2023 Traceability Webinar Series

DSCSA Implementation: A Phased Approach and Other Industry Recommendations

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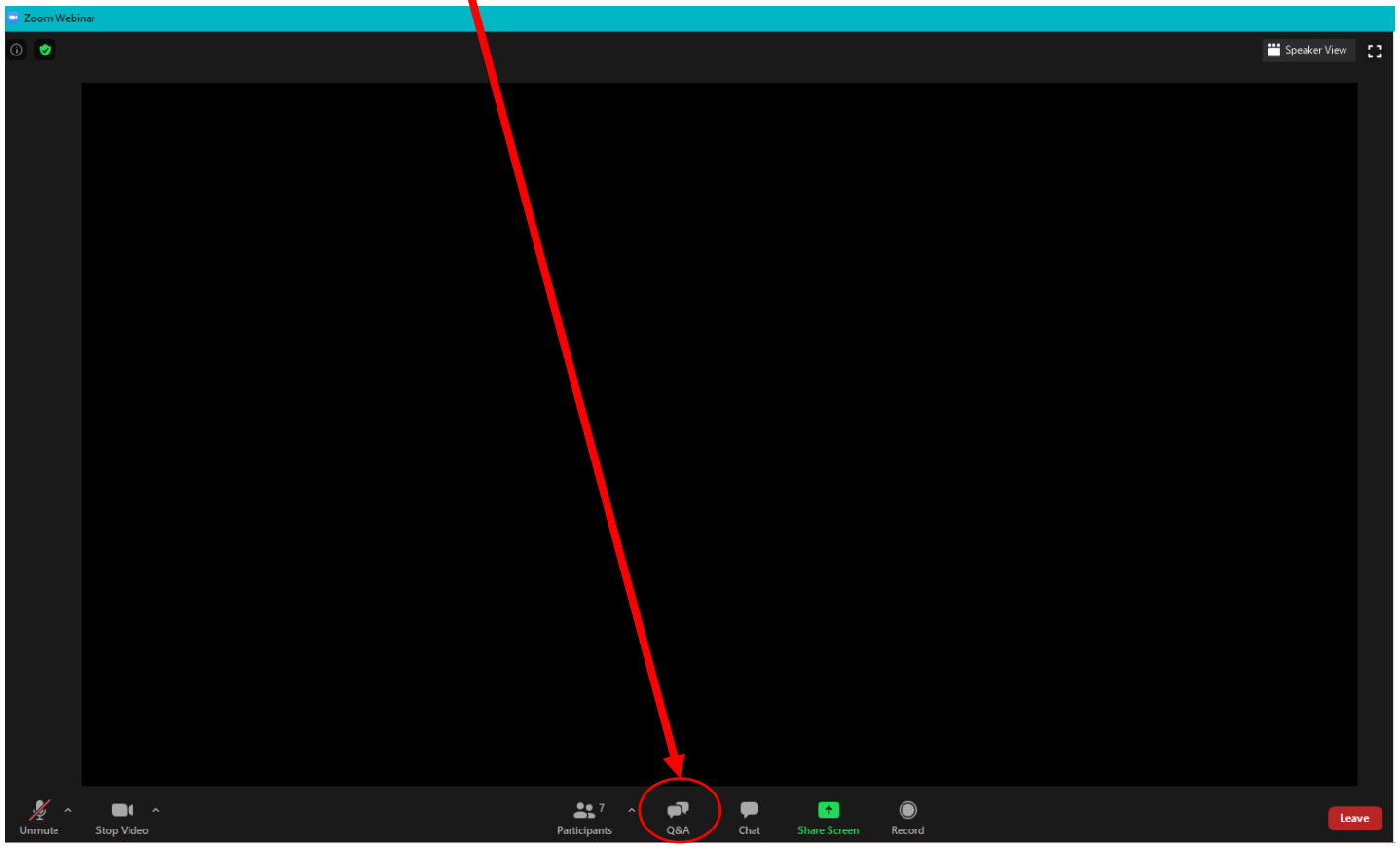

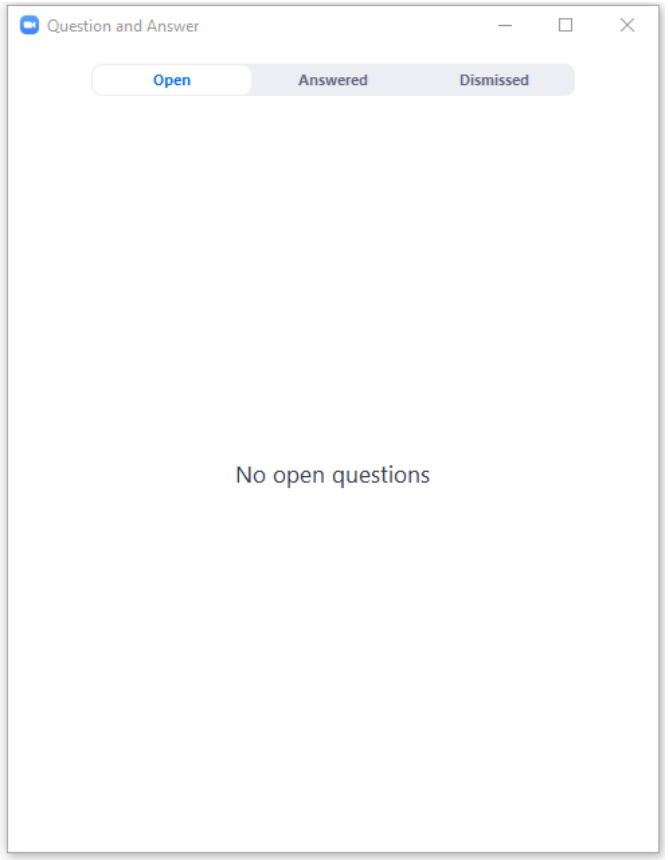

Speakers

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Final Stages of DSCSA Effective On November 27, 2023

- Section 582(g)(1) goes into effect.
  - §582(g)(1)(A) trading partners must exchange transaction data electronically and interoperably.
  - §582(g)(1)(B), the transaction data must include the unique identifier of each package in the transaction (referred to as “serialized data”).
  - §582(g)(1)(C), verification of the product identifier at the package level.
  - §582(g)(1)(D) and (E), tracing at the package level.
  - §582(g)(1)(F) – association of saleable returns at the package level.

Final Stages of DSCSA Effective On November 27, 2023

- FDA has stated trading partners exchanging Electronic Product Code Information Services (EPCIS) event files with accurate product identifiers for each package in the transaction satisfies §582(g)(1)(A) and (B).
- Exchanging EPCIS event files with accurate serialized data also enables compliance with other §582(g)(1) requirements.
- **No trading partner can**
  - **sell a covered prescription drug package to another trading partner unless it provides serialized data for the packages transacted,**
  - **accept ownership of a prescription drug package if its supplier does not provide serialized data for the packages transacted, or**
  - **resell the prescription drug package unless it provides serialized data for the packages transacted to its trading partner customer.**

The Issue(s)

- Not everyone has made the necessary EPCIS connections.
- Not everyone can send accurate and complete data.
- The supply chain is interdependent – the ability of a supplier to send accurate and complete serialized data in an EPCIS event file to its customers depends on having received accurate and complete serialized data in an EPCIS file from ***its*** supplier.
- Unlike the phase-in for product identifiers, this happens all at once.
- We ***know*** things will go wrong at first – the systems are complex and immature; data and file errors are certain.
- And when something does go wrong – file error, data error, scan of package identifier shows no data – there's no option in the DSCSA except quarantining the package.
- ***Shortages and disruptions to patient care are very likely!***

The Operational Challenges

- Need to keep good products moving while still remaining vigilant for suspect products and continuing current security measures already in place.
- But blanket enforcement discretion giving everyone more time isn't the answer.
  - Need to keep pushing toward secure, electronic, interoperable data exchange or we'll never get tracing at the package level.
  - Problems inherent in the transition from lot-level to package-level data exchange -- system stability and immaturity, data accuracy, lack of serialized data in the supply chain -- won't go away with more time. You just delay the point at which you have to deal with the problems.
  - A wholesaler ***cannot*** operate dual DSCSA systems at receiving with some manufacturers providing EPCIS files and others continuing to provide ASNs.

The Phased Approach

HDA's Proposed Solution: Phase-In November 2023 Requirements

- Over a two-year period, the supply chain should reach the DSCSA's final requirements in phases that:
  - Build serialized data capacity in the supply chain,
  - Stabilize interoperable exchange of accurate serialized data,
  - Keep needed medicines flowing to patients, and,
  - Maintain existing safeguards.
- The approach balances keeping pressure on unprepared trading partners while not excessively burdening those trading partners who are prepared.
- The phased approach is implemented through,
  - FDA-granted exemption requests,
  - FDA grant of limited enforcement discretion for certain requirements, for certain trading partners, for defined time periods, and
  - Defined trading partner actions that are phased in over time.

Phased Approach Summary

- Three phases over 2 years.
  - Phase 1 - November 27, 2023 – November 26, 2024.
  - Phase 2 - November 27, 2024 – May 26, 2025.
  - Phase 3 - May 27, 2025 – November 27, 2025.

Phase 1 Summary
November 27, 2023 – November 26, 2024

- Manufacturers
  - All manufacturers provide serialized data to customers or obtain an exemption from FDA exempting their NDC(s) from serialized data exchange and related requirements.
  - Manufacturers continue to also provide lot-level data to customers.
- Wholesale distributors
  - Wholesale distributors continue current practices and receive enforcement discretion for purposes of receiving and providing serialized data and related DSCSA requirements.
- Dispensers
  - Dispensers continue current practices and receive enforcement discretion for purposes of receiving serialized data and related DSCSA requirements.

Phase 1 – Deep Dive Manufacturers

- If a manufacturer cannot provide serialized data for an NDC, it must obtain an exemption from FDA for that NDC.
  - The exemption would excuse a manufacturer from all §582(g)(1) requirements except verification.
  - The manufacturer must continue to provide lot-level data to customers following current practices (typically in an ASN).
- If a manufacturer can provide accurate serialized data for an NDC in an EPCIS event file, it must also continue current practice and provide lot-level data (typically in an ASN) to customers.

Importance of Continuing the ASN

- Continuation of the ASN throughout early serialized data exchange is a key difference between “blanket” enforcement discretion and the phased approach.
- Continuing to use ASN solves multiple problems.
  - A wholesale distributor can receive a product based on the lot-level data and resell products ***even if it discovers a serialized data problem*** (absent other indicia of a concern).
  - If the ASN ***didn’t*** continue from ***all*** suppliers, wholesalers might have to switch to EPCIS for receiving for ***all*** manufacturers since it can’t operate two DSCSA systems.
- In the phased approach, a manufacturer that can comply with §582(g)(1) and provide serialized data should also continue sending the ASN because:
  - If there is a data or file problem (and we know there will be), the wholesaler would have to quarantine the product and won’t be able to resell it.
  - If the wholesaler had received an ASN, it would be able to continue to move the product through the supply chain to dispensers and patients.

Phase 1 – Deep Dive
Wholesale Distributors

- Wholesale distributors receive enforcement discretion from FDA for all §582(g)(1) requirements.
- On inbound, a wholesale distributor continues to receive against lot-level data (typically the ASN) while working with suppliers on EPCIS data and file problems.
  - If it received the ASN, the wholesale distributor can continue to move the product even if it finds a problem with the serialized data also received (absent other indicia of a concern).
- On outbound, a wholesale distributor provides lot-level data to customers (in an ASN, a portal, or other means appropriate for the customer) while working to onboard customers for EPCIS file exchange.

Phase 1 - Deep Dive
Dispensers

- Dispensers receive enforcement discretion from FDA limited to §582(g)(1)(A), (B), (C), (D), (E), and (F).
- Dispensers continue other current practices and requirements, including transactions only with authorized trading partners and suspect and illegitimate product investigations.
- Dispensers continue receiving lot-level data from their suppliers via an ASN, in a portal, or other appropriate means.

Phase 2 Summary
November 27, 2024 – May 26, 2025

- Manufacturers
  - All manufacturers provide accurate and complete serialized data to all customers for all NDCs in EPCIS event files and obtain exemption from FDA if they cannot.
  - Manufacturers also continue to provide lot-level data in an ASN.
- Wholesale distributors:
  - Enforcement discretion ends for purposes of receipt of serialized data from suppliers.
  - Enforcement discretion continues for the other §582(g)(1) requirements.
- Dispensers
  - Dispensers continue current practices and receive enforcement discretion from §582(g)(1) requirements.

Phase 2 – Deep Dive Manufacturers

- All requirements of §582(g)(1) apply and for all covered transactions, manufacturers must provide accurate serialized data in accurate, complete, and stable EPCIS event files to all customers for all NDCs.
- If a manufacturer cannot do so, it must obtain an exemption from FDA.
- All manufacturers also continue current practice and provide accurate and complete lot-level data (typically in an ASN) to all customers in order to accommodate transactions with dispensers and wholesale distributor transactions with other wholesale distributors.

Phase 2 – Deep Dive
Wholesale Distributors

- Enforcement discretion ends for some §582(g)(1) requirements, continues for others.
- As to §582(g)(1)(A) and (B):
  - For transactions from manufacturers (and their exclusive distributors), a wholesale distributor must receive and maintain EPCIS files for each transaction.
  - For transactions between wholesale distributors, seller and purchaser must be providing EPCIS event files by the end of the 3rd month of Phase 2.
  - For transactions between wholesale distributors and dispensers, enforcement discretion continues; wholesaler must continue to provide lot-level data in an ASN or other appropriate means.
- A wholesale distributor is expected to comply with §582(g)(1)(C) and verify at the package level.

Phase 2 – Deep Dive
Wholesale Distributors

- As to §582(g)(1)(D) and (E) – tracing at the package level:
  - A wholesale distributor is expected to be able to trace at the package level backward if it received serialized data from its supplier.
  - A wholesale distributor has enforcement discretion as to tracing products at the package level forward.
- §582(g)(1)(F) – a wholesale distributor has enforcement discretion as to association of saleable returns at the package level.
- The wholesale distributor also continues to onboard dispensers for EPCIS file exchange or other means appropriate for each dispenser and prepare for the provision of serialized data.

Phase 2 - Deep Dive Dispensers

- A continuation of Phase 1; dispensers continue to receive enforcement discretion from FDA limited to §582(g)(1)(A), (B), (C), (D), (E), and (F).
- Dispensers continue other current practices and requirements.
- Dispensers continue to work with their suppliers to get onboarded and receive serialized data.

End of Phase 2
May 27, 2025

- By the end of Phase 2, manufacturers and wholesale distributors are all interoperably and electronically providing accurate transaction data at the package level in accurate, complete, and stable EPCIS event files to all customers or otherwise providing serialized data by posting it to a portal or some other appropriate means.
- Enforcement discretion ends for manufacturers and wholesale distributors and all §582(g)(1) requirements apply.
- Any manufacturer or wholesale distributor still not compliant at the end of Phase 2, must obtain an exemption from FDA.

Phase 3
May 27, 2025 – November 27, 2025.

- Enforcement discretion has ended for manufacturers and wholesale distributors; all transactions comply with § 582(g)(1) requirements.
- Dispensers are in compliance with § 582(g)(1)(A) and (B) because they are receiving from manufacturers and wholesale distributors accurate serialized data in EPCIS event files or by other appropriate means for all transactions.
- However, to give time for dispenser systems and processes to mature and stabilize, dispensers continue to receive enforcement discretion from FDA as to §582(g)(1) requirements until the end of Phase 3.

End of Phase 3
November 27, 2025

- Enforcement discretion ends for all trading partners.
- All requirements of § 582(g)(1) apply.
- All trading partners are securely, interoperably, and electronically exchanging and maintaining accurate transaction data at the package level.
  - Important to remember that until a trading partner is receiving and providing serialized data, package-level requirements like tracing are not possible.
- Any trading partner still not compliant at the end of Phase 3 must obtain an exemption from FDA.

HDA Phased Approach / Next Steps

- HDA submitted the proposal to FDA on June 2, 2023.
- Proposal was submitted to Office of Compliance ODSIR (responsible for DSCSA) and other parts of FDA concerned about drug shortages.
- HDA shared widely with stakeholders and their trades, and industry groups.
  - https://hda.org/getmedia/d989d7c7-3961-4df0-bff4-7c92621866f4/HDA-Recommended-Phased-Approach-Letter-6-2-23.pdf
  - Or, search “HDA phased approach”
- Pharmacy trades have written to FDA supporting the proposal, others are working on comments.
- We understand FDA is looking at it and wants to hear from stakeholders,
  - Submissions to drugtrackandtrace@fda.hhs.gov
  - WEEs to DSCSA-WEER@fda.hhs.gov

Questions & Answers

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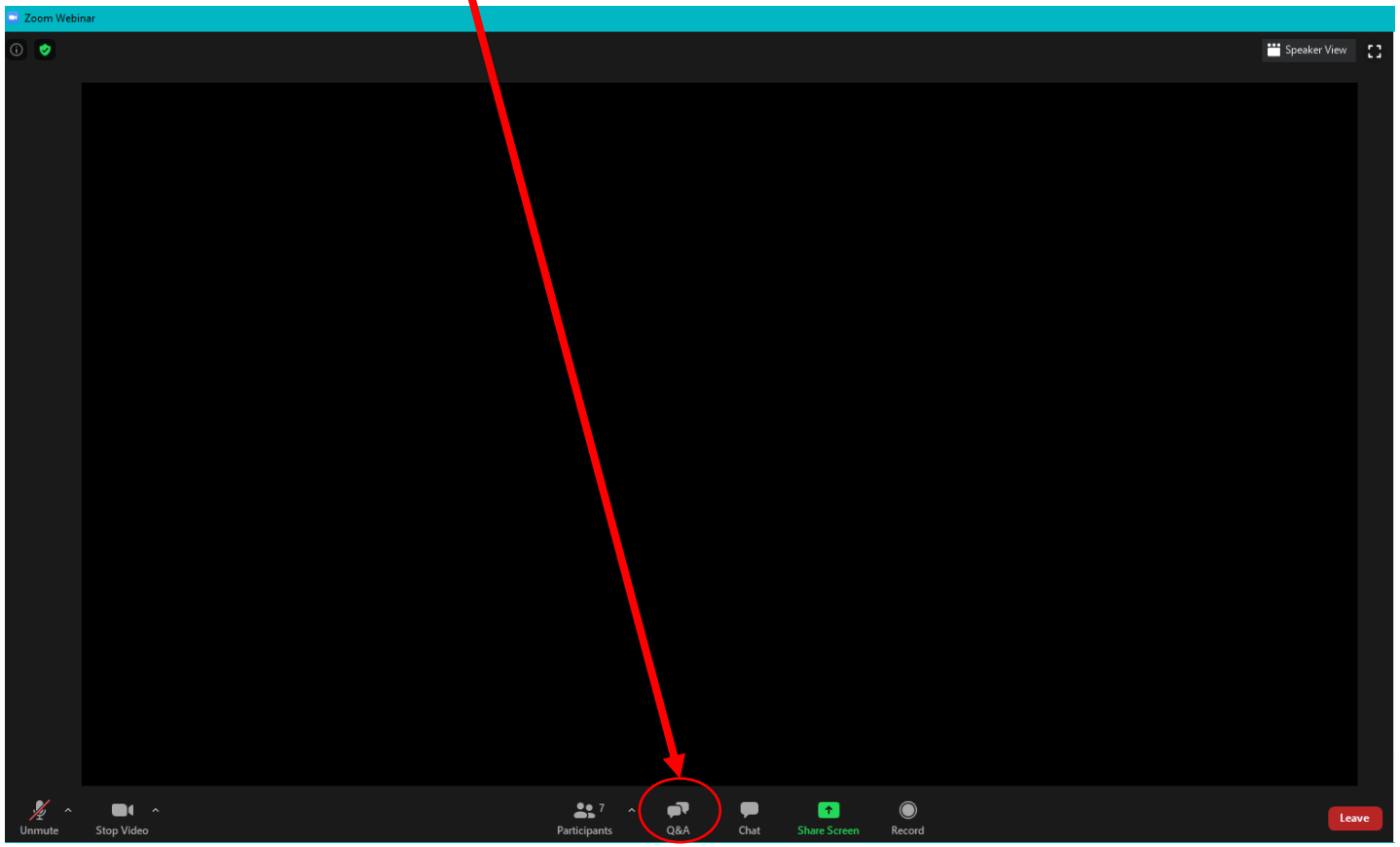

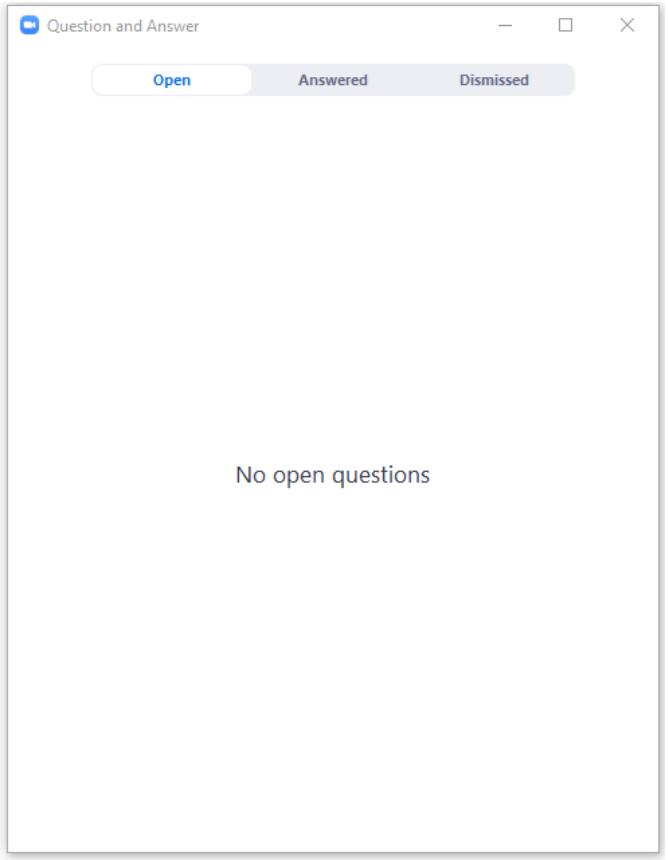

Upcoming Events

Traceability Webinar Series | Thursday, August 17, 2023, 1:00 PM - 2:15 PM ET | DSCSA Solutions Panel: Innovative Systems for Solving Compliance Requirements

2023 Traceability Seminar | August 29—31, 2023 | Marriott Marquis, Washington, D.C.

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