Title: Small Dispenser Study: Understanding the Impact of the Oncoming Track and Trace Legislation on Small Dispensers

Performer: Providence Health Technologies, LLC

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Project Duration: 9/30/2019 – 4/30/2020

Regulatory Science Challenge

The Drug Supply Chain Security Act (DSCSA), was enacted by Congress on November 27, 2013 to maintain security of the drug supply for U.S. citizens and to prevent introduction of counterfeit medications into the drug supply chain. Members of the U.S. drug supply chain must participate in maintaining the integrity of the medication supply to fulfill the mission of dispensing safe medications to patients.

DSCSA outlines steps to build an electronic, interoperable system to identify and trace certain medications as they are distributed in the United States. The DSCSA supports FDA's efforts in protecting consumers from exposure to medications that may be counterfeit, stolen, contaminated, or otherwise harmful. The system will also improve detection and removal of potentially dangerous medications from the supply chain to protect U.S. consumers.

Small Dispensers, having 25 or fewer full-time employees, are often disadvantaged any time new laws are implemented. Yet, small dispensers are critical to the health and well-being of patients in rural or underserved healthcare areas of the country. Generally, dispensers see patients at a frequency 6 – 8 times more often than other healthcare providers, and their participation in the security of medications within the supply chain is paramount.

Project Description

Providence Health Technologies (PHT) is piloting a process to collect and validate serialized data present within barcodes on individual prescription medications. The study will determine the ability of Small Dispensers to comply with the Drug Supply Chain Security Act without increasing their costs or introducing labor burdens. The study will introduce new technologies into current dispenser workflows, provide dispenser access to DSCSA data at a reasonable cost, and develop templates for data submission to other supply chain partners.

PHT will include all four (4) major sectors of the U.S. drug supply chain: Retail, Hospital, Long-Term Care, and Specialty Pharmacy. Testing a representative sample within each

of these pharmacy sectors will create a data set to demonstrate processes to collect, analyze and report DSCSA data.

These sectors differ in procurement and workflow processes and separate analysis is necessary to determine best practices for collecting DSCSA data in each of these small dispenser types.

Processes for collecting data include:
1. Scanning of 2D barcodes on packages received from wholesalers, repackagers, and manufacturers,
2. Comparing barcode data with human readable data,
3. Quantifying the number of packages without 2D barcodes,
4. Scanning 1D barcodes in the absence of 2D barcodes on packages,
5. Measuring the time and space commitments for Small Dispensers in collecting DSCSA data and
6. Quantification of barcode read errors, in the event a barcode is not readable.

Project Goals

- Measure awareness of the requirements to comply with DSCSA among four small dispenser segments
- Assess current state of small dispenser readiness for 2020 and 2023 requirements of the DSCSA
- Estimate average costs for small dispensers to comply with requirements
- Develop best practices model for small dispensers' compliance