Addressing DSCSA Compliance Requirements: *2020 and Beyond*

ConsortiEX ...from Pedigree to Patient®

DSCSA Timeline of Events, per FDA Guidance*

2021

Develop regulation for package-level tracing*

2022

FDA: Publish guidance on necessary system attributes to secure package-level tracing

FDA: Publish guidance on interoperable data exchange standards, enhancing secure package-level tracing

GS1: EPCIS Data Interchange

Industry Scramble to Implement Solutions

EPCIS Changes take Effect

2023

Pharmacies must have Package-Level tracability. Including validation of T3s and tracing to the package-level.

* *Timeline is subject to future change.*

2020 DSCSA Dispenser Changes:

As of November 2020, dispensers must:

1. Only accept products that have FDA-specified, 2D Data-Matrix barcodes
2. Have system in place to capture and verify 2D-Barcode Data

*Note: 97% of Vendors are Compliant with the 2D Barcode Requirement. Products may also have linear-barcodes **in addition to** 2D Barcodes.*

2022 EPCIS Changes:

All GS1 and PDG Standards work necessary for EPCIS Implementation will be published in Q4 2022.

1. Receive EPCIS data prior to receiving product, followed by the verification of received product against EPCIS data.

   Note: Roughly 1/3 of EPCIS Manufacturer to Wholesaler Connections are complete. EPCIS connections to Dispensers are just beggining.

2. Must have the ability to respond to electronic audits
3. Electronically document and communicate salable returns (Sending EPCIS data)

How to be Compliant with 2020 Requirements:

1. Update policies for drug shipment receiving to include:
   - ☐ Within the scope of DSCSA, verify received products have the required 2D-Barcode.
   - ☐ Within the scope of DSCSA, a process to REJECT products without the required 2D-Barcode.
2. Request that your wholesale distributors provide Lot Number and Expiration Date for all DSCSA transactions.
3. Work with 503B Compounding Facilities to ensure all products have 2D-Barcodes.

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

4. Recommended, not required: Implement or update existing barcode-scanning systems to:
   - ☐ Scan and interpret the new 2D-Barcodes.
   - ☐ Capture Lot Number and Expiration Date from the 2D-Barcode

   Note: Bedside Scanning Systems would benefit from Lot and Expiration data, although it is not a requirement. ConsortiEX Assure-Trak® Compounding Management System is 2D-Barcode Capable.

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Preparing for 2023 DSCSA Requirements

Dispensers are encouraged have process in place to meet serialization and package-level tracing requirements.

Recommendations include:

1. Subscribing to "Verification Routing Services"
2. Expectations that each serialized package will need to be scanned and decommissioned after use.

ConsortiEX urges dispensers to take action NOW, in pursuing 2023 Requirements. Despite pending Guidance, Return on Investment is available TODAY, for Verification Systems and Services.

ConsortiEX is Ready...

ConsortiEX DSCSA Compliance as a Service currently captures all Lot Numbers and Expiration Date data that is received.

Electronic T3s without Lot Numbers and Expiration Dates are considered valid. Currently, our system does not flag T3s with missing Lot Numbers or Expiration Dates.

ConsortiEX Verify on Receipt™ is the ideal barcode-scanning solution to meet 2023 DSCSA Guidance.

ConsortiEX is Ready...

On November 16, 2021 the FDA held a public meeting discussing the 2023 DSCSA Package-Level traceability requirements. See below for a list of relevant DSCSA Guidances surrounding 2023 requirements:

Issue Date	Guidance Topic	Status
03/10/2022	Verification Systems Under the Drug Supply Chain Security Act for Certain Prescription Drugs	Draft Guidance
06/03/2021	Product Identifiers Under the Drug Supply Chain Security Act: Questions and Answers; Guidance for Industry	Final Guidance
06/03/2021	Drug Supply Chain Security Act Implementation: Identification of Suspect Product and Notification	Final Guidance
10/22/2020	Wholesale Distributor Verification Requirement for Saleable Returned Drug Product and Dispenser Verification Requirements When Investigating a Suspect or Illegitimate Product—Compliance Policies	Final Guidance
10/28/2015	DSCSA Implementation: Product Tracing Requirements for Dispensers – Compliance Policy Guidance for Industry	Final Guidance

ConsortiEX can help you Simplify Product Recall Management

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 NDC.

ConsortiEX is ready for all DSCSA Requirements. We stand by our promise to make compliance worry-free for our customers.