



Partnership for DSCSA Governance

**Advancing Collaborative, Timely Implementation
of DSCSA Interoperability**

DSCSA Implementation

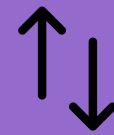
DSCSA – The Issues



Threats to
drug
security
and patient
safety



Prevalence
of stolen
drug
product



Little
coordination
between
states to
ensure
security

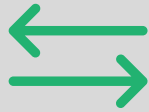


Grey
market and
drug
shortage
risks

DSCSA – Key Requirements



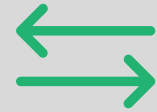
Entities must only work with “Authorized Trading Partners”



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

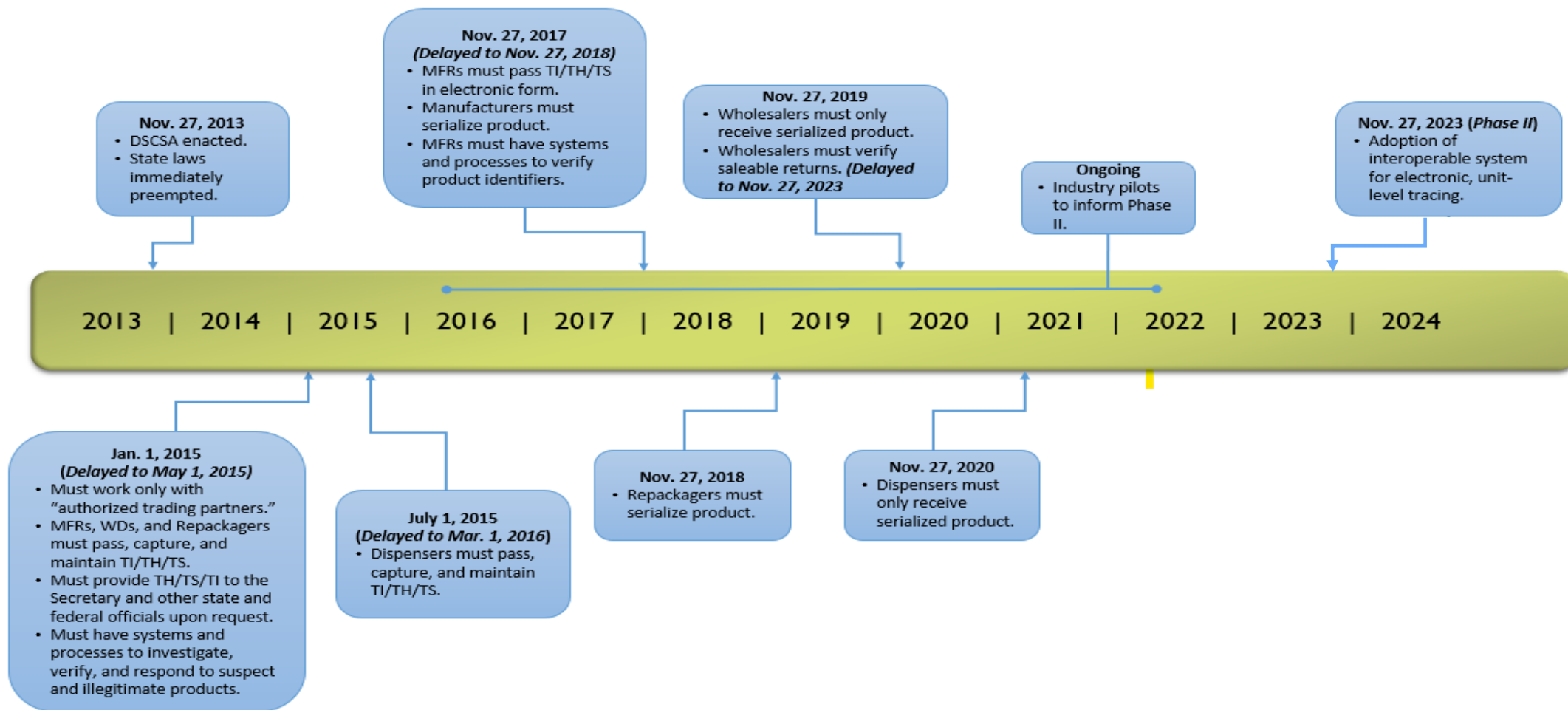


Entities must have processes to investigate, verify, and respond to suspect and illegitimate products



Entities must only sell and purchase product that is serialized

DSCSA - Timeline

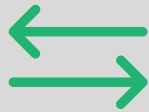


DSCSA – Tools



ATP Controls

Identity
+
Authorization



Data Exchange

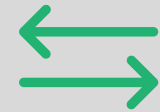
Transaction Information (TI)
+
Transaction Statement (TS)



Product Verification

PI Assignment

[NDC + Serial] + Lot + Exp



Product Tracing

Ownership Path

Enhanced Drug Distribution Security (EDDS)

TI Data Exchange Requirements Apply To Every
Transaction of a **Product**

Virtual = **Physical**

Today

Several-hundred-thousand lots
tracked by TI and TH

DSCSA – Perspective

Post-November

~4.5 Billion Units
Traced by TI



~2 Transactions per
Unit



~8-10 Billion
Transactions



~16-20 Billion
Instances of TI



6 Years of Record
Retention



~100 Billion
Instances of TI

Today

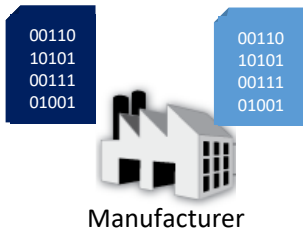
Post-
November

***10,000 –
20,000 times
as many
DSCSA
instances
recorded***

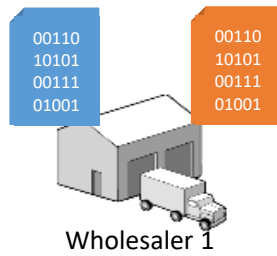
Tracing



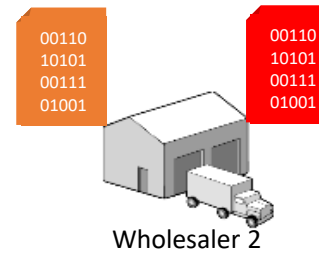
Product Identifier Verification



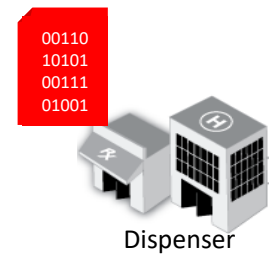
Product Flow



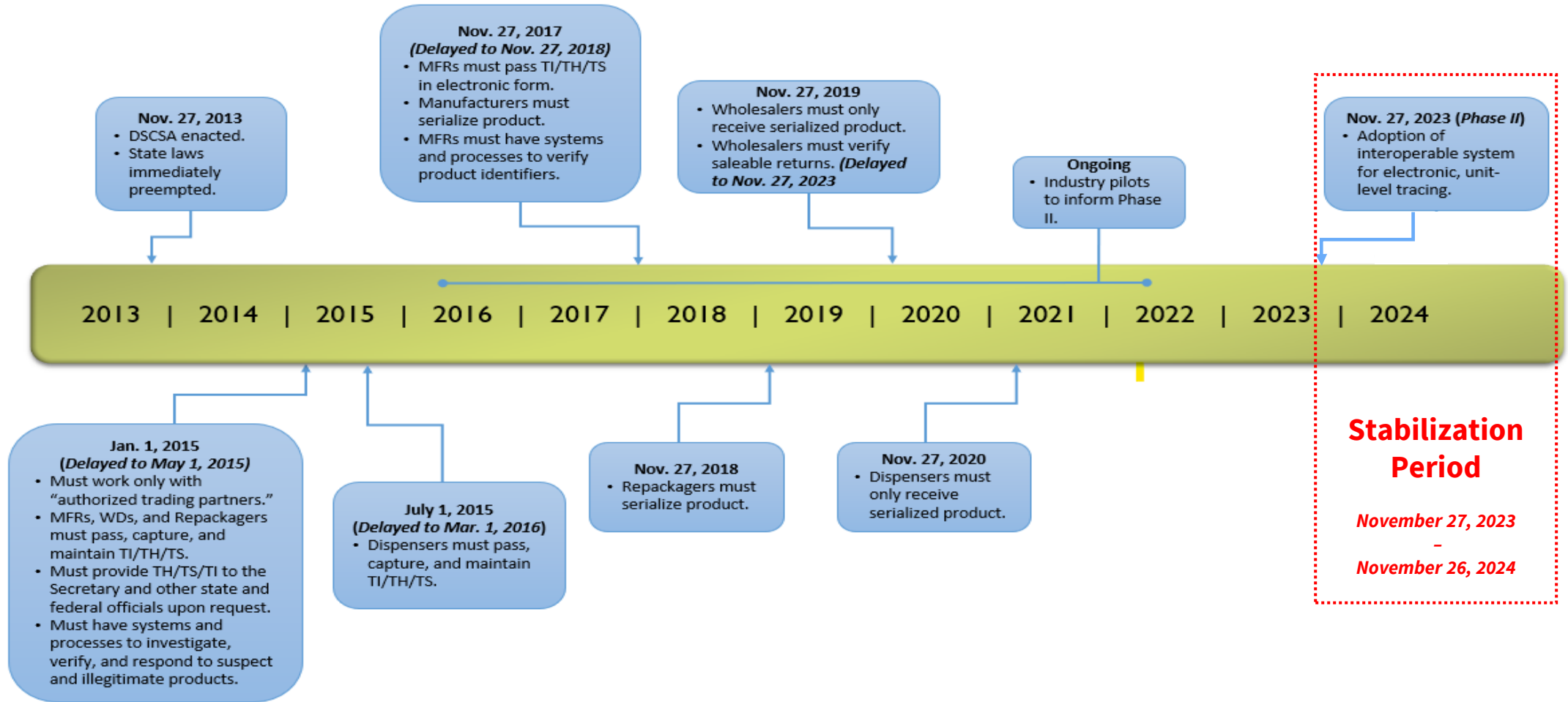
Product Flow



Product Flow



DSCSA – EDDS Launch



DSCSA – Stabilization Period

Considerations:

- ✓ Systems – implementation, integration & validation
- ✓ Trading Partners – authorization & connection
- ✓ Business Processes – new or adjusted
- ✓ Master Data – accuracy & consistency
- ✓ Product Labeling – quality & integrity
- ✓ Data Association & Use – aggregation & inference
- ✓ Exception Handling – identification, correction & communication
- ✓ Records – retention, access & security
- ✓ People – education & training

More Information?



dscsagovernance.org



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