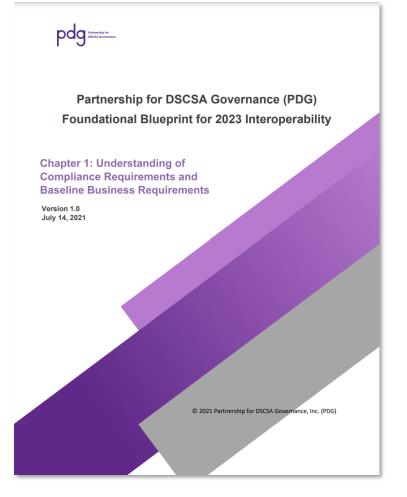
Partnership for DSCSA Governance

Advancing Collaborative, Timely Implementation of DSCSA Interoperability

DSCSA for Dispensers and their Trading Partners - Virtual Conference NOVEMBER 18, 2022

PDG Foundational Blueprint for 2023 Interoperability



Partnership for DSCSA Governance

- Formally approved
- Initial chapter
- Compliance and business
 requirements and recommendations
- Not legally binding
- 2023 interoperability
- Continued feedback encouraged

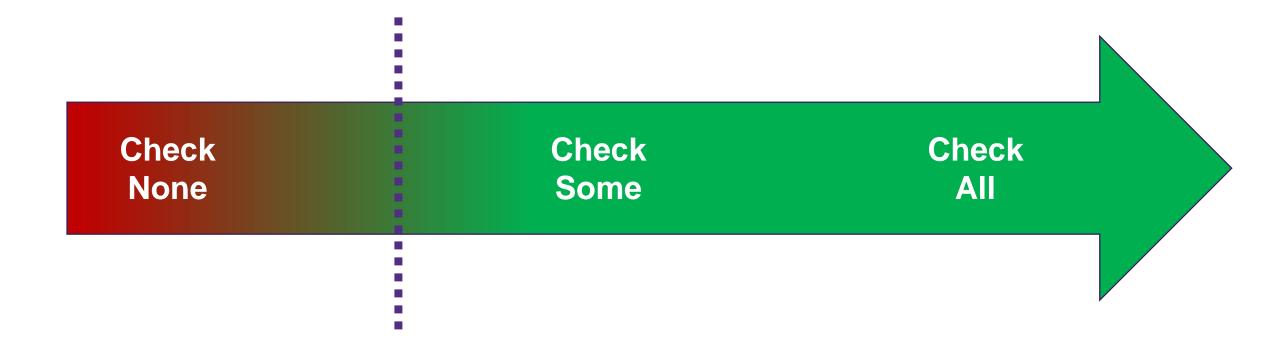
Key Questions and Challenges for Dispensers

Common Questions

- 1. Do I have to scan every product?
- 2. How do I handle misalignment exceptions?
- 3. How do I trace?
- 4. Can I still engage in dispenser-to-dispenser transactions?
- 5. Can I really get in trouble for this?

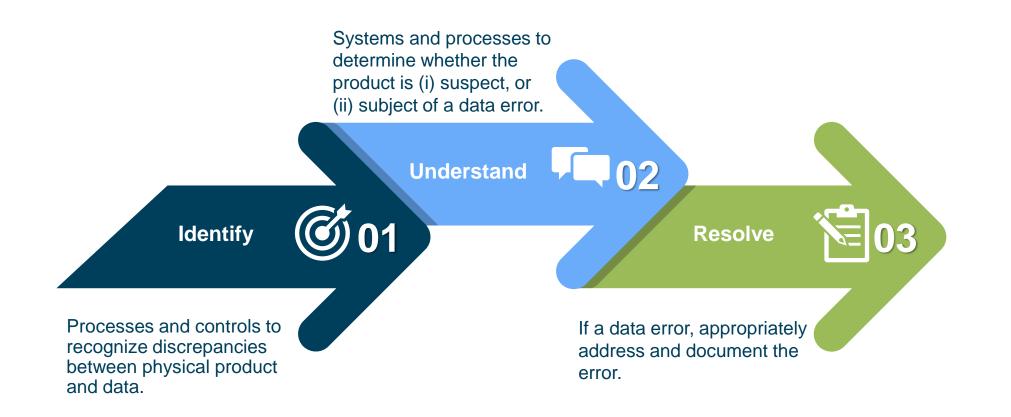


Do I have to scan every product?



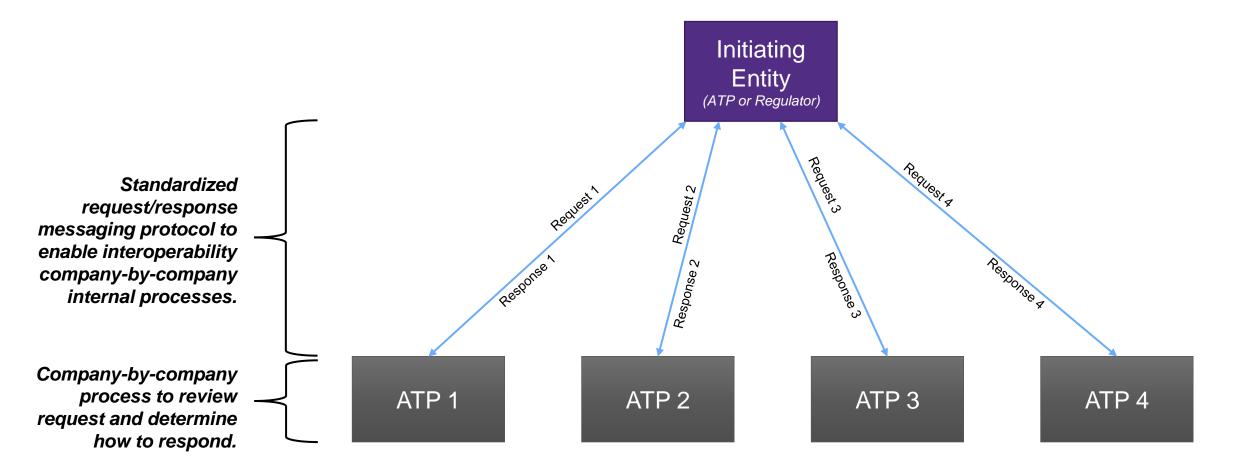


Misalignment Exceptions Process



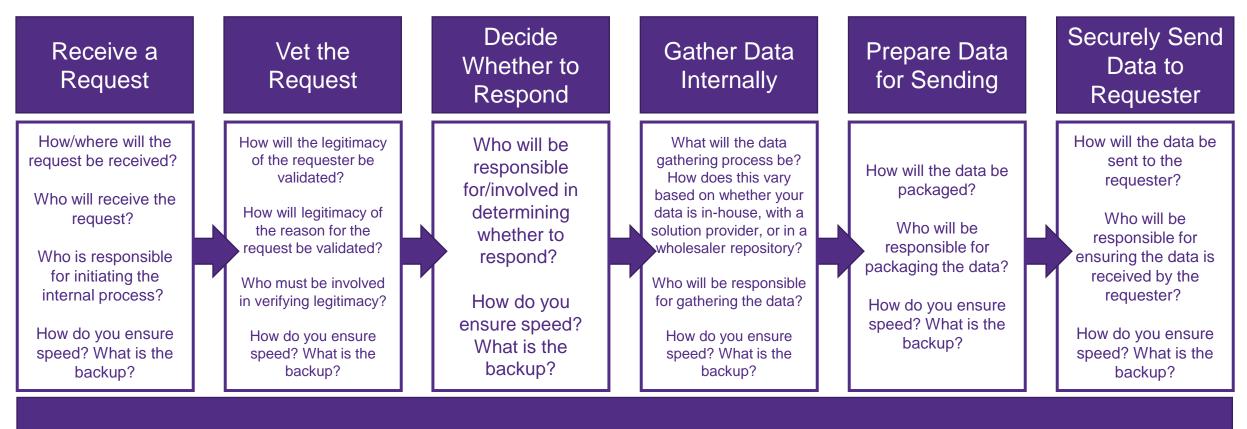


PDG Process for Tracing





Responding to a Tracing Request



To what extent does internal compliance, legal, business, data security need to be involved in each step?



Initiating a Tracing Request

Suspect,	Send Request	Prove Identity	Communicate	Receive	Verify Correct
Illegitimate, or	to Required		with Requested	Requested	Information
Recall Product	Entities		Entities	Information	was Received
How will tracing fit into investigation processes? Who will be responsible for determining whether and when tracing should be initiated?	How will requests be sent to ATPs? Who will be responsible for sending requests?	How will requesting entities verify their identity? What information needs to be provided to requested entities to prove identity?	Who will be responsible for communicating and coordinating with requested entities throughout the process?	How will the requested information be received? Who will be responsible for receiving the information? How will the information from each ATP be compiled?	What checks will be in place to receive the correct information was received? Who will be responsible for providing information to required parties?

To what extent does internal compliance, legal, business, data security need to be involved in each step?



Dispenser-to-Dispenser

Partnership for DSCSA Governance Can I still sell or loan product to the pharmacy down the street? Yes, <u>**BUT</u>** you probably need to be licensed as a wholesaler and provide them TI/TS documentation?</u>

Dispenser-to-Dispenser

You must be licensed as a wholesaler and provide TI in the dispenserto-dispenser sale unless:

- 1. The dispensers are under common control.
- 2. The sale is to fill a prescription for an <u>identified patient</u>, which does <u>not</u> include the transfer of a product from one pharmacy to another for the purpose of increasing or replenishing stock in anticipation of a potential need.
- 3. It is a sale of minimal quantities of product by a licensed <u>retail</u> pharmacy to a licensed <u>practitioner for office use</u>, meaning all such sales do not exceed 5 percent of the total dollar volume of the retail pharmacy's annual prescription sales.



Can I really get in trouble for this?

- The DSCSA establishes stiffer penalties for entities and individuals who fail to comply with the DSCSA requirements.
 - **<u>Penalties</u>** for a prohibited act include:
 - Imprisonment for not more than one year and/or a fine of not more than \$1,000.
 - Imprisonment of not more than three years and/or a fine of not more than \$10,000 for subsequent or intentional violations.
 - Equitable remedies, such as restitution, disgorgement of profits, and product seizure.
 - The Federal Criminal Code also authorizes a general fine of up to \$250,000 for individuals and \$500,000 for entities.
- Additional state-by-state penalties may be triggered.



Additional Information

For more information on PDG and how to join:

Visit: <u>www.DSCSAgovernance.org</u> Email: admin@members.dscsagovernance.org

