

Stakeholder Presentations

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DSCSA Implementation and Readiness Efforts for 2023

Public Meeting – December 7, 2022

Oral Remarks from Stakeholders – Group A

Moderated by: Dan Bellingham

FDA/CDER/OC/ODSIR



DSCSA Implementation and Readiness Efforts for 2023

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Oral Remarks from Stakeholders

Brian Rezach

Association for Accessible Medicines (AAM)



DSCSA Implementation and Readiness Efforts for 2023

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Oral Remarks from Stakeholders

Ryan Kaat

**Pharmaceutical Research and Manufacturers of America
(PhRMA)**



DSCSA Implementation and Readiness Efforts for 2023

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Oral Remarks from Stakeholders

Gurdeep Sidhu

Apotex

APOTEX

Innovating for
patient affordability



Apotex DSCSA Readiness - FDA Public Meeting

December 7th - 8th

Gurdeep Sidhu - Manager, QA Global Policy & Standards



Agenda



- Industry Involvement
- Apotex Readiness
- Challenges & Concerns

Industry Involvement



Working Group Participation:

- PDSA, PDG, GS1 RX Secure Supply Chain, AAM DSCSA WG

Pilots done with downstream trading partners:

- Trials done with University / AB 2019 (End-to-End EPCIS)
- Aggregation Data Accuracy Studies (Ongoing)
- AB Pilots - Data Errors (Completed) & Data Analytics (Ongoing)

Apotex Readiness



Serialization data is **GMP** and is as important as the physical product

- **100%** of inbound product coming with EPCIS
- Currently processing outbound EPCIS data for approximately **85%** of volume
- Continue to **mature** internal processes related to **exceptions processing** on the inbound & outbound

Challenges & Concerns



- Exceptions Processing (Inbound & Outbound)
 - Aggregation Accuracy, Volume & Frequency of Exceptions, Barcode & Data Quality
- Lack of Understanding & Inconsistency from Regulators
 - Tracing & Verifications
 - Define the mechanism for regulator requests
 - How to authenticate incoming requests
- Reporting 3911 Process
 - NDC Owner vs. CMO / Supplier
 - NDC Owner vs. Customer
 - Multiple notifications for same Incident seems redundant
 - Not all Customers reporting 3911 for stolen products

Challenges & Concerns Cont.



- Downstream Connectivity
 - How to connect with customers who are not engaged
- No industry standards for exceptions processing & not expected to be in place for 2023
- Volume of exceptions & the staffing required to support
 - Difficult to quantify how much staffing support is needed, etc.
 - Using Quality Management Systems to address supply chain exceptions utilizes overhead



DSCSA Implementation and Readiness Efforts for 2023 Public Meeting – December 7, 2022

Break



DSCSA Implementation and Readiness Efforts for 2023

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FDA/CDER/OC/ODSIR



DSCSA Implementation and Readiness Efforts for 2023

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Oral Remarks from Stakeholders

Eric Marshall

Partnership for DSCSA Governance (PDG)



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Oral Remarks from Stakeholders

Robert Celeste

Dave Mason

Max Peoples

Open Credentialing Initiative (OCI)



Open Credentialing Initiative (OCI) Interoperable Digital Credentials: Ecosystem Update

Presentation to FDA Public Meeting: “DSCSA Implementation
and Readiness Efforts for 2023”

December 7-8, 2022

Thanks for your time today!

Broad coalition of DSCSA stakeholders committed to enhancing INTEROPERABILITY – a key call-out of the DSCSA statute. Open standards are a critical element of interoperability, and we are very appreciative of FDA’s leadership in the selection, design and promulgation of open standards within the DSCSA community to support enhanced drug distribution security.

Gregg Gorniak
AMERISOURCEBERGEN
Member, HDA, GS1

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**JOHNSON & JOHNSON
SUPPLY CHAIN**
Member, PDG, GS1

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OCI Contributors:

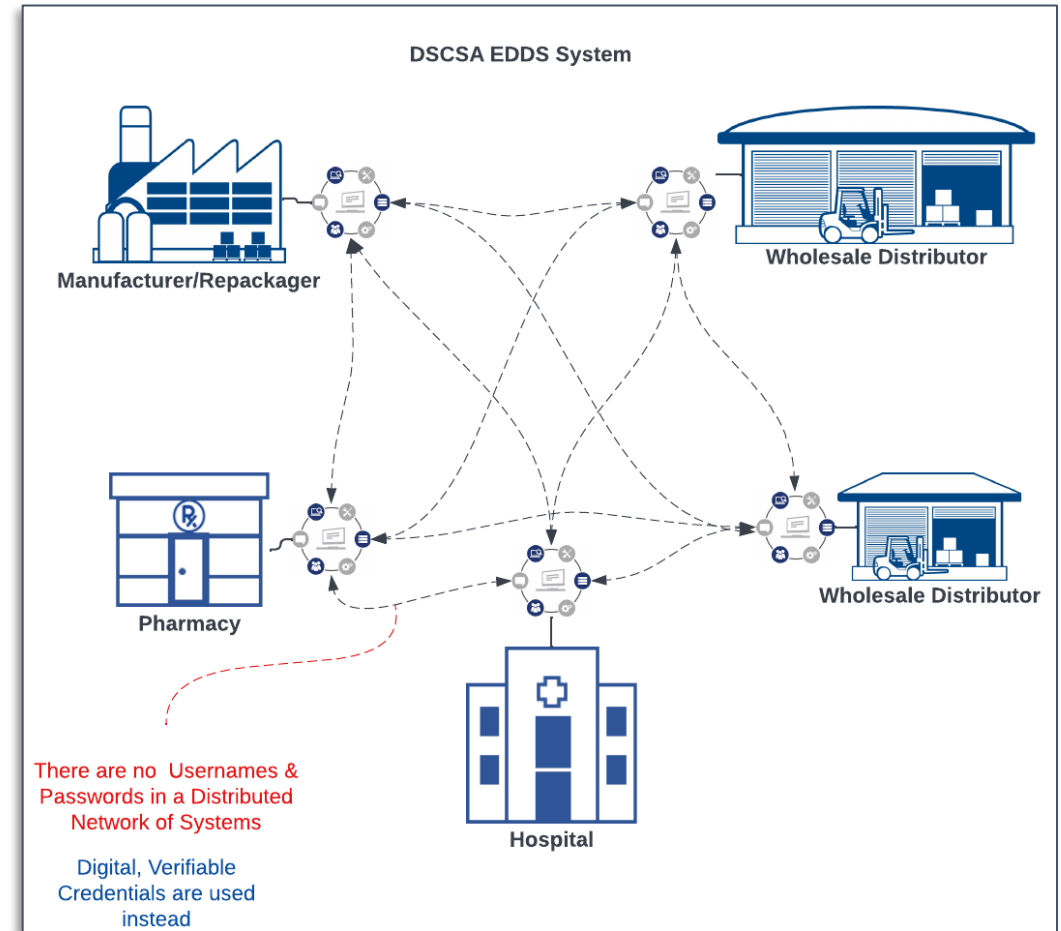
*Atlantic Biologicals
Center for Supply Chain Studies
GS1 US
HDA
Legisym
Movilitas
Navitas
Novartis
.Med
rfxcel
RxScan
Spherity
Systech
TraceLink
TrackTrace RX
Vantage Solutions
XATP*



DSCSA Challenges

The DSCSA EDDS System – A highly distributed network of systems

- In a **highly distributed digital ecosystem**, there are no usernames and passwords – no way to know whether a counterparty is “real”
- Need to **establish ATP status** to protect confidentiality and secure the supply chain
- How can we do this in a digital, interoperable way? With **digital credentials** built on open standards!



Moving into 2023, OCI works closely with stakeholders to deliver interoperability based on open standards

- **Published open specifications** for secure interoperable credential exchange to establish ATP status and identity for indirect relationships (**supporting verification and tracing**)
- **Initiated interoperability testing** with the Verification Router Service (VRS) community
- **Widespread adoption and recognition** to recognize the OCI architecture as the standard for establishing ATP status in appropriate DSCSA digital transactions:
 - GS1 US Lightweight Verification Message Standard 1.3
 - HDA VRS Interoperability Testing for PI Verification
 - PDG Blueprint for DSCSA Interoperability & Tracing Schema
- **“TSA Precheck” for all stakeholders:** manufacturers, repackagers, wholesalers, 3PLs, dispensers, and regulators
- **Roadmap for 2023** includes issuer compliance auditing program, wallet-to-wallet communications, and piloting credential use beyond DSCSA



Dispenser Perspective

Path to Adoption

- Standard Operating Procedure (SOP) adoption
 - Need to consider manual vs credential used processes for:
 - Verification of Suspect & Illegitimate Product
 - Tracing Activities
- Staff education about 2023 DSCSA requirements and how they will be met
- If using a commercial solution, contract for it and implement it sooner rather than later.

Do not get caught in a last "months" mad rush to implement your path.

If everyone waits to the last few months before November 2023 there will be approximately 30,000 pharmacy non-chain dispensers that will be trying to implement at the same time.



Manufacturer Perspective

- Authenticating ATPs for Verification Requests
- Supporting Validation Requirements
- Confidentiality & Compliance Concerns



Summary

- OCI-Compliant Digital Credentials built on open specifications
- Broad adoption by industry and standards organizations
- Only specification addressing ATP + Identity
 - (*“Jim’s Pharmacy is a dispenser” + “this is Jim’s Pharmacy”*)
- Involvement by all stakeholders needed to drive interoperability
- Call on FDA to establish awareness that a digital solution for the ATP requirement is available and validated by compliance teams

LEARN MORE: oc-i.org





DSCSA Implementation and Readiness Efforts for 2023

Public Meeting – December 7, 2022

Oral Remarks from Stakeholders

Pat O'Connor

International Warehouse Logistics Association (IWLA)



DSCSA Implementation and Readiness Efforts for 2023

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Oral Remarks from Stakeholders

Mark Hendrickson

Pharmaceutical Distribution Security Alliance (PDSA)



DSCSA Implementation and Readiness Efforts for 2023

Public Meeting – December 8, 2022

Oral Remarks from Stakeholders Session - Group C

Moderated by: Kelli Dobilas, Branch Chief

FDA/CDER/OC/ODSIR



DSCSA Implementation and Readiness Efforts for 2023

Public Meeting – December 8, 2022

Oral Remarks from Stakeholders

Anita Ducca

Healthcare Distribution Alliance (HDA)



**DSCSA Implementation and Readiness
Efforts for 2023
Public Meeting – December 8, 2022**

Oral Remarks from Stakeholders

Scott Mooney

McKesson Corporation



DSCSA Implementation and Readiness Efforts for 2023

Public Meeting – December 8, 2022

Oral Remarks from Stakeholders

Brad Pine

J M Smith Corporation



DSCSA Implementation and Readiness Efforts for 2023

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Oral Remarks from Stakeholders

Matt Sample

AmerisourceBergen

Labeling & Barcoding Challenges

-Issues currently seen in Production

Barcode issues*; **

- Incorrectly encoded barcodes*
- Date formatting issues*
- Sub-standard barcode size*
- Barcode curvature*
- Shrink wrapped / “Shiny”
- Ink/Print quality/degradation**



* Not compliant to GS1 General Specification Standards, or HDA Barcode Guideline

** Not meeting ISO Grade C 2D Standards

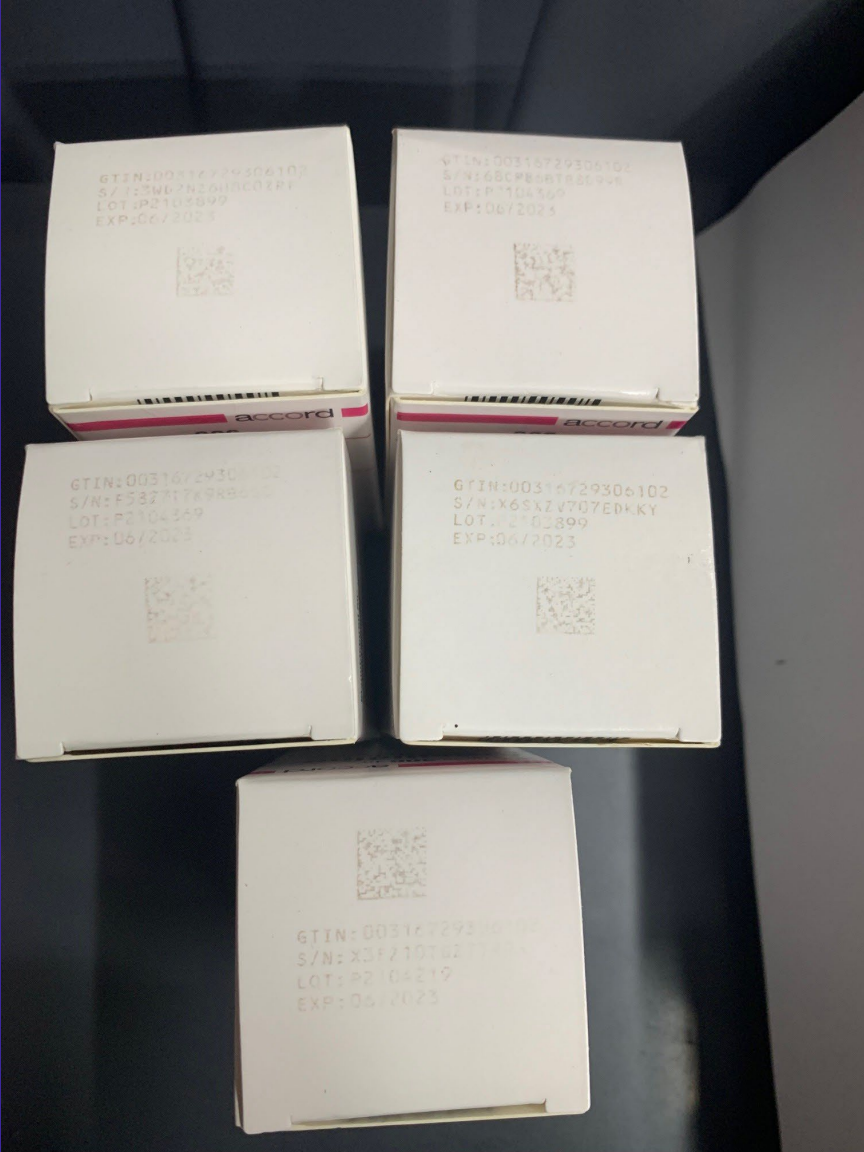
*** All issues communicated to manufacturers

Published communications: <https://www.amerisourcebergen.com/manufacturing-operations-and-replenishment>

Recent Barcode Issues



Recent Barcode Issues







DSCSA Implementation and Readiness Efforts for 2023 Public Meeting – December 8, 2022

Break



DSCSA Implementation and Readiness Efforts for 2023

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Oral Remarks from Stakeholders Session - Group D

Moderated by: Kelli Dobilas, Branch Chief

FDA/CDER/OC/ODSIR



DSCSA Implementation and Readiness Efforts for 2023

Public Meeting – December 8, 2022

Oral Remarks from Stakeholders

Josh Bolin

National Association of Boards of Pharmacy



NABP

National Association of
Boards of Pharmacy

DSCSA Interoperability Network

December 8, 2022

About NABP

The National Association of Boards of Pharmacy[®] (NABP[®]) is a 501(c)(3) nonprofit organization founded in 1904. We support and work with our members, the state boards of pharmacy, to protect the public health.

Our Mission

NABP is the independent, international, and impartial association that assists its member boards and jurisdictions for the purpose of protecting the public health.

Our Members

Our members consist of the 50 United States state boards of pharmacy, as well as the boards in District of Columbia, Guam, Puerto Rico, the US Virgin Islands, 10 Canadian provinces, and the Bahamas.

Impact of DSCSA on State Regulation

- Is the dispenser community prepared for DSCSA compliance?
- How will regulators assess trading partner compliance with DSCSA?
- How will regulators request transaction information from trading partners within the secure, electronic, and interoperable system?
 - Illegitimate, suspect product investigations
 - Fraudulent activity
 - Product recalls

Drug Supply Chain Security Act Document Doc# 0000019002

(TI) Transaction Information

Drug Name, Strength, Dosage Form, Container Size: BIKTARVY 30CT, 50/200/25 MG NDC: 61958-2501-01			Reference Number: 01140811
			Document Type: Invoice
			Reference Date: 01/08/21
Lot Number	Quantity	Unique Serial #	
6400506A	3		
CDGX8A	1		
CCZCFA	1		

(TH) Transaction History

Manufacturer's Name: **GILEAD SCIENCES**
Manufacturer's information:

SOLD TO: Name: GENTEK LLC Address: 45 CEDAR ST UNIT 3 STAMFORD CT 06902 Date Purchased & Ref :	SHIPPED TO: Name: GENTEK LLC Address: 45 CEDAR ST UNIT 3 STAMFORD CT 06902 Date Received & Ref :
SOLD TO: Name: SAFE CHAIN SOLUTIONS, LLC Address: 822 CHESAPEAKE DR CAMBRIDGE MD 21613 Date Purchased & Ref : 01/07/21 PO#012113	SHIPPED TO: Name: SAFE CHAIN SOLUTIONS Address: 822 CHESAPEAKE DR CAMBRIDGE MD 21613 Date Received & Ref : 01/08/21 RC#016349
SOLD TO: Name: MEDICINE SHOPPE #1802 Address: 10313 GEORGIA AVENUE #101 SILVER SPRING MD 20902 Date Purchased & Ref : 01/08/21 0153675800	SHIPPED TO: Name: MEDICINE SHOPPE #1802 Address: 10313 GEORGIA AVENUE #101 SILVER SPRING MD 20902 Date Received & Ref : 01/08/21 01536758001
SOLD TO: Name: Address: Date Purchased & Ref :	SHIPPED TO: Name: Address: Date Received & Ref :
SOLD TO: Name: Address: Date Purchased & Ref :	SHIPPED TO: Name: Address: Date Received & Ref :

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Drug Name, Strength, Dosage Form, Container Size: BIKTARVY 30CT, 50/200/25 MG NDC: 61958-2501-01			Reference Number: 01140811
			Document Type: Invoice
			Reference Date: 01/08/21
Lot Number	Quantity	Unique Serial #	
6400506A	3		
CDGX8A	1		
CCZCFA	1		

(TH) Transaction History

Manufacturer's Name: **GILEAD SCIENCES, INC**
Manufacturer's information: 1800 WHEELER AVENUE LA VERNE, CA 91750

SOLD TO: Name: DROGUERIA BETANCES Address: LUIS MUNOZ MARIN AVE CAGUAS PR 00725 Date Purchased & Ref : 10/05/20 85160	SHIPPED TO: Name: DROGUERIA BETANCES Address: LUIS MUNOZ MARIN AVE CAGUAS PR 00725 Date Received & Ref : 10/05/20 85160
SOLD TO: Name: GENTEK LLC Address: 45 CEDAR ST UNIT 3 STAMFORD CT 06902 Date Purchased & Ref : 10/06/20 2719	SHIPPED TO: Name: GENTEK LLC Address: 45 CEDAR ST UNIT 3 STAMFORD CT 06902 Date Received & Ref : 10/06/20 2719
SOLD TO: Name: SAFE CHAIN SOLUTIONS, LLC Address: 822 CHESAPEAKE DR CAMBRIDGE MD 21613 Date Purchased & Ref : 01/07/21 PO#01211389	SHIPPED TO: Name: SAFE CHAIN SOLUTIONS Address: 822 CHESAPEAKE DR CAMBRIDGE MD 21613 Date Received & Ref : 01/08/21 RC#016349
SOLD TO: Name: MEDICINE SHOPPE #1802 Address: 10313 GEORGIA AVENUE #101 SILVER SPRING MD 20902 Date Purchased & Ref : 01/08/21 01536758001	SHIPPED TO: Name: MEDICINE SHOPPE #1802 Address: 10313 GEORGIA AVENUE #101 SILVER SPRING MD 20902 Date Received & Ref : 01/08/21 01536758001
SOLD TO: Name: Address: Date Purchased & Ref :	SHIPPED TO: Name: Address: Date Received & Ref :

State Regulator & Industry Participation

	State Regulators	Primary Role: Manufacturer	Primary Role: Distributor	Primary Role: Dispenser	Solution Providers	Trade, Standards, Other Orgs	Service Providers
Pilot and/or POC Participant	<ul style="list-style-type: none"> California Idaho Kansas North Dakota Massachusetts Ohio 	<ul style="list-style-type: none"> Apotex EMD Serono Genentech Johnson and Johnson Pfizer Sanofi 	<ul style="list-style-type: none"> Amerisource Bergen Hercules Pharmaceuticals McKesson Premier Rx Wholesale 	<ul style="list-style-type: none"> CVS Health Mart Pharmacy Mississippi Senior Care The Transplant Pharmacy Sam's Healthmart Uptown Pharmacy Walgreens Walmart 			
Observers & Stay Informed	<ul style="list-style-type: none"> State BOP Executive Officers NABP District 3 NABP District 5 CA Board of Pharmacy 	<ul style="list-style-type: none"> Amgen Bristol Myers Squibb Eli Lilly Gilead Novartis 	<ul style="list-style-type: none"> ANDA Inc Cardinal Health Medline Industries Morris & Dickson Co. NC Mutual Drug Smith Drug Company Value Drug Company 	<ul style="list-style-type: none"> Ro 	<ul style="list-style-type: none"> .Med Registry Auto-ID Solutions ConsortiEx InfiniTrak InfoNetworks Inmar Legisym Ledger Domain LSPediA RfXcel/ Antares SAP Spherity Systech RxScan TraceLink TrackTrace Rx Vantage Solutions XATP 	<ul style="list-style-type: none"> APhA GS1 US HDA NCPA OCI PDG The Partnership for Safe Medicines USP 	<ul style="list-style-type: none"> ArentFox BBF Consulting Center for Supply Chain Studies Excellis OFW Law PHT Storemed
<p>*POC Participants in red</p> <p>*Recently Added</p>							

Q1 2022 DSCSA Pilot Outcomes

- NABP led work on:
 - Data exchange methods for tracing
 - State regulator authorization
 - Dispenser authorization
 - Trading partner directory
- NABP committed to facilitate collaboration and communication between regulators and trading partners
- Pilot Report (released May 2022) and further information can be found at NABP's DSCSA webpage: <https://nabp.pharmacy/members/programs-services/industry-information-networks/dscsa-state-regulator-network/>

What Is Expected To Be Included?

NABP to provide the following functionality at no cost:

- Claim or create (and maintain) your trading partner directory profile
- Surface ATP status via existing data repositories
- Set data-sharing preferences
- Respond to regulator trace and verification requests (for all trading partners)
- Initiate and respond to trading partner trace requests (for dispensers)
- Initiate verification requests to manufacturers (for dispensers)

Authorized Trading Partner Credentialing

More than any sector of the supply chain, the small dispenser community needs tools like product tracing and product verification.

- Concerned that existing ATP credentialing approach places financial and operational barriers to adoption—particularly for the small dispenser community.
- Unnecessary barriers on interoperability within the supply chain risk frustrating the primary purpose of DSCSA by simultaneously ***decreasing the security of the supply chain and increasing the regulatory burden*** for all industry participants through unscalable communications.
 - For example: If standards for tracing and verification **REQUIRE** credentialing as currently explored, a significant number of dispensers **WILL NOT** participate in the electronic and interoperable system, which will lead to manual tracing and verification requests.

Up Next: Detailed Activities

- **November 2022** - Conduct Survey of Trading Partners and Solution Providers
- **December 2022** - Stakeholder Follow-Up Interviews
- **Q1 2023** - Begin Interoperability Workshops by Topic:
 - Trading Partner Identifiers
 - Product Tracing Methods/Messaging
 - Product Verification Routing/Messaging
 - ATP Status Requirements & Methods by Use Case

We welcome thoughts on any other areas of alignment or updates on related standards. Please email us at dscsapilot@nabp.pharmacy

Final Points

- We are supportive of the FDA's Guidance regarding DSCSA Standards for Interoperable Exchange from July 2022, in particular maintaining a standards-based, but technologically agnostic approach to interoperability.
- NABP is committed to work with our member boards, state pharmacy associations and other trade and professional associations to educate the dispenser community around their compliance obligations under DSCSA.
- Regarding FDA's mechanism to request product tracing or verification information, while NABP is building our network to facilitate communication for all regulators—state and federal—we are committed to work to ensure alignment and consistency with the DSCSA.

Useful Links:

- Demonstration of NABP DSCSA Interoperable Network (Nov 2022): <https://www.youtube.com/watch?v=YrP41rlAgqo>
- Tracing Pilot Report (May 2022) found at NABP's DSCSA webpage: <https://nabp.pharmacy/members/programs-services/industry-information-networks/dscsa-state-regulator-network/>
- NABP Press Release of Start of Full Development: <https://nabp.pharmacy/news/news-releases/nabp-enters-final-development-phase-of-dscsa-interoperability-network/>



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Oral Remarks from Stakeholders

Allan Bowyer

TraceLink



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Sean Lockhead

Innovit

DSCSA Oral Comments

December 2022

innovit

DSCSA Comments

- 🍃 Solution Provider perspective but also on behalf of all stakeholders
- 🍃 Agree with the use of GS1 Standards, including use of GS1 EPCIS
 - Need to understand impact of various versions, especially EPCIS
- 🍃 Foundational elements are the identification and master data
- 🍃 Significant efforts for the technical implementation of master to transactional to traceability data
- 🍃 Interested in learning more about additional forums for continued implementation discussions

S e a n L o c k h e a d , I n n o v i t , s e a n . l o c k h e a d @ i n n o v i t . c o m

