RxScan
DSCSA Solution

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The final part of these regulations take affect this November 27th.
They are all about making it harder for counterfeit drugs to get to your pharmacy and thus to your patients.

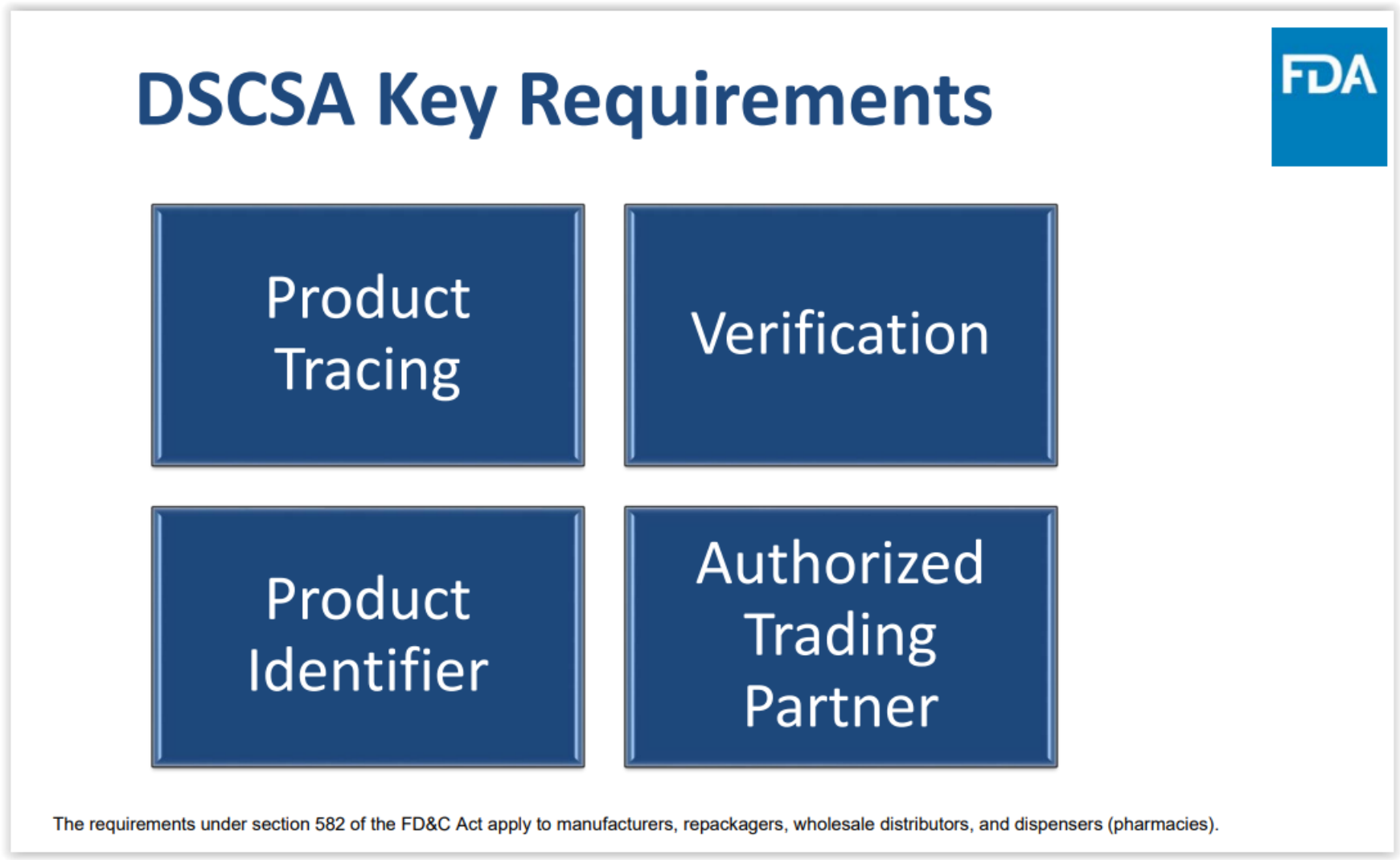
DSCSA Goals

1. Implement interoperable, electronic tracing of products at the package level by 2023 that will:

- Enable secure tracing of product at the package level
- Use product identifiers to verify product at the package level
- Enable prompt response to suspect and illegitimate products when found
- Improve efficiency of recalls

2. Establish national standards for licensure for wholesale distributors and third-party logistics providers (3PLs)

https://www.fda.gov/media/154798/download



https://www.fda.gov/media/154798/download

Key parts of the act are that you have:

1. Access to the new serialized drug information your suppliers are required to send you before you dispense the medication to your patients.

   You will need a process to verify that you have access to or have received the data and some policy in place to verify the accuracy and completeness of the data. It needs to match the physical product you received.

2. A way to check with a manufacturer about if they made a particular serialized drug. (PI Verification)

3. The ability to quickly provide information on a drug, such as where and when did you get it (Tracing), to a regulator such as; your state board of pharmacy, local or state police departments, FBI, FDA

4. Access to this serialized information for at least 6 years

Key parts of the act are that you have:

5. Ways to identify, investigate and document a suspect product and report illegitimate product to the FDA and your suppliers

6. Have DSCSA SOPs in place (We provide SOP templates)

7. A process to know by an item's serial number the supplier you received the item from

   Note: You will now only be allowed to return a serialized, resaleable item back to the supplier you received it from.

   So, if you buy from more than one supplier and you do on occasion return unused items you need to have an easy, quick way to identify who you got a particular serialized item from.

   Distributors are going to require the PO number that the item by serial number was acquired under. Some are also going to require the matching invoice number as part of the return documentation. This is to make sure you receive the correct credit amount.

Here are a few of Your Outcomes from utilizing our Drug Supply Chain Security Act solution

- *Greatly simplifies your being in compliance with the Act*
- *Turns manual, time consuming processes into computerized ones*
- *Improves your receiving processes*
  - This helps you financially by shortening the time needed to;
    - *Document and double check the accuracy of what you are receiving compared to what you are being billed for.*
    - *Verify that you have received the serialized data from the supplier and that it matches the physical product you received*

We offer a complete DSCSA solution. Key features, it:

- 1) Serves as a repository for all of the EPCIS, ASN and invoice data received from the pharmacy's suppliers
- 2) Documents the TI (NDC, lot #, expiration date, serial # and GTIN-14) of each item received. This information is linked to the PO and invoice(s) it is related to
- 3) Verifies the physical item's TI against the EPCIS file's TI received from the supplier and warns of any data discrepancies
- 4) Stores all of a suspect product's investigation and quarantine documentation
- 5) Provides for transferring TI & Transaction Statement (TS) information to an item’s new owner when items are loaned or sold between unrelated pharmacies. This includes documenting if the transfer is being done for a patient specific need
- 6) Provides a means for reporting an item's tracing information to a regulator

- 7) Enables applying for a credential (used for the electronic PI Verification process)
- 8) Documents the destruction of an item at the pharmacy
- 9) Includes several types of DSCSA focused reports
- 10) Provides for electronic PI Verification. This is verifying with an item's manufacturer that they made a product with a particular NDC/GTIN-14, lot #, expiration date and serial number combination
- 11) Documents the data detailing the returning of an item by serial # to a supplier, this include the item's PO and invoice #s
- 12) Documents the data detailing the sending of a recalled item by serial # to a returns processor
- 13) Enables searching an organization's items received against a recalled items database
- 14) Subscription includes a "credential" needed for computerized PI Verification

Lets now take a look at the RxScan solution and how it helps you meet these requirements.