



DSCSA & 340B: BEST PRACTICES AMID ENHANCED DSCSA GUIDELINES

WEBINAR

Agenda

- DSCSA Overview
- Roles of the Covered Entity
- Roles of the Contract Pharmacy
- Key Considerations for Covered Entities
- Reviewing DSCSA Policies for 340B
- Questions



DSCSA Overview

- Drug Supply Chain Security Act (DSCSA)
- Key components for Dispensers
 - Ensure serialized data is available
 - Develop workflows for verification
 - Outline policies and procedures



Role of the Covered Entity

- Covered Entity as the "Sold To" in 340B purchases
- Ensure DSCSA data is sent to "Ship To" location
- Review 340B Account setup
- Discuss DSCSA Policies with Contract Pharmacies



Role of the Contract Pharmacy

- Contract Pharmacy as the "Ship To" in 340B purchases
- Verification of products received / maintaining DSCSA compliance
- Establish Policies and Procedures for 340B purchases



Key Considerations for Covered Entities

- Alternate Distribution Model (ADM)
 - Receiving and Sending EPCIS data
- Saleable Returns



Reviewing DSCSA Policies for 340B

- Ensure specific policies for 340B purchases are discussed in SOPs
- Following policies to ensure DSCSA compliance



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Questions?



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