



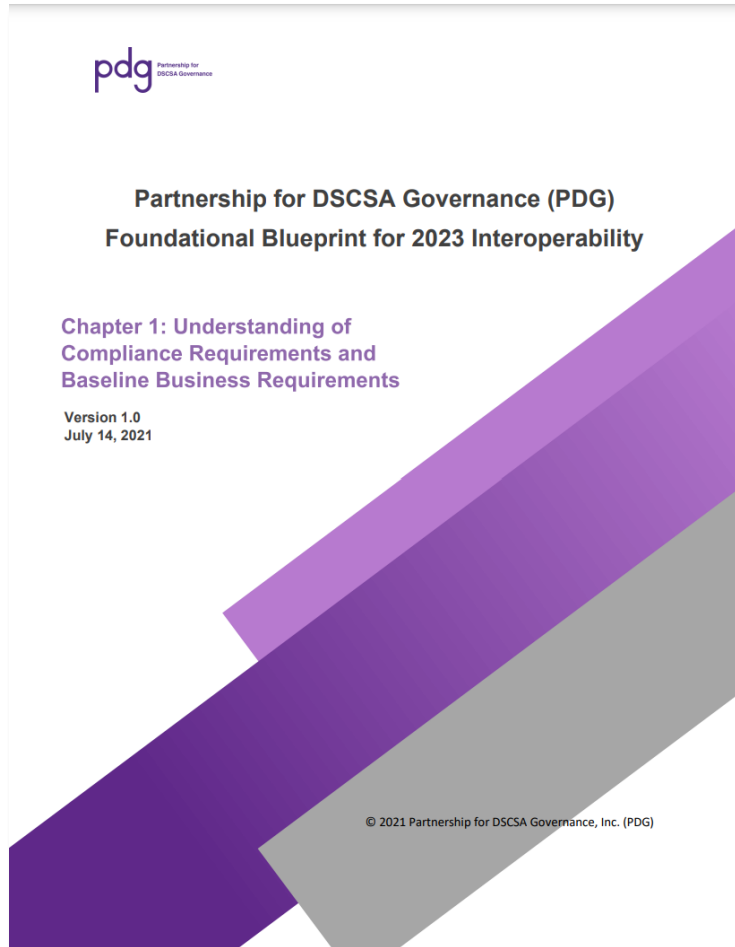
Partnership for  
DSCSA Governance

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



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

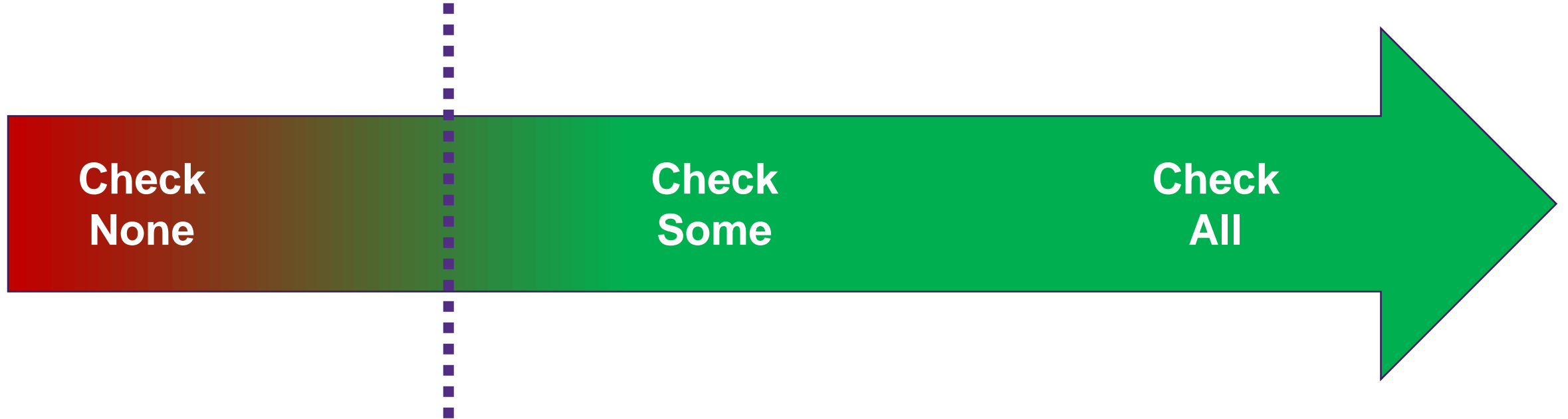


## Key Questions and Challenges for Dispensers

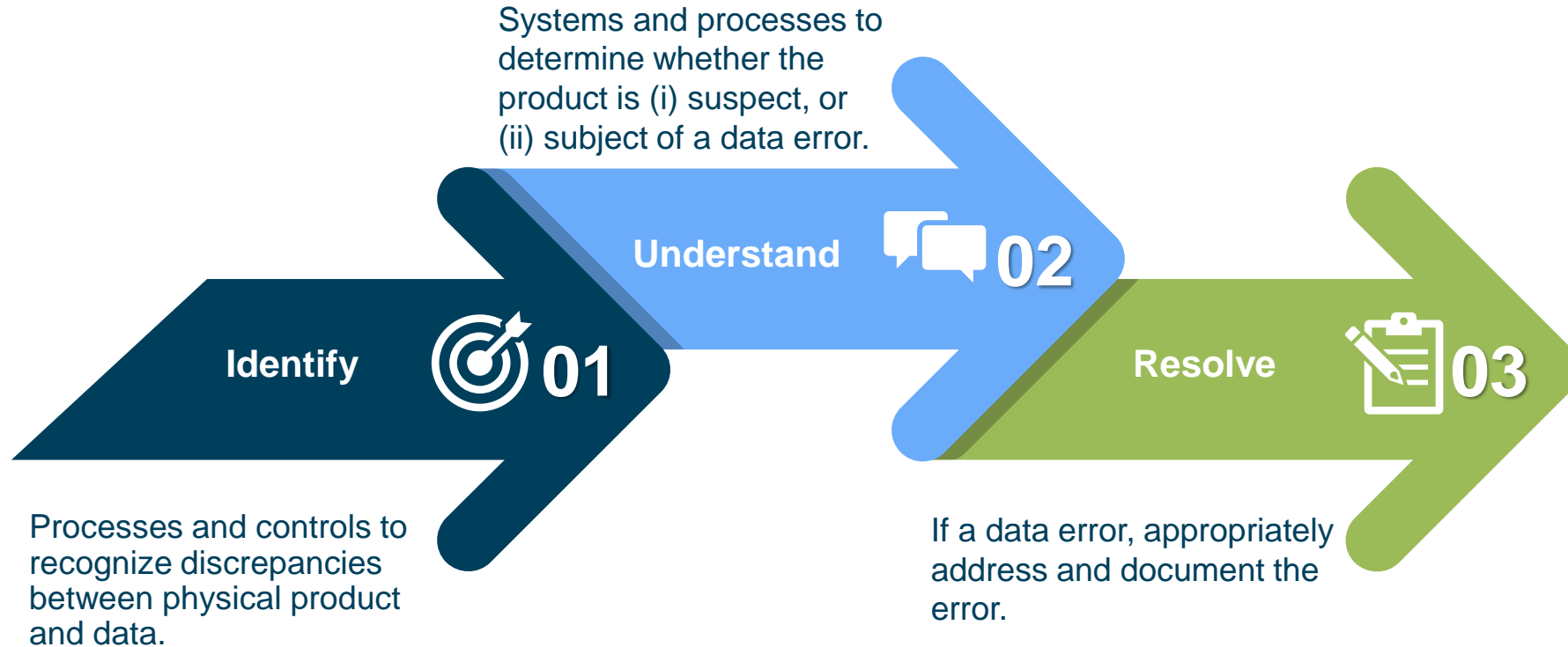
# Common Questions

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?



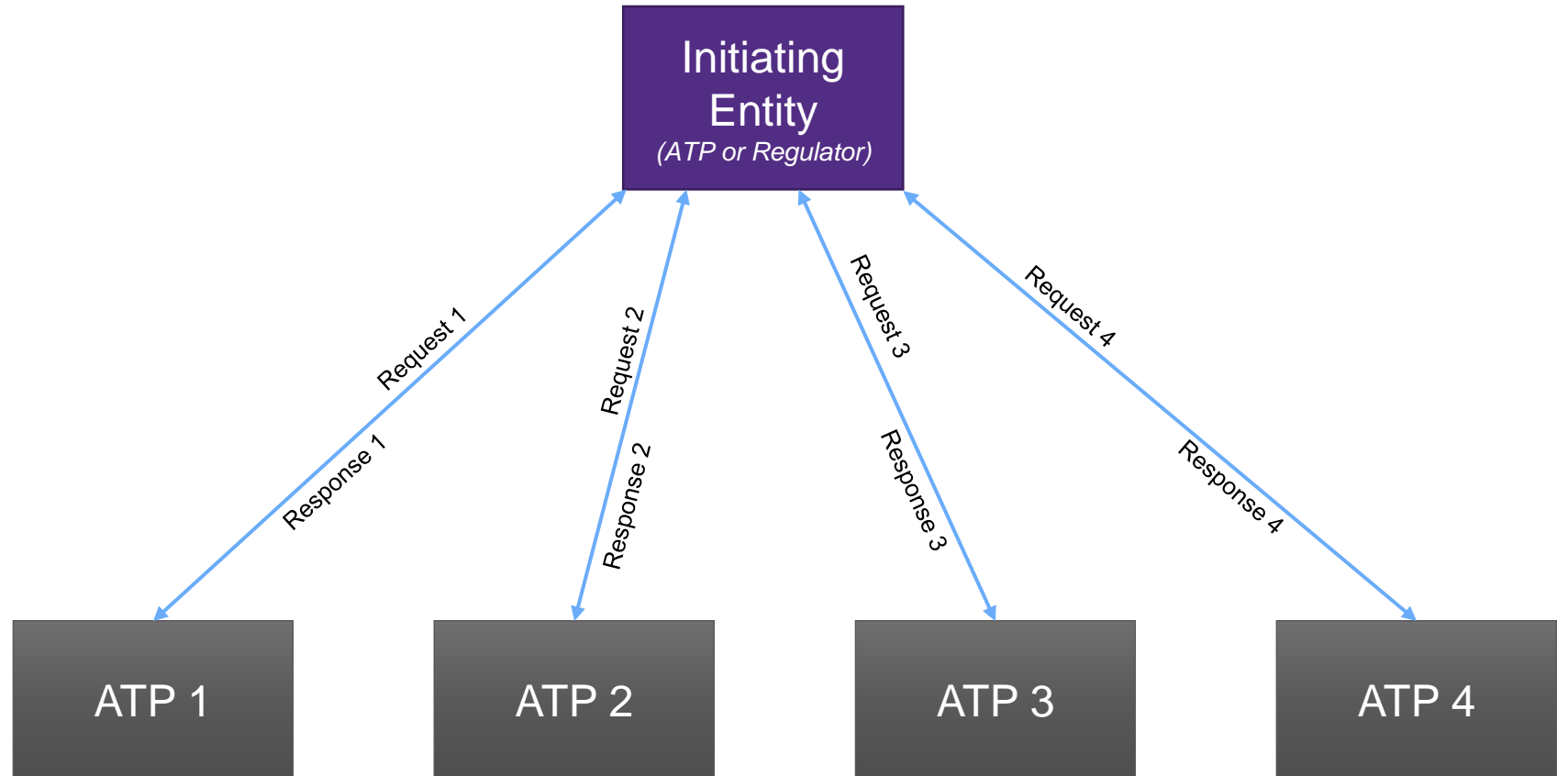
# Misalignment Exceptions Process



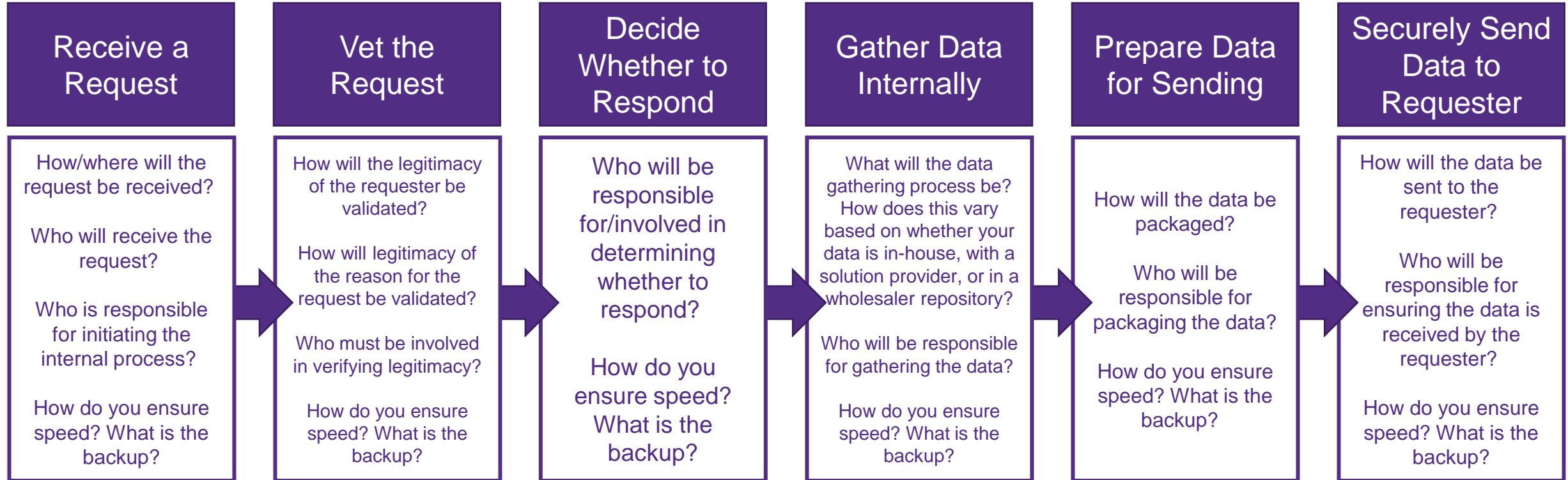
# PDG Process for Tracing

*Standardized request/response messaging protocol to enable interoperability company-by-company internal processes.*

*Company-by-company process to review request and determine how to respond.*



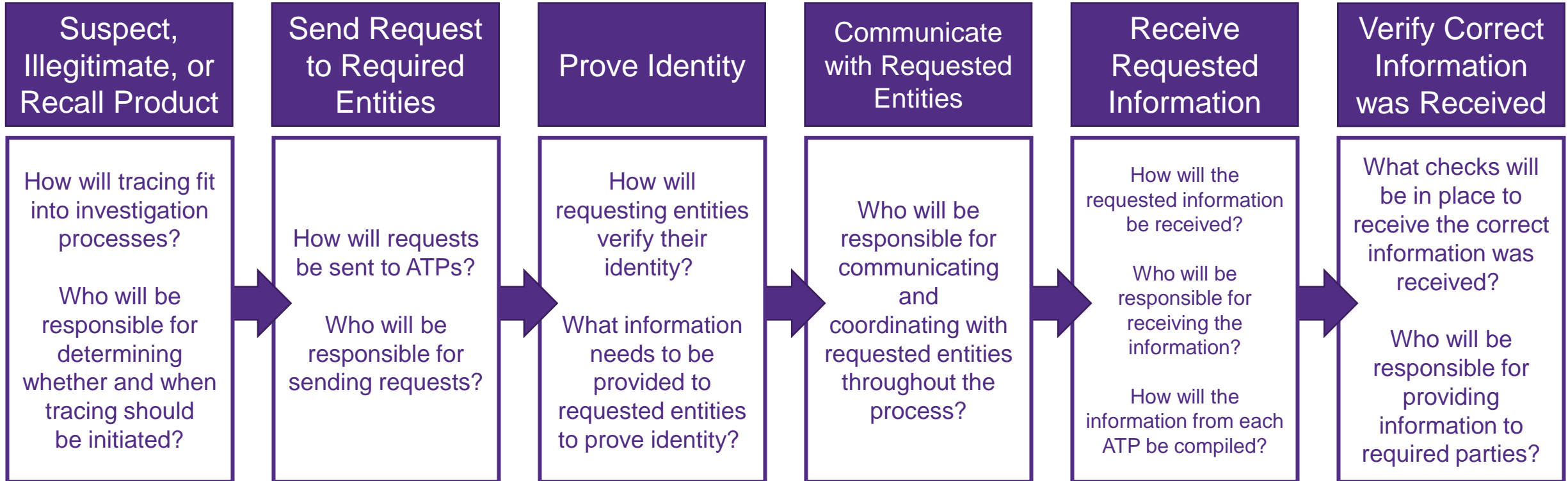
# Responding to a Tracing Request



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



# Initiating a Tracing Request



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

# Dispenser-to-Dispenser



Can I still sell or loan product to the pharmacy down the street?

Yes, ***BUT*** you probably need to be licensed as a wholesaler and provide them TI/TS documentation?



# Dispenser-to-Dispenser

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

1. The dispensers are under common control.
2. The sale is to fill a prescription for an identified patient, which does not 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 retail pharmacy to a licensed practitioner for office use, 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.
  - **Penalties** 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: [www.DSCSAgovernance.org](http://www.DSCSAgovernance.org)

Email: [admin@members.dscsagovernance.org](mailto:admin@members.dscsagovernance.org)

