requirements:

1. Only accept products that have FDA-specified, 2D, Data Matrix barcodes
Note: Products may also have linear NDC barcodes
2. Implement processes and procedures to be able to track products to the Lot-Level



What Actions Should Health System Pharmacies Take to Comply With 2020 DSCSA Lot-Level Traceability Requirements?

2020 DSCSA requirements for Lot-Level traceability will impact the process a health-system uses to receive incoming shipments in two ways:

1. Products without 2D barcodes must be rejected upon receipt
2. Policies and procedures for investigating a suspect product must be updated to trace NDCs with Lot Numbers. Tracing requires contacting the manufacturer to verify the product.

There are no requirements to track movement or administration of products within the health-system after receiving. Dispensing is exempt from DSCSA requirements.

ConsortiEX is Ready

As a ConsortiEX customer, your DSCSA Compliance as a Service system is already compliant with DSCSA requirements for 2020. Our DSCSA Compliance as a Service system currently captures all Lot Numbers and Expiration Date information received via EDI.

Prior to November 27, 2020, electronic T3s without Lot Numbers and Expiration Dates are considered valid. Currently, our system doesn't flag T3s with missing Lot Numbers or Expiration Dates.

Internal Processes and Systems Updates to be Ready for the November 2020 Deadline:

1. Update policies for drug shipment receiving to include:
 - A process verifying that all eligible drug products received have the required 2D barcode.
 - A process to REJECT products without 2D barcodes.
 - Update Policies and Procedures for investigating a SUSPECT product to include verifying both NDC and LOT with the manufacturer
2. Recommended, but not required: Update, or upgrade to, internal systems that currently scan linear/NDC barcodes, such as bedside barcode/BCMA, dispensing cabinet loading, and IV workflow systems, to:
 - Scan and interpret the new 2D barcodes.
 - If current systems are capable, capture Lot Number and Expiration Date from the new 2D barcodes (Although bedside scanning/BCMA systems would benefit from capturing and checking Lot Number and Expiration Date, they are **not** required to do so)

ConsortiEX Assure-Trak[®] modules currently scan and interpret 2D barcodes, and automatically capture Lot Numbers and Expiration Dates.

3. Request that all wholesale distributors provide Lot Numbers and Expiration Dates within all DSCSA communications.
4. Work with 503B Compounding Facilities to ensure that all provided products have new 2D barcodes.

Although products from 503B compounders are exempt from DSCSA requirements, products that only have linear barcodes might be misidentified as suspect.

ConsortiEX can help you Simplify Product Recall Management

By capturing lot numbers as drugs are received, use your ConsortiEX DSCSA Compliance as a Service system to quickly, and reliably, determine if, and when, your pharmacy received any product from a recalled lot.

What Should Health-System Pharmacies do to Prepare for 2023 DSCSA Requirements (Serialization and Package-Level Tracing)?

Today, many vendors are encouraging hospitals to focus on serialization and Package-Level tracing requirements. Recommendations include:

1. Subscribing to "Verification Routing Services"
2. Implementing IT changes to be ready for EPCIS messaging for serial numbers
3. Expectations that each serialized package will need to be scanned and decommissioned after use.

The FDA has not issued final guidance for the implementation of 2023 DSCSA Requirements. Initial Guidance is not expected until November 2021, at the earliest. We expect that 2023 DSCSA changes for dispensers will be a moving target through, at least, late-2021.

ConsortiEX urges health-system pharmacies to take no action in pursuing 2023 DSCSA requirements until FDA Guidance is available. Making DSCSA compliance investments to meet assumed 2023 requirements without FDA Guidance is quite literally, flying blind.

Our systems and staff will be ready, well in advance, for all actual DSCSA changes. We stand by our promise to make DSCSA compliance worry-free for our customers.