Progress Toward Implementing the Product Identification Requirements of the Drug Supply Chain Security Act
Pharmaceutical Distribution Security Alliance (PDSA)
Lessons Learned from 2015

- Collaboration
- Implementation of standards
- Regulatory flexibility and early guidance
- Preemption
2017 Readiness

- PDSA members are working diligently to meet the 2017 electronic exchange and serialization requirements

- Readiness may vary depending on the supply chain participant
2017 Challenges

◦ Guidance on grandfathering, exceptions, exemptions, and waivers
◦ Solution providers and equipment vendors
◦ Maturing software systems
◦ Contract manufacturers
◦ Changing business relationships
◦ Technical issues
◦ Aggregation
◦ Downstream impact
2019 Saleable Return Requirements & Progress

- Industry collaboration
- Relationship to Phase II
2023 Requirements & Progress

- Early industry understanding
- Early completion of piloting
- Regulator/industry dialogue, feedback, and collaboration
- Guardrails