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Drug Traceability Under the DSCSA: Building on Progress and Finishing the Job

NCPA 2024 Annual Convention and Expo

Columbus, Ohio

Speaker

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Disclosure Statement

Eric Marshall has a financial interest with Pharmaceutical Distribution Security Alliance and RxGPS alliance and the relationship has been mitigated through peer review of this presentation. There are no relevant financial relationships with ACPE defined commercial interests for anyone else in control of the content of the activity.

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Partnership for DSCSA Governance

An independent, sector-neutral governance body, and an FDA public-private partnership dedicated to developing, advancing, and sustaining an effective and efficient model for interoperable tracing and verification of prescription pharmaceuticals in the U.S.

www.DSCSAgovernance.org

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Learning Objectives

1. List the core compliance requirements of the DSCSA.
2. Discuss the applicability of the small business dispenser exemption established by FDA on DSCSA implementation.
3. Describe the current state of DSCSA implementation across the industry.
4. Identify remaining actions needed to achieve full compliance.

September 30, 2024: 27 individuals indicted in Puerto Rico over wholesale distri… misbranded and diverted medicin…

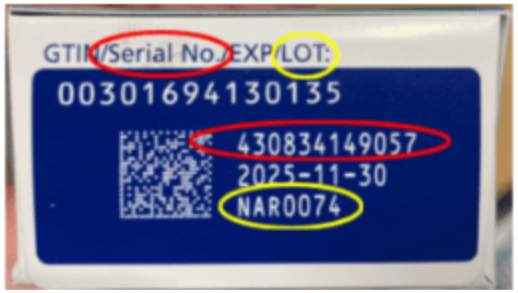
September 30, 2024

Twenty-seven… Rico indicted… diverted drug…

April 15, 2024: Fake Botox investigation expands to five states; six hospitalized

"The CDC clinically diagnosed me with botulism."

July… victims…



July 22, 2024: A Michigan pharmacy sues supplier over fake Ozempic

July 22, 2024

A Michigan company is suing a telepharmacy that allegedly… risks of… ancer drug…

February 26, 2024: Safe Chain Solutions settles HIV drug diversion lawsuit with Gilead Sciences

February 26, 2024

A Maryland drug distributor lost $2.7 million in a settlement over selling secondhand medicine to U.S. pharmacies. Additional news in Alabama, California, New Jersey, Tennessee and more.

*This presentation contains product names and images for educational purposes only. It is not meant to be an endorsement or advertisement of any particular product or product categories.

Source: Partnership for Safe Medicines (https://www.safemedicines.org/)

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1. Know your source.
2. Have, follow, and exercise SOPs to identify and respond to suspicious products.
3. Work with your suppliers to establish electronic record keeping practices.
4. Be prepared to support regulator- and industry-led investigations of suspicious products.

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DSCSA: 5 Letters in 5 Minutes

TITLE II—DRUG SUPPLY CHAIN SECURITY

Drug Supply Chain Security Act.

SEC. 201. SHORT TITLE. 21 USC 301 note.

This title may be cited as the "Drug Supply Chain Security Act".

SEC. 202. PHARMACEUTICAL DISTRIBUTION SUPPLY CHAIN.

Chapter V (21 U.S.C. 351 et seq.) is amended by adding at the end the following:

"Subchapter H—Pharmaceutical Distribution Supply Chain 21 USC prec. 360eee.

"SEC. 581. DEFINITIONS. 21 USC 360eee.

"In this subchapter:

"(1) AFFILIATE.—The term 'affiliate' means a business entity that has a relationship with a second business entity if, directly or indirectly—

"(A) one business entity controls, or has the power to control, the other business entity; or

"(B) a third party controls, or has the power to control, both of the business entities.

"(2) AUTHORIZED.—The term 'authorized' means—

"(A) in the case of a manufacturer or repackager, having a valid registration in accordance with section 510;

"(B) in the case of a wholesale distributor, having a valid license under State law or section 583, in accordance with section 582(a)(6), and complying with the licensure reporting requirements under section 503(e), as amended

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Preemption

2013

Lot-Level Traceability

2015

2017

Unit-Level Verification

2019+

Unit-Level Traceability

2023

Stabilization

2024

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Key Requirements of the DSCSA

Entities must only work with "Authorized Trading Partners"

2015

Entities must pass, capture, and maintain certain information with respect to each product transaction.

Entities must have processes to investigate, verify, and respond to suspect and illegitimate products.

2015

Entities must only sell and purchase product that is serialized

2020

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TI/TS Data Exchange Requirements Apply To Every

Transaction of a Product

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Specific Dispenser Requirements

Accept

Only accept prescription drugs that are accompanied by three pieces of product tracing documentation – **transaction information**, **transaction history***, and **transaction statement**.

Generate and Provide

Generate and provide all product tracing documentation with the transaction if you sell a prescription drug to a trading partner.

Store

Store the product tracing documentation you receive in paper or electronic format for **six years**.

Respond

Respond to a request for information by providing the requested TI within 24 hours.

*Transaction history sunsets on November 27, 2023.

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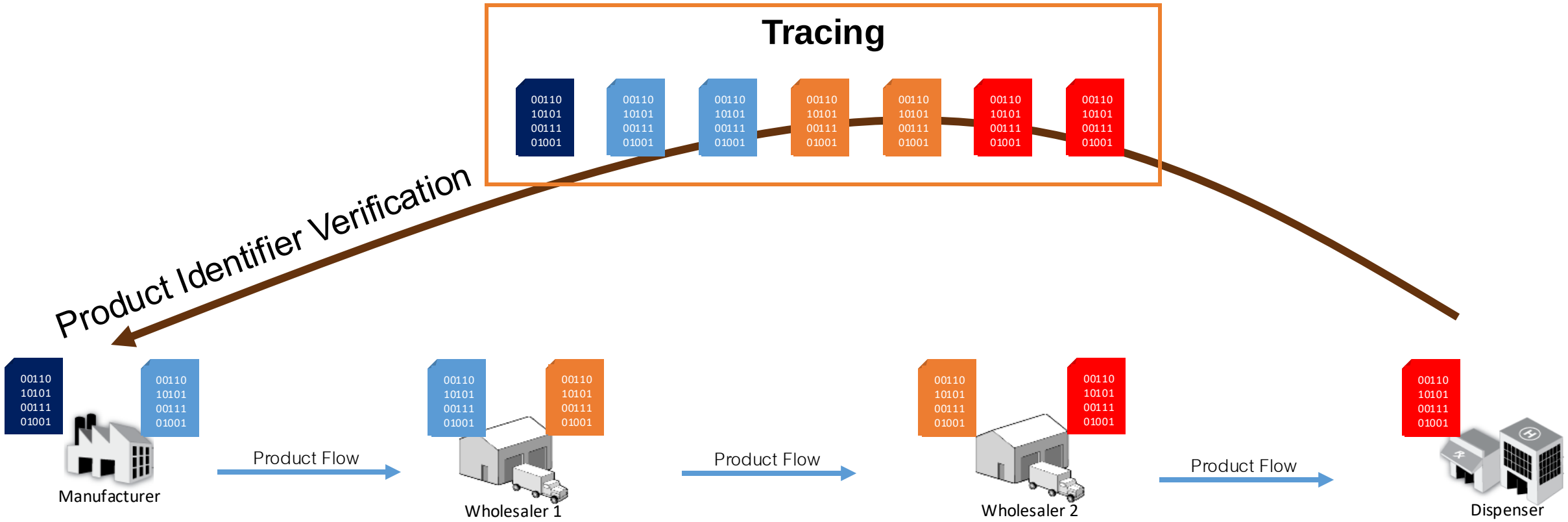

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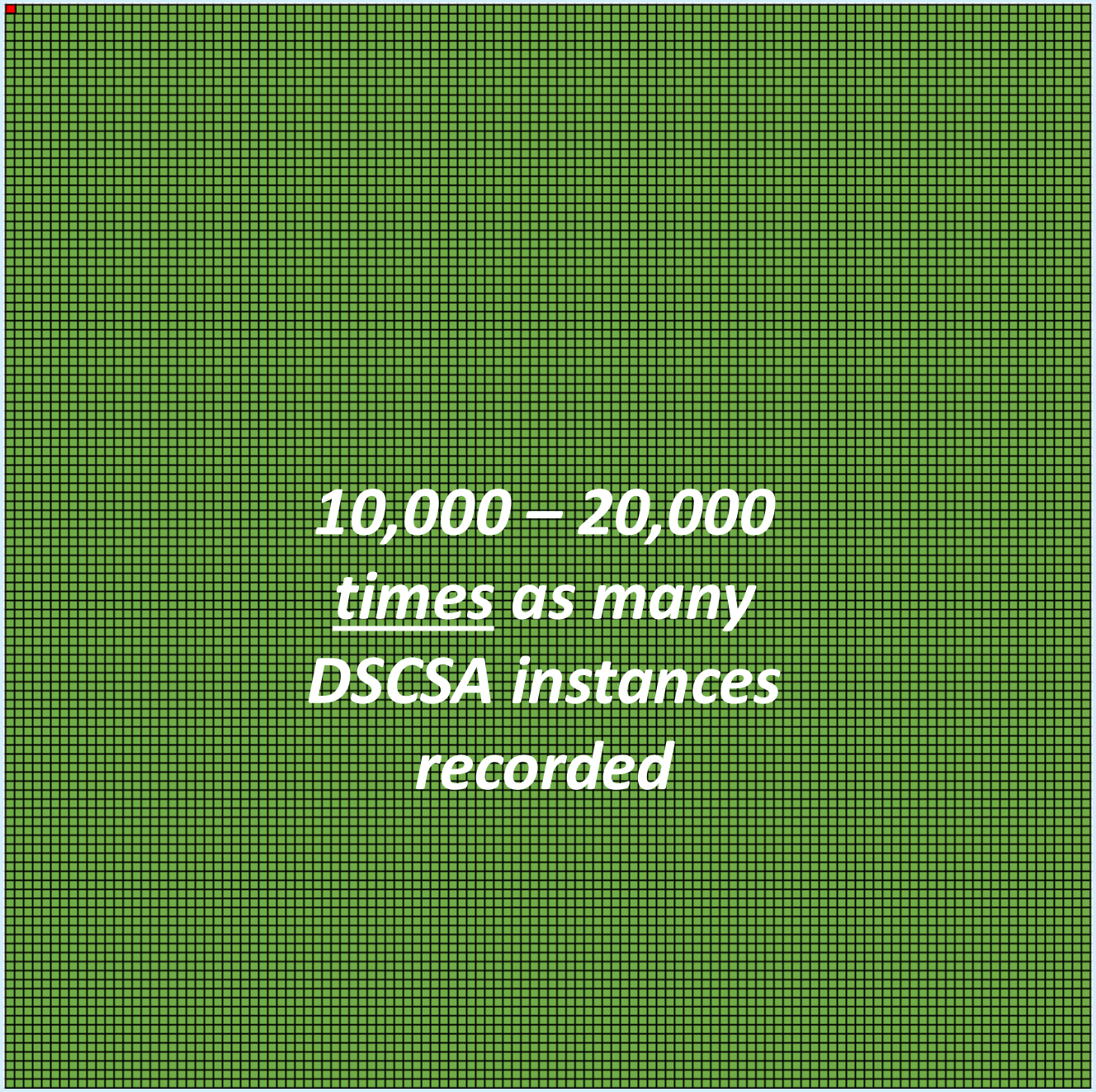
Today

2023/2024



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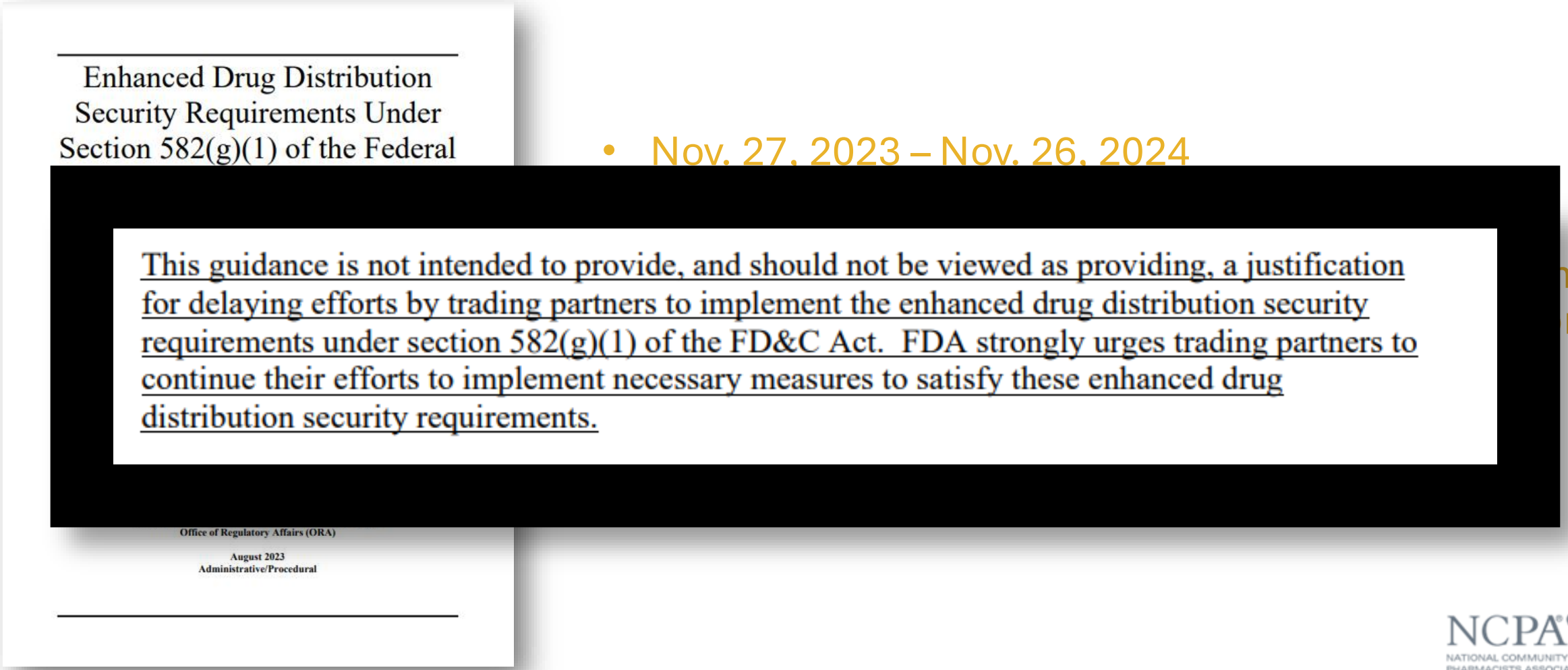
Stabilization Period



Enhanced Drug Distribution Security Requirements Under Section 582(g)(1) of the Federal

This guidance is not intended to provide, and should not be viewed as providing, a justification for delaying efforts by trading partners to implement the enhanced drug distribution security requirements under section 582(g)(1) of the FD&C Act. FDA strongly urges trading partners to continue their efforts to implement necessary measures to satisfy these enhanced drug distribution security requirements.

Office of Regulatory Affairs (ORA)

August 2023
Administrative/Procedural

- Nov. 27, 2023 – Nov. 26, 2024

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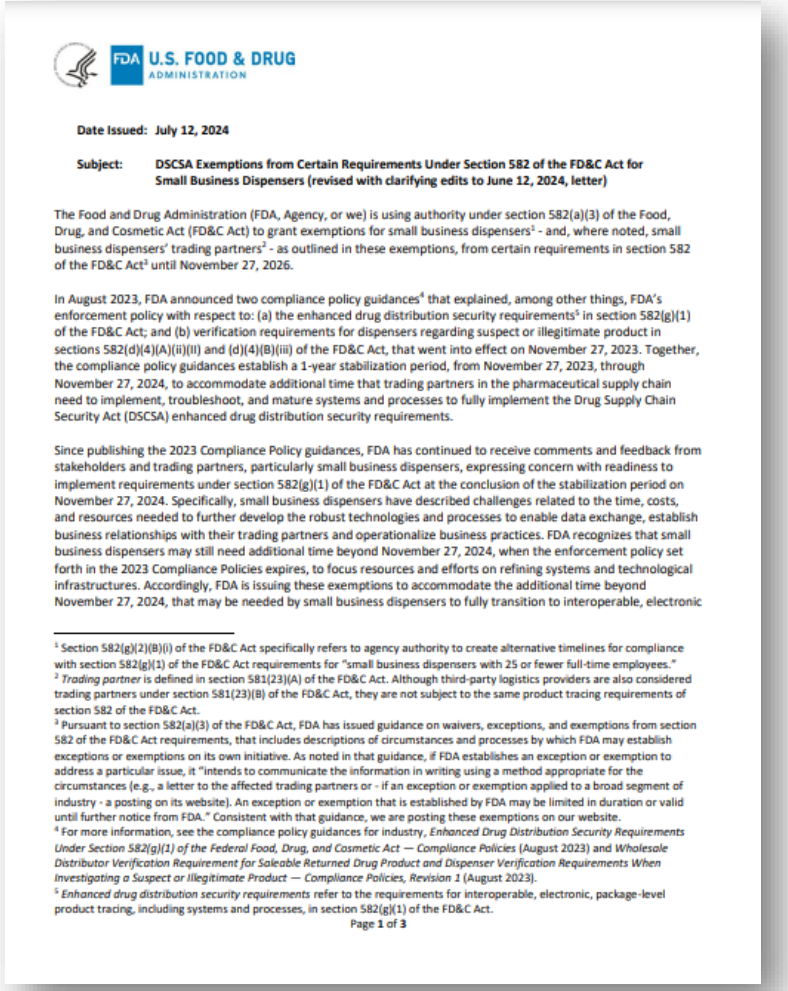
Small Dispenser Enforcement Discretion



U.S. FOOD & DRUG ADMINISTRATION

Date Issued: July 12, 2024

Subject: DSCSA Exemptions from Certain Requirements Under Section 582 of the FD&C Act for Small Business Dispensers (revised with clarifying edits to June 12, 2024, letter)

The Food and Drug Administration (FDA, Agency, or we) is using authority under section 582(a)(3) of the Food, Drug, and Cosmetic Act (FD&C Act) to grant exemptions for small business dispensers[1] - and, where noted, small business dispensers' trading partners[2] - as outlined in these exemptions, from certain requirements in section 582 of the FD&C Act[3] until November 27, 2026.

In August 2023, FDA announced two compliance policy guidances[4] that explained, among other things, FDA's enforcement policy with respect to: (a) the enhanced drug distribution security requirements[5] in section 582(g)(1) of the FD&C Act; and (b) verification requirements for dispensers regarding suspect or illegitimate product in sections 582(d)(4)(A)(ii)(II) and (d)(4)(B)(iii) of the FD&C Act, that went into effect on November 27, 2023. Together, the compliance policy guidances establish a 1-year stabilization period, from November 27, 2023, through November 27, 2024, to accommodate additional time that trading partners in the pharmaceutical supply chain need to implement, troubleshoot, and mature systems and processes to fully implement the Drug Supply Chain Security Act (DSCSA) enhanced drug distribution security requirements.

Since publishing the 2023 Compliance Policy guidances, FDA has continued to receive comments and feedback from stakeholders and trading partners, particularly small business dispensers, expressing concern with readiness to implement requirements under section 582(g)(1) of the FD&C Act at the conclusion of the stabilization period on November 27, 2024. Specifically, small business dispensers have described challenges related to the time, costs, and resources needed to further develop the robust technologies and processes to enable data exchange, establish business relationships with their trading partners and operationalize business practices. FDA recognizes that small business dispensers may still need additional time beyond November 27, 2024, when the enforcement policy set forth in the 2023 Compliance Policies expires, to focus resources and efforts on refining systems and technological infrastructures. Accordingly, FDA is issuing these exemptions to accommodate the additional time beyond November 27, 2024, that may be needed by small business dispensers to fully transition to interoperable, electronic

[1] Section 582(g)(2)(B)(i) of the FD&C Act specifically refers to agency authority to create alternative timelines for compliance with section 582(g)(1) of the FD&C Act requirements for "small business dispensers with 25 or fewer full-time employees."
[2] *Trading partner* is defined in section 581(23)(A) of the FD&C Act. Although third-party logistics providers are also considered trading partners under section 581(23)(B) of the FD&C Act, they are not subject to the same product tracing requirements of section 582 of the FD&C Act.
[3] Pursuant to section 582(a)(3) of the FD&C Act, FDA has issued guidance on waivers, exceptions, and exemptions from section 582 of the FD&C Act requirements, that includes descriptions of circumstances and processes by which FDA may establish exceptions or exemptions on its own initiative. As noted in that guidance, if FDA establishes an exception or exemption to address a particular issue, it "intends to communicate the information in writing using a method appropriate for the circumstances (e.g., a letter to the affected trading partners or - if an exception or exemption applied to a broad segment of industry - a posting on its website). An exception or exemption that is established by FDA may be limited in duration or valid until further notice from FDA." Consistent with that guidance, we are posting these exemptions on our website.
[4] For more information, see the compliance policy guidances for industry, *Enhanced Drug Distribution Security Requirements Under Section 582(g)(1) of the Federal Food, Drug, and Cosmetic Act — Compliance Policies* (August 2023) and *Wholesale Distributor Verification Requirement for Saleable Returned Drug Product and Dispenser Verification Requirements When Investigating a Suspect or Illegitimate Product — Compliance Policies, Revision 1* (August 2023).
[5] *Enhanced drug distribution security requirements* refer to the requirements for interoperable, electronic, package-level product tracing, including systems and processes, in section 582(g)(1) of the FD&C Act.

- Nov. 27, 2024 – Nov. 26, 2026
- Only exempts **serialized** data exchange, verification, and tracing
- Applies if the dispenser (corporate entity) has 25 or fewer full-time employees licensed as pharmacists or qualified as pharmacy technicians
- Exemption is automatic, but trading partner notice recommended
- Suppliers proceeding as is

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Waivers, Exceptions, and Exemptions (WEEs)

- Other than small dispenser, “The agency is not extending the stabilization period beyond November 27, 2024.”

- Trading partners that are unable to meet the enhanced drug distribution security requirements by November 27, 2024, may request a waiver or exemption from those requirements

- Although requests can be submitted at any time, FDA recommends trading partners submit a waiver or an exemption request by August 1, 2024

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PDG-FDA Joint Public Meeting: DSCSA Stabilization Period Midway Checkpoint

- The Public Meeting in June 2024 highlighted a critical distinction between the Stabilization Period and stabilization activities.
- Managing expected imperfection is a key to success.
- The Public Meeting provided a landscape of the current demographics of industry readiness.
- The Public Meeting developed cross-stakeholder understanding of what it means for interoperable systems and processes to be stabilized.
- Collaboration and communication are essential to stabilization.

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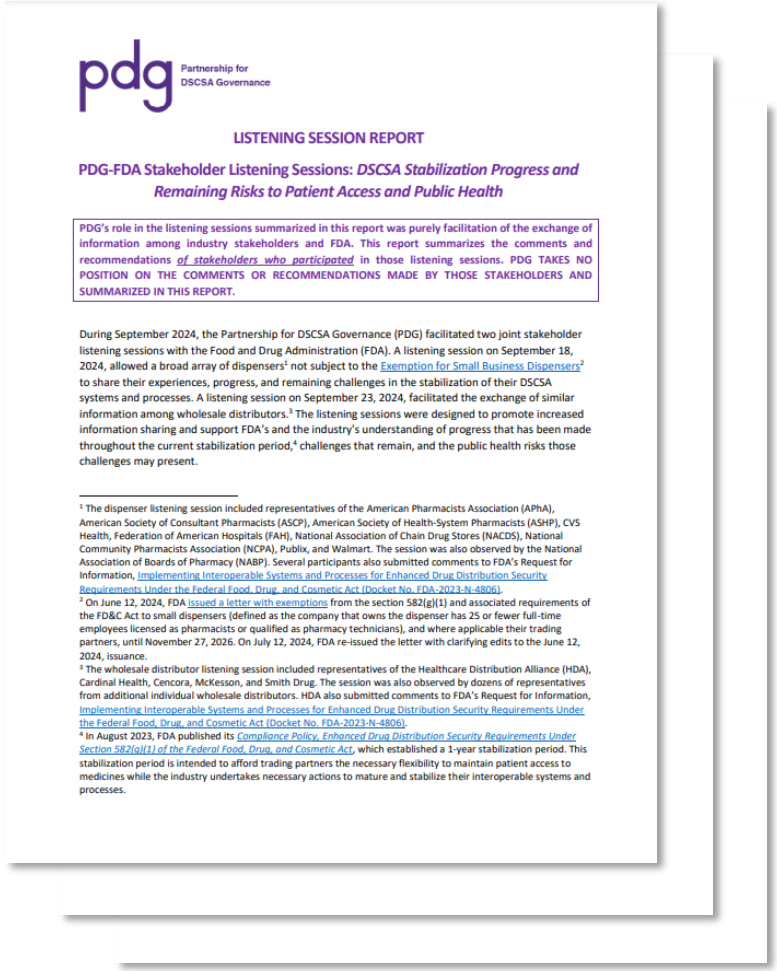
PDG-FDA Stakeholder Listening Sessions



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LISTENING SESSION REPORT

PDG-FDA Stakeholder Listening Sessions: *DSCSA Stabilization Progress and Remaining Risks to Patient Access and Public Health*

PDG's role in the listening sessions summarized in this report was purely facilitation of the exchange of information among industry stakeholders and FDA. This report summarizes the comments and recommendations *of stakeholders who participated* in those listening sessions. PDG TAKES NO POSITION ON THE COMMENTS OR RECOMMENDATIONS MADE BY THOSE STAKEHOLDERS AND SUMMARIZED IN THIS REPORT.

During September 2024, the Partnership for DSCSA Governance (PDG) facilitated two joint stakeholder listening sessions with the Food and Drug Administration (FDA). A listening session on September 18, 2024, allowed a broad array of dispensers[1] not subject to the Exemption for Small Business Dispensers[2] to share their experiences, progress, and remaining challenges in the stabilization of their DSCSA systems and processes. A listening session on September 23, 2024, facilitated the exchange of similar information among wholesale distributors.[3] The listening sessions were designed to promote increased information sharing and support FDA's and the industry's understanding of progress that has been made throughout the current stabilization period,[4] challenges that remain, and the public health risks those challenges may present.

[1] The dispenser listening session included representatives of the American Pharmacists Association (APhA), American Society of Consultant Pharmacists (ASCP), American Society of Health-System Pharmacists (ASHP), CVS Health, Federation of American Hospitals (FAH), National Association of Chain Drug Stores (NACDS), National Community Pharmacists Association (NCPA), Publix, and Walmart. The session was also observed by the National Association of Boards of Pharmacy (NABP). Several participants also submitted comments to FDA's Request for Information, Implementing Interoperable Systems and Processes for Enhanced Drug Distribution Security Requirements Under the Federal Food, Drug, and Cosmetic Act (Docket No. FDA-2023-N-4806).

[2] On June 12, 2024, FDA issued a letter with exemptions from the section 582(g)(1) and associated requirements of the FD&C Act to small dispensers (defined as the company that owns the dispenser has 25 or fewer full-time employees licensed as pharmacists or qualified as pharmacy technicians), and where applicable their trading partners, until November 27, 2026. On July 12, 2024, FDA re-issued the letter with clarifying edits to the June 12, 2024, issuance.

[3] The wholesale distributor listening session included representatives of the Healthcare Distribution Alliance (HDA), Cardinal Health, Cencora, McKesson, and Smith Drug. The session was also observed by dozens of representatives from additional individual wholesale distributors. HDA also submitted comments to FDA's Request for Information, Implementing Interoperable Systems and Processes for Enhanced Drug Distribution Security Requirements Under the Federal Food, Drug, and Cosmetic Act (Docket No. FDA-2023-N-4806).

[4] In August 2023, FDA published its *Compliance Policy, Enhanced Drug Distribution Security Requirements Under Section 582(g)(1) of the Federal Food, Drug, and Cosmetic Act*, which established a 1-year stabilization period. This stabilization period is intended to afford trading partners the necessary flexibility to maintain patient access to medicines while the industry undertakes necessary actions to mature and stabilize their interoperable systems and processes.

- Dispenser and wholesaler sessions in Sept.
- Highlighted important role of stabilization period.
- Systems and processes are generally established.
- Data challenges remain and create access and public health risks.
- Stakeholders urged FDA to establish an exemption that will ensure patient access and maintain public health while technologies and data quality improve.

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FDA-Initiated Exemptions

- Applies to any product transacted by **eligible trading partners**.
- **Eligible trading partners** are trading partners who have **successfully completed or made documented efforts to** complete data connections with their immediate trading partners, but still face challenges exchanging data.
- Exemption **applies automatically** if the ATP chooses to avail itself to it.
- The duration of the exemption varies depending on the eligible trading partners:
  - Manufacturers and Repackagers: May 27, 2025
  - Wholesale Distributors: August 27, 2025
  - Dispensers with 26 or more full-time employees: November 27, 2025

Full exemption available at: https://www.fda.gov/media/182584/download?attachment

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Supply Chain-Wide Enforcement Discretion
Nov 27, 2023 to Nov 27, 2024

Exemption for "Eligible" Mfrs
Nov 27, 2024 to May 27, 2025

Exemption for "Eligible" Wholesalers
Nov 27, 2024 to Aug 27, 2025

Exemption for "Eligible" Non-Small Dispensers
Nov 27, 2024 to Nov 27, 2025

Small Business Dispenser Exemption
Nov 27, 2024 to Nov 27, 2026

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To scan or not to scan?

Graphic created by PDG

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Saleable Return Restrictions

"(F) Each person accepting a saleable return shall have systems and processes in place to allow acceptance of such product and may accept saleable returns only if such person can associate the saleable return product with the transaction information and transaction statement associated with that product.

FDCA 582(g)(1)(F).

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Resources

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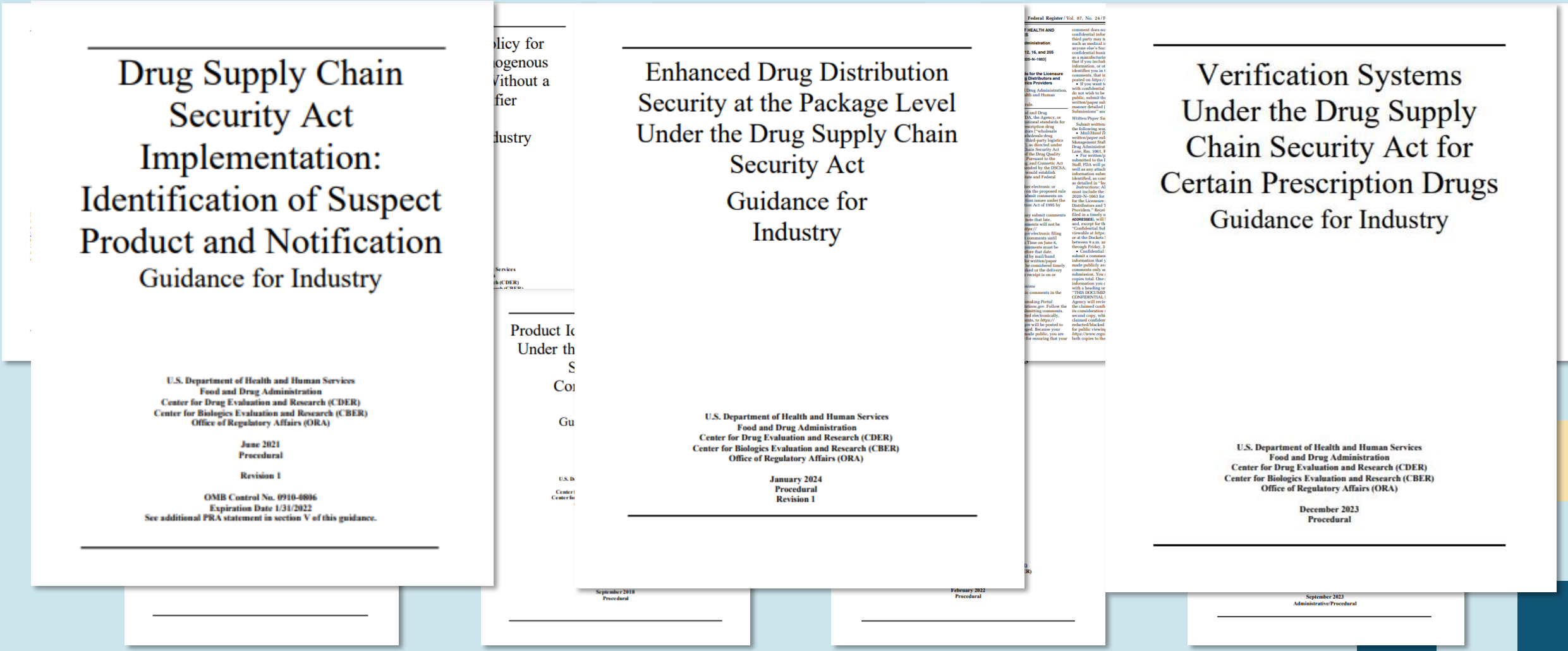
https://www.fda.gov/drugs/drug-supply-chain-security-act-dscsa/drug-supply-chain-security-act-law-and-policies



https://dscsa.pharmacy/

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www.DSCSAgovernance.org/blueprint

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Partnership for DSCSA Governance (PDG)
Foundational Blueprint for 2023 Interoperability

Chapter 5: Tracing Architecture Functional Design

Version 1.0
February 2, 2023

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Interoperable Tracing
PDG Blueprint

To support a sequential request-and-response tracing model, the *Blueprint* defines a standardized protocol for requesting TI information and responding to such requests.

Why It Matters: The standardized protocol provides predictability to authorized trading partners (ATPs) and supports interoperability *between* ATPs while permitting each ATP to define its own *internal* processes.

Key Terminology

Interoperable Tracing is the DSCSA 2023 requirement that trading partners maintain secure, electronic, interoperable systems and processes to provide TI and TS in response to a valid request and promptly facilitate gathering the information necessary to produce the TI for each transaction going back to the manufacturer.

TI Request Messages provide interoperable information about the requester, the products being traced, the circumstance of the trace, and the kind of information requested to be returned.

TI Response Messages provide interoperable information about the responder, the products traced, and trace endpoints associated with known buyers and sellers for the requester to use in the trace.

Trace Endpoints are the endpoint where TI request and response messages can be submitted, such as an email address or an OpenAPI or DIDComm endpoint.

Five Things to Know

1. **Interoperable tracing is achieved when the ATP or regulatory authority executing the trace sequentially requests and receives relevant TI data from each of the owners of the product.**
2. **ATPs may only trace product as part of a suspect or illegitimate product investigation; regulators may trace on account of a suspect/illegitimate product investigation *or a recall*.**
3. **The *Blueprint* defines a standardized protocol (i.e., message format) for requesting TI and responding with TI to support a trace.**
4. **Each ATP will define their own internal process for evaluating requests, determining whether to respond, and collecting the data to respond.**
5. **Each ATP must determine how they will be able to provide the trace endpoint/contact for each ATP they bought from/sold to.**

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1. Know your source.
2. Have, follow, and exercise SOPs to identify and respond to suspicious products.
3. Work with your suppliers to establish electronic record keeping practices.
4. Be prepared to support regulator- and industry-led investigations of suspicious products.

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Action Items

- Hopefully your pharmacy is already abiding by current DSCSA requirements and is well-prepared for unit-level data exchange.
- If not, the best time to start is now. Make sure you:
  - Are transacting with Authorized Trading Partners.
  - Are passing, capturing, and maintaining TI, TS, and TH.
  - Have suspect product investigation processes.
  - Engage your suppliers *quickly* to develop a plan for serialized data management.

Questions?

For additional information and to join:

Visit www.DSCSAgovernance.org

Email Eric.Marshall@LeavittPartners.com

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Background Information

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Problems the DSCSA aims to solve

Threats to drug security and patient safety

Prevalence of stolen drug product

Little coordination between states to ensure security

Grey market and drug shortage risks

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The DSCSA

- The Drug Supply Chain Security Act (DSCSA) was signed into law by President Obama on **November 27, 2013**.
- The bill aimed to create a **single**, **uniform, and national** response to drug supply chain safety concerns.
- The Food and Drug Administration has implemented the law in multiple stages. The final compliance stage goes active on **November 27, 2023**.

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Who is covered?

- Manufacturers
- Repackagers
- Wholesale Distributors
- Dispensers

Note: An individual entity can operate in more than one capacity.

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What is covered?

Product

- **Prescription** drugs in **finished** dosage form intended for **human** use.
- Does **not** include:
  - Blood or blood components for transfusion
  - Radioactive drugs or biologics
  - Imaging drugs
  - Intravenous product for hydration and replenishment
  - Medical gas
  - Homeopathic drugs
  - Compounded drugs

Transaction

- The transfer of product between persons in which a **change of ownership** occurs
- Does **not** include:
  - Intra-company or intra-health-system transfers
  - Dispensing
  - Product sample transfers
  - Sale, purchase, or trade to or from charitable organizations
  - Other product types and activities

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Key Requirements of the DSCSA

Entities must only work with “Authorized Trading Partners”

Entities must pass, capture, and maintain certain information with respect to each product transaction.

Entities must have processes to investigate, verify, and respond to suspect and illegitimate products.

Entities must only sell and purchase product that is serialized

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How to determine ATP status

Manufacturer or Repackager registered with the FDA.

Check the licensing of wholesale distributors and third-party logistics providers through the respective state or Federal authority.

Check the licensing of pharmacies through the respective state authority.

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Transaction Information (TI)

Core Interoperability Data Elements

Data elements that are key to the transaction and interoperability and therefore MUST be standardized.

Elements:

1. NDC / GTIN
2. *Serial Number*
3. Lot Number
4. ***Expiration Date***
- GLN
5. Date of Transaction
6. Date of Shipment
7. Number of Containers

Contextual Data Elements

Data elements that are provided to add context based on and tied to a core interoperability data element

Elements:

8. Drug Name
9. Strength
10. Dosage Form
11. Container Size
12. Proprietary Business Name
13. Business Address

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Further Data Required by DSCSA

Transaction History (TH)

- A statement in **paper or electronic** form, including the transaction information for each prior transaction going back to the manufacturer of the product.
- ***SUNSETS ON NOVEMBER 27, 2023***

Transaction Statement (TS)

- A statement, in **paper or electronic** form, that the entity transferring ownership in a transaction:
  - is authorized as required under the DSCSA;
  - received the product from a person that is authorized as required under the DSCSA;
  - received TI and a TS from the prior owner of the product, as required by the DSCSA;
  - did not knowingly ship a suspect or illegitimate product;
  - had systems and processes in place to comply with verification requirements of the DSCSA;
  - did not knowingly provide false TI; and
  - did not knowingly alter the TH.

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New Product Identifier (PI) Requirements

Source: https://www.fda.gov/media/101406/download

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Suspect Product Investigations

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“Suspect Product”

Reason to believe:

- Potentially counterfeit, diverted, or stolen;
- Potentially intentionally adulterated;
- Potentially the subject of a fraudulent transaction; or
- Appears otherwise unfit for distribution such that the product would result in serious adverse health consequences or death to humans.

“Illegitimate Product”

Credible evidence that:

- Counterfeit, diverted, or stolen;
- Intentionally adulterated;
- The subject of a fraudulent transaction; or
- Appears otherwise unfit for distribution such that the product would result in serious adverse health consequences or death to humans.

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Suspect Product Investigation Process

Detect/Identify Suspect Product

Quarantine the Product

Investigate

- Coordinate with the manufacturer
- Validate TH and TI
- Maintain investigation records for six years
- If not illegitimate, must notify HHS Secretary.

If Illegitimate

- Notify the Secretary and all immediate trading partners with **24 hours**.
- Dispose
- Retain Sample

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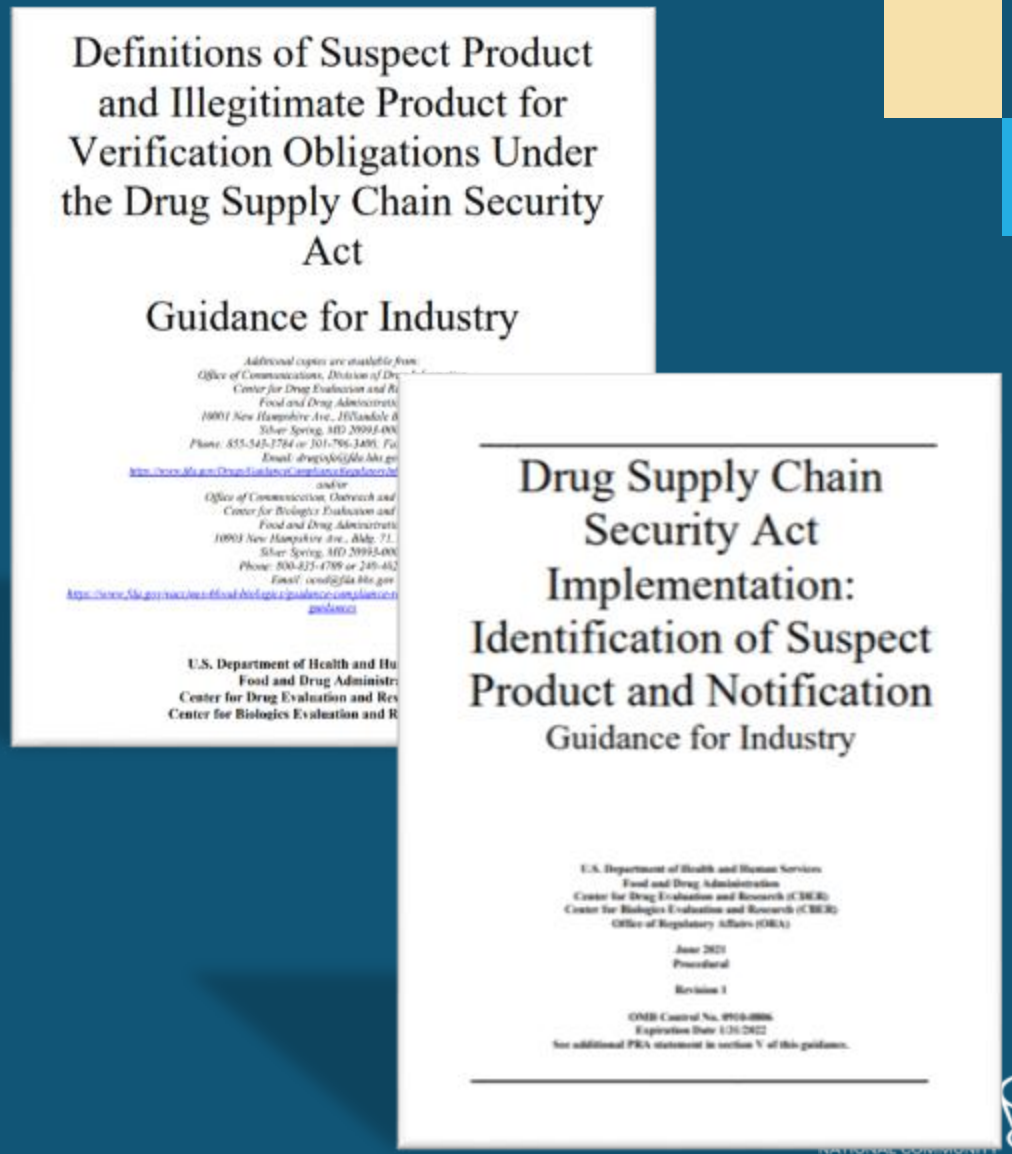
FDA Suspect Product Guidance

- Examples of Suspect Product
  - Product that left the U.S. pharmaceutical distribution supply chain
  - Product that is labeled for sale in a non-U.S. market
  - Any packaging of a product that has been taken or removed without the permission of the owner

- Factors in Assessing Product
  - •Purchasing from a new source
  - •Product that is generally in high demand in the U.S. market.
  - •Product offered at a price that is “too good to be true.”
  - •Product that has been previously or is currently being counterfeited or diverted.
  - •Appearance of a transport container seems questionable (e.g., misspellings).
  - •Package exhibits unusual or excessive adhesive residue.
  - •Package is missing information, such as the lot number or the expiration date.



How to Report Illegitimate Product

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FDA Form 3911

- Trading partners should provide information about the:
  - person or entity initiating the notification;
  - product determined to be illegitimate that is the subject of the notification to FDA; and
  - description of the circumstances surrounding the event that prompted the notification.
- Use this link to access the 3911 form: https://www.fda.gov/drugs/drug-supply-chain-security-act-dscsa/notify-fda-illegitimate-products

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TI Exchange Methods

Preferred: EPCIS

Providing GS1 EPCIS events is the primary or preferred method of TI exchange.

Secondary: Portal Access

Suppliers serving customers that are not capable of receiving EPCIS events may make TI available through portals access.

Alternate Methods

By special arrangement, trading partner pairs or solution providers and trading partner pairs may agree to exchange TI through other methods or formats

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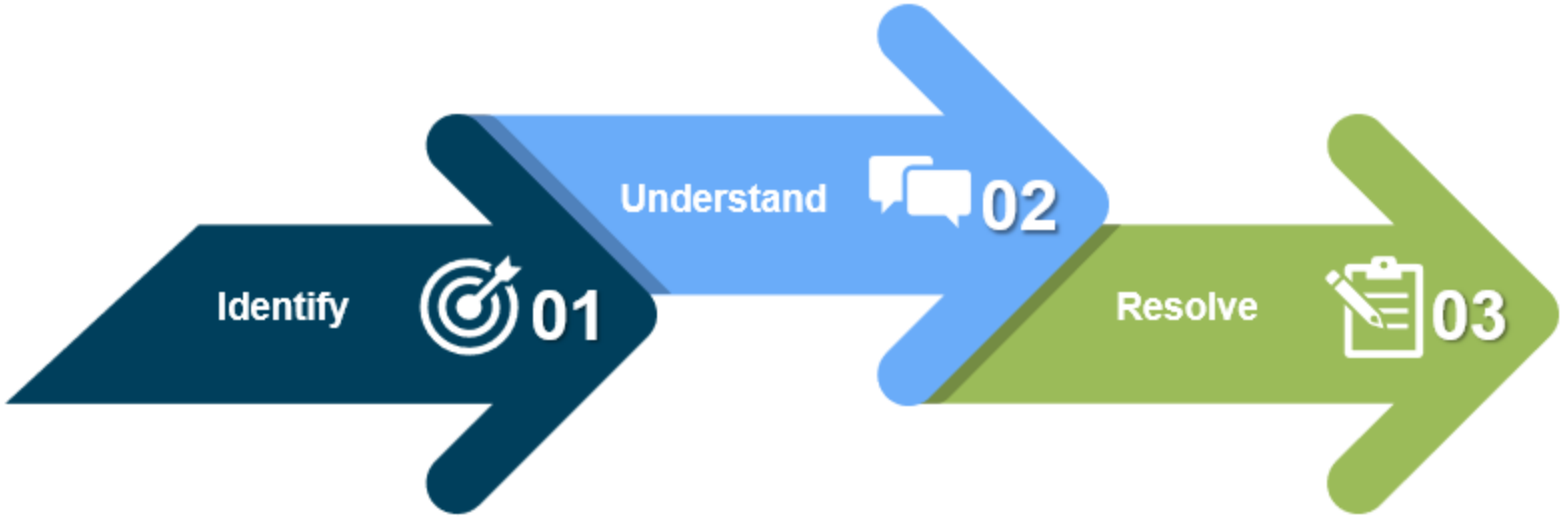
Misalignment Exception Processing



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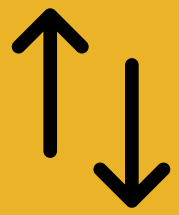
When is PI Verification Required?

Suspect Product Investigations



Saleable Returns

Key Consideration: When is Verification Helpful? Heightened scrutiny in higher-risk situations.

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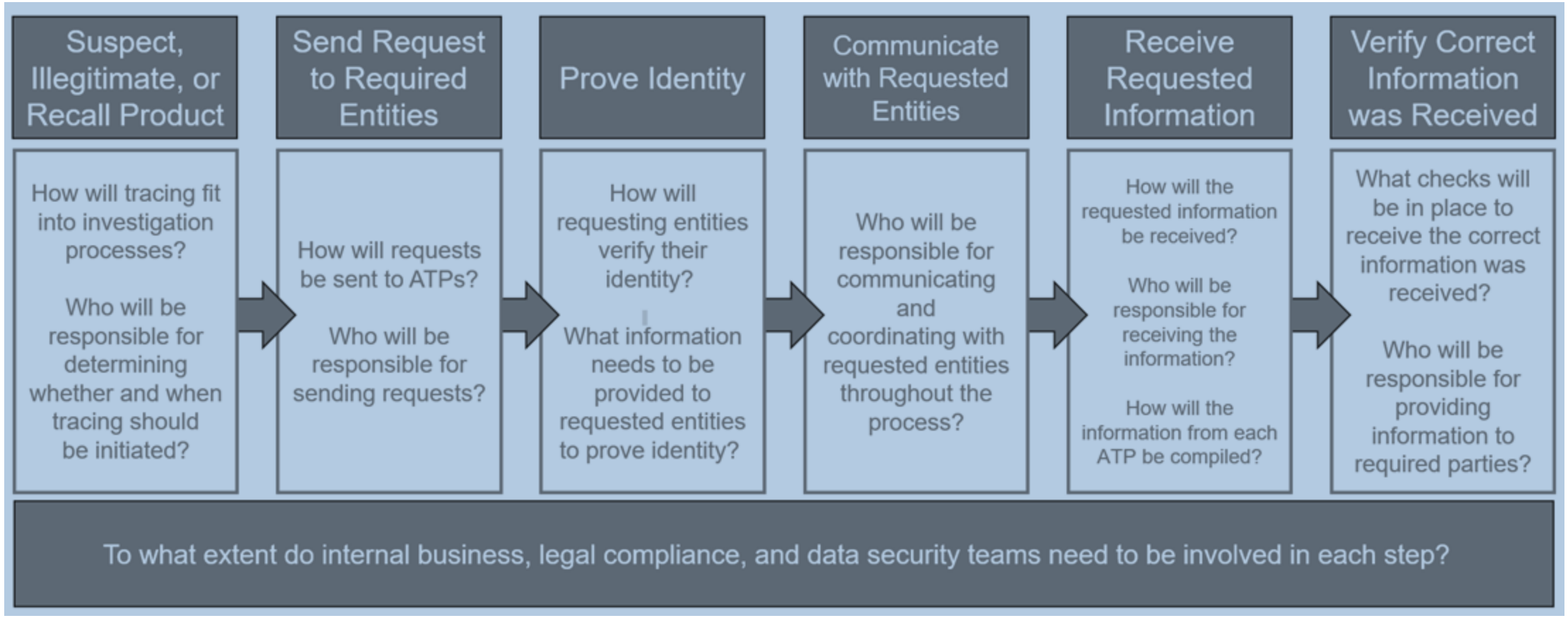
Initiating a Tracing Request



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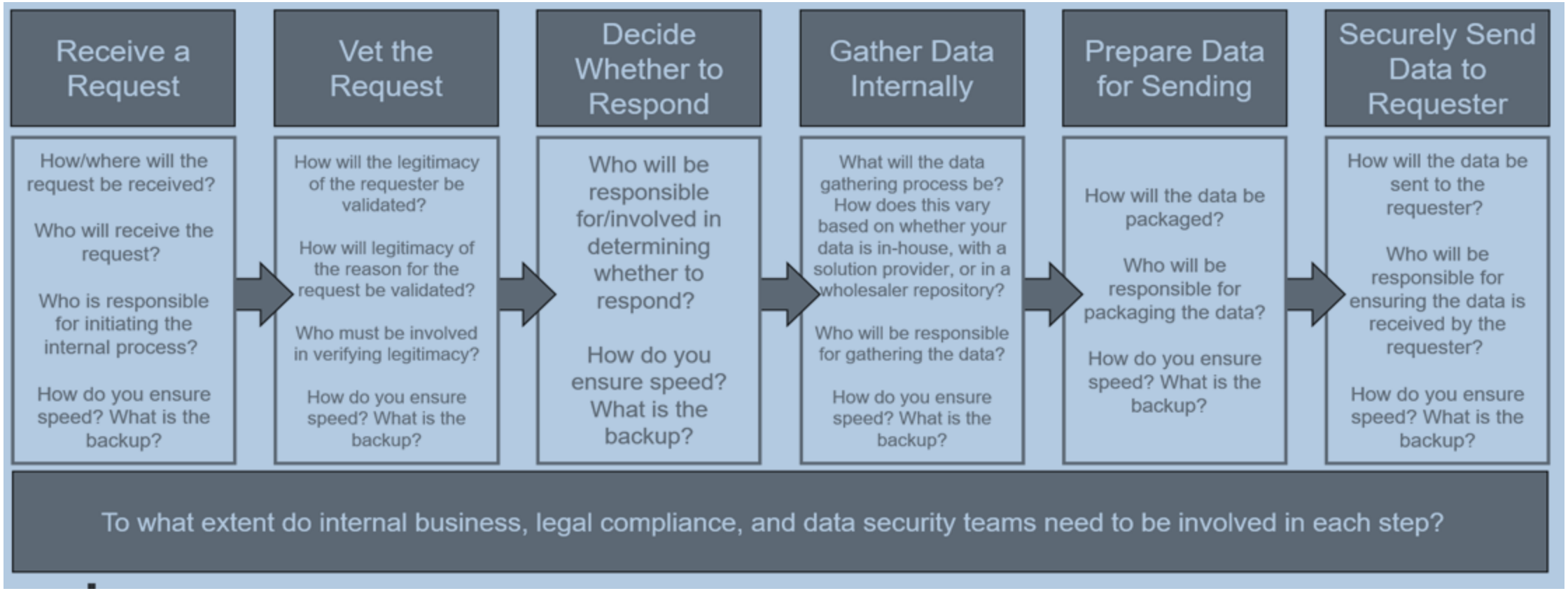
Responding to a Tracing Request



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