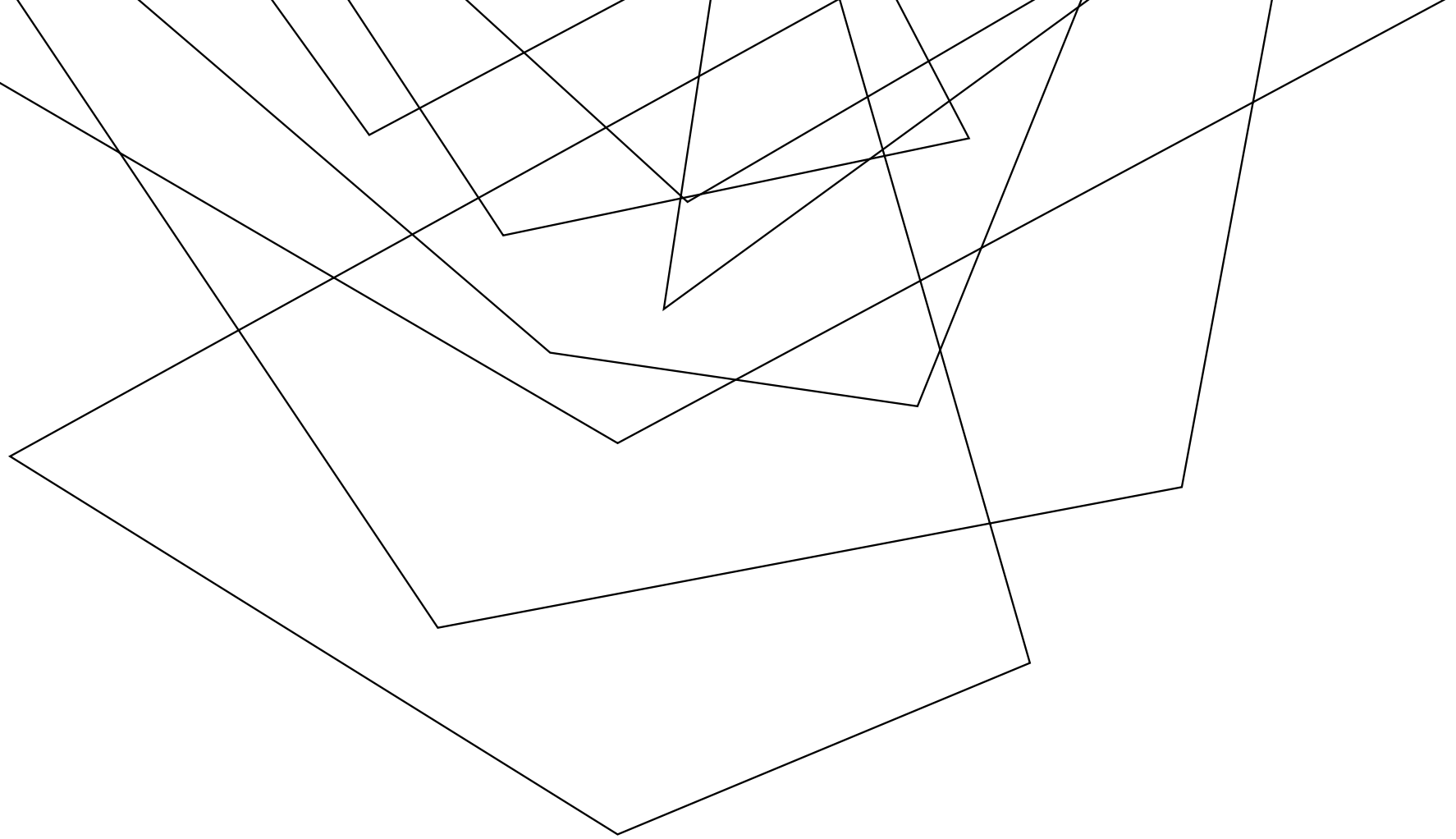

DSCSA: WHERE ARE WE NOW?

Tonya Soper PharmD

WHAT IS DSCSA?[2]

DSCSA stands for Drug Supply Chain Security Act

Signed into law November 27, 2013

Phased implementation over 10 years

Leading to a fully interoperable, electronic system for the tracking and tracing of products throughout the supply chain[1]

1 YEAR STABILIZATION PERIOD

- August 2023 – FDA announces 1 year stabilization period to allow trading partners to implement, troubleshoot, and mature electronic interoperable systems[3]
- Stabilization period is intended to avoid disruption to supply chain and ensure continued patient access to drug products
- Not intended to provide a justification for delaying efforts to comply with DSCSA

EXEMPTIONS[4]

- Blood or blood components intended for transfusion
- Radioactive drugs or radioactive biological products that are already regulated by the Nuclear Regulatory Commission (NRC) or by a State under an agreement with the NRC
- Imaging drugs
- Medical gases
- Appropriately marked homeopathic drugs
- Compounded drugs (now regulated by the Compounding Quality Act)
- Intravenous products that are intended for the replenishment of fluids and electrolytes or calories
- Intravenous products used to maintain the equilibrium of water and minerals in the body, such as dialysis solutions
- Products intended for irrigation, or sterile water, whether intended for such purposes or for injection

EXEMPT TRANSACTIONS[4]

- Intracompany distribution of any product between members of an affiliate or within a manufacturer
- The distribution of product samples by a manufacturer or licensed wholesale distributor
- The distribution of “medical convenience kits”, a collection of finished medical devices, which may include a drug product or biological product, assembled in kit form strictly for the convenience of the purchaser or user if:
  - The kit is assembled in an establishment that is registered by the FDA as a device manufacturer
  - The kit does not contain any controlled substance, and
  - The kit manufacturer purchased the drug or biologic product contained in the kit directly from the pharmaceutical manufacturer or from a wholesale distributor that purchased it directly from the pharmaceutical manufacturer, and the primary container label of the drug or biologic product contained in the kit is not altered;
  - *and*, the drug or biologic product contained in the kit is:
    - *An intravenous solution intended for the replenishment of fluids and electrolytes;*
    - *A product intended to maintain the equilibrium of water and minerals in the body;*
    - *A product intended for irrigation or reconstitution*
    - *An anesthetic;*
    - *An anticoagulant;*
    - *A vasopressor; or*
    - *A sympathomimetic*

DO IT YOURSELF VS USING 3RD PARTY VENDOR

- Time
- Staff
- Cost
- Problems that arise
- Manufacturer checks

ARE YOU READY CHECKLIST?

- Confirm trading partners are licensed and registered
- Confirm product tracing information to be true, accurate and complete
- Pass along transaction data with transfer of ownership
- Store and manage large amounts of data related to drugs
- Quarantine and investigate suspect prescription drugs

OPEN DISCUSSION

Questions?

REFERENCES

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THANK YOU

Tonya Soper PharmD

tsoper@famhealthcare.org