RECOMMENDED STRATEGY

- Create multiple captivate recordings of DSCSA Management Module
- Create online module that features captivate recordings
- Post module/recordings within DSCSA Management Module and in future Omnicell Training Institute. HealthStream may not be applicable unless requested by customers.

Development Estimate: 100 hrs/30 minutes of e-learning (estimate will be created after fully reviewing videos)

RISKS

- **Lack of ETS Staffing:** ETS has not been able to hire a replacement ID to cover Joe Alberti's position. All IDs are assigned to other products leaving this project at risk.
- **Release timeline**: The release of the DSCSA management module is aligned with the 22.0 Omnicell release. Discussion of the software releasing sooner leaves ETS at risk for not having training ready in time.
- **Interface update:** The branding of the module is being updated to Omnicell's current look and feel. ETS must wait until after this is complete to start work.

OPEN QUESTIONS

- How will ETS access the module?
- Can we get access to the 10 videos related to the module?
- Who will answer customer questions about the module? (Long-term plan?)
- Besides DOPs, who else would be using app?
- Explain the workflow that InPharma provides related to the module. Faxes, support, etc.

DEVELOPMENT REQUIREMENTS

- Access to Bill Jantso, SME
- Access to module with live data or simulated data
- Availability of reviewers to complete reviews in a timely manner
- Ability to test final deployment of content (in Module or Omnicell Training Institute)

TIMELINE

- Start date + 4 weeks (1 ID, 25 hours per week)

Needs Analysis: DSCSA Management Module

BACKGROUND

Resources

- SMEs
  - Bill Jantso, Product Manager Marketing, Aesynt-Performance Center
  - Laurie Garda, Sr. Product Manager Marketing (Legacy Aesynt)
- Ten existing videos on the module (part of larger group of videos)

Audience

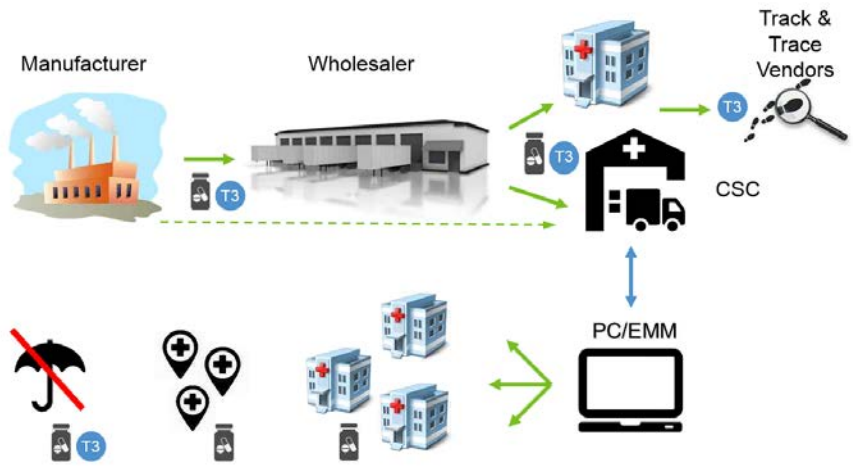
- 150 hospitals
- DOPs

Background

Omnicell acquired InPharmics in April 2017. Currently, InPharmics serves more than 150 hospitals with tools that help to optimize supply chain performance and comply with drug pedigree regulations. Omnicell has decided to commercialize one piece of the platform, the DCSCA module for drug pedigree regulations. The module does not interface with EMM.

The Drug Supply Chain Security Act (DSCSA) is part of the overarching Drug Quality and Security Act (DQSA) of 2013. The goal of DQSA is to facilitate the exchange of information about where a drug has been in the supply chain. (Goals: Support more efficient drug recalls, verify legitimacy of a drug product, and detect illegitimate products). The Act increases requirements over a 10-year period. DSCSA is under Title II of the DQSA and requires manufacturers, wholesaler drug distributors, repackagers, and many dispensers (primarily pharmacies) in the drug supply chain to provide information about a drug and who handled it each time it is sold in the U.S. market (aka **traceability**). The focus of the DSCSA is on the **chain of custody**.

The DSCSA Module helps pharmacies (aka dispensers) track the **T3** – transaction information, transaction history, and transaction statements (manufacturer is licensed and did not knowingly provide false information). This data must be kept for 6 years.



DSCSA module cannot support separate locations for the same NDC.

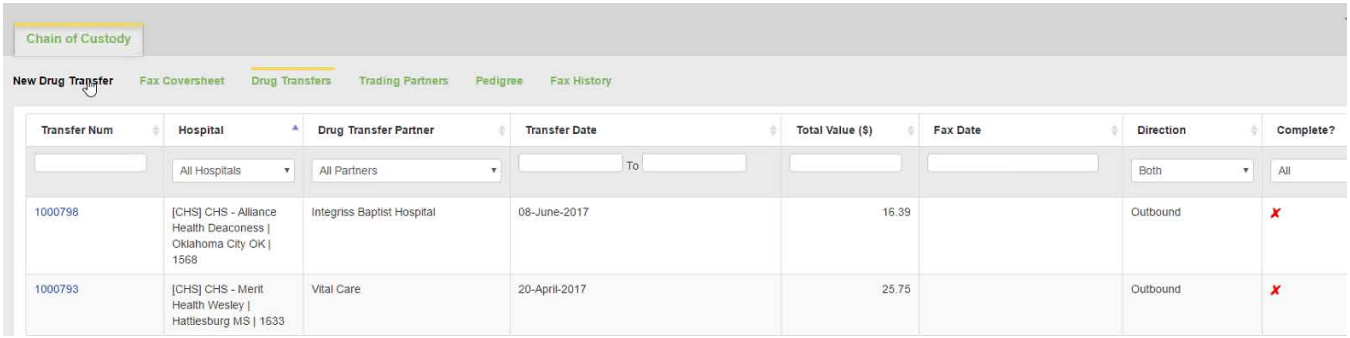
What is happening on November 27, 2017?

In November, manufacturers must provide electronic T3 records and begin using 2D bar codes at the package level.

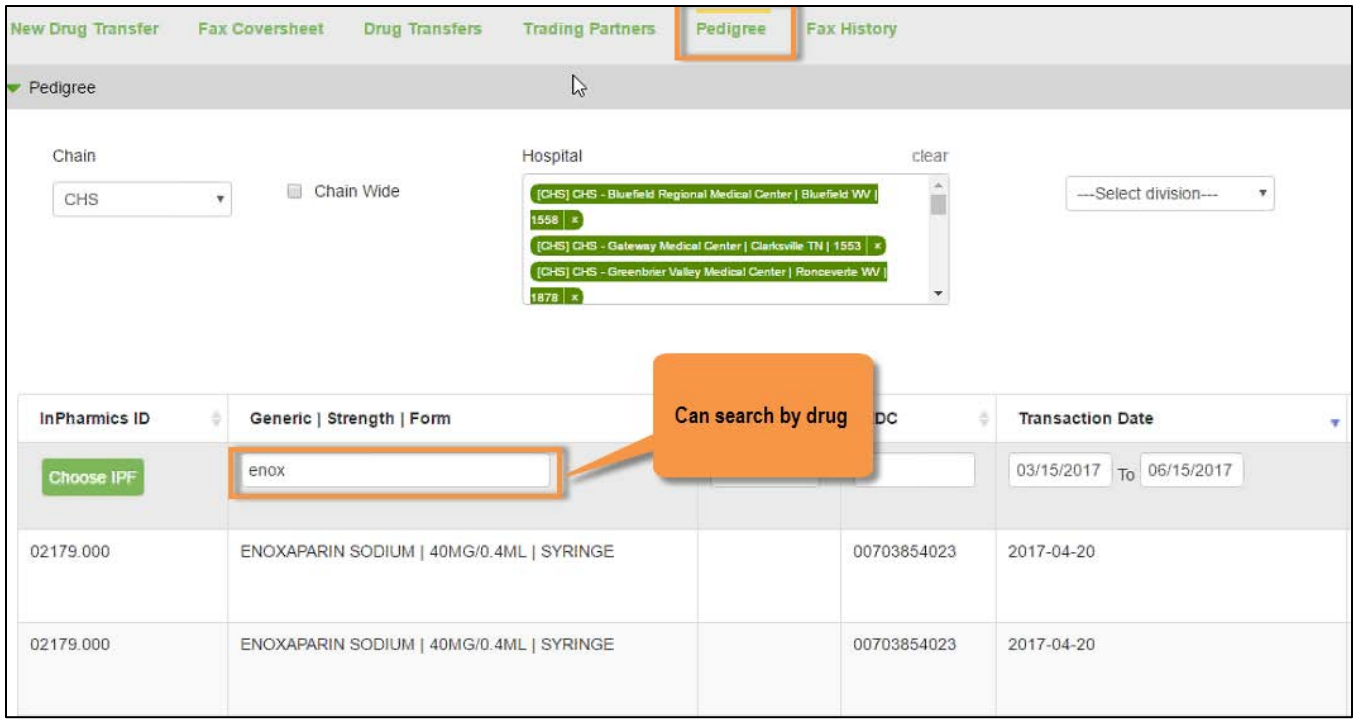
What are pharmacies currently using to support this requirement?

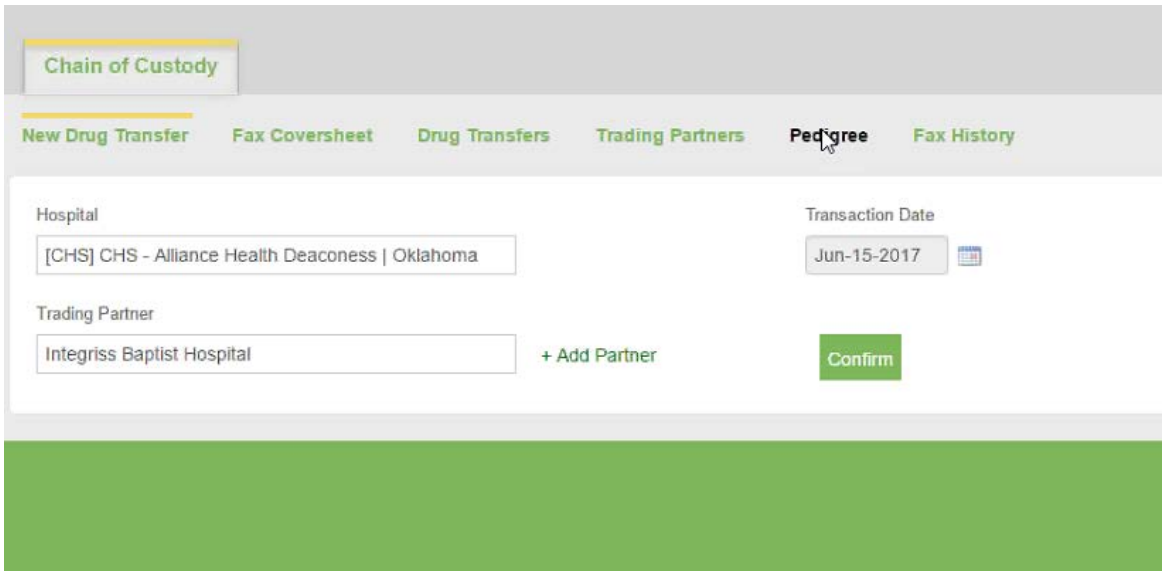
Some pharmacies have moved to a product like the DSCSA module. Others have a home grown system or no system at all (e.g., paper filing system).

Product Images



Needs Analysis: DSCSA Management Module





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Chain of Custody Statistics (July, 2016)

- **EDI *lines* received for Chain of Custody:**
  - Cardinal: **1,964,000**
  - ASD and all Other Suppliers: **96,000**
- **Manual *Documents* Processed:**
  - Processed: **3,753**
  - Invalid: **2,404**
- **Manual Documents Received from CHS Clinics:**
  - ***Faxes*** received **528**
  - Total ***Pages*** received **3,246**
  - Number of Clinic Entities **46**

Note: In this example, 800 were trade and borrow transactions