Small Dispenser Pilot Study

Understanding the Impact of the Current and Upcoming Track and Trace Federal Requirements on Small Dispensers

Final Report: April 2020

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Introduction & Background

The Drug Quality and Security Act (DQSA) is legislation passed by Congress on November 27, 2013. Title II of the DQSA is known as the Drug Supply Chain Security Act (DSCSA) and outlines the requirements for a system to identify and trace certain prescription drugs as they travel through the US pharmaceutical supply chain. Designed to enhance FDA's ability to help protect consumers from exposure to drugs that may be counterfeit, stolen, contaminated, or otherwise harmful, the system will also improve detection and removal of potentially dangerous drugs from the drug supply chain and protect U.S. consumers.

The implementation of the new regulations is scheduled to occur over a 10-year period, beginning in November 2013 and impacts fulfillment processes for manufacturers, wholesalers, repackagers, and dispensers. Each of these supply chain participants is impacted by new compliance responsibilities at differing times during the implementation period. Most of the Dispensers' compliance responsibilities begin in the second half of the implementation period.

Final distribution of prescription pharmaceuticals to the U.S. public occurs through 67,000 providers/dispensers including pharmacies, facilities, clinics, and hospitals[1]. Each of these dispensers may obtain medications through a variety of wholesale distributors or, in some cases, directly from manufacturers. Securing each of these distribution channels from the introduction of counterfeit, stolen, or contaminated medication is a mammoth task. Serialization of each saleable prescription item will allow for tracking and validation of legitimate items as they travel through the US pharmaceutical supply chain.

Providence Health Technologies, LLC (PHT), Hamacher Resource Group, Inc. (HRG), and Advasur, LLC (Advasur), collectively, the Contractors, have piloted a process to collect and validate serialized data present within barcodes on individual prescription pharmaceuticals. The study measures the ability of Small Dispensers, defined as those dispensers with twenty-five (25) or fewer full-time employees, to comply with the enacted legislation. Small Dispensers are particularly disadvantaged when process changes negatively impact workflow, introduce unanticipated costs, or create new demands on already stretched labor resources. Good, workable, solutions are dependent on processes that are inexpensive, scalable, and easy to implement and maintain. Also, good solutions should fit within existing pharmacy workflow processes. New workflow changes must include the ability to automate data collection and validation to meet these conditions.

[1] Qato, Dima Mazen; Zenk, Shannon; Wilder, Jocelyn; Harrington, Rachel; Gaskin, Darrell; Alexander, G. Caleb (2017-08-16). "The availability of pharmacies in the United States: 2007–2015"

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FDA Small Dispenser Pilot Study

Understanding the impact of the oncoming Track and Trace Legislation on Small Dispensers

Tracing of pharmaceuticals within the US drug supply chain begins with serializing each saleable container at the manufacturer or labeler. FDA provided guidance in September 2018 addressing the requirements in section 582(b)(2) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360eee-1(b)(2)) that manufacturers "affix or imprint a product identifier to each package and homogenous case of a product intended to be introduced in a transaction into commerce" beginning not later than November 27, 2017[2]. A product identifier is defined in section 581(14) of the FD&C Act (21 U.S.C. 360eee(14)) as a standardized graphic that includes, in both human-readable form and on a machine-readable data carrier that conforms to the standards developed by a widely recognized international standards development organization, the standardized numerical identifier, lot number, and expiration date of the product.

This generally means that two-dimensional (2D), DataMatrix formatted, barcodes are required to be present on individual packages of medications currently shipping from manufacturers. These barcodes must contain the National Drug Code number (NDC), lot number, expiration date, and a serial number for a package. These data allow for identification of unique packages within the supply chain. In our study, we accessed and parsed the data embedded within the 2D barcodes by scanning prescription packages and bottles upon receipt by the pharmacy. The data obtained from the 2D barcode was decoded, parsed, and analyzed for compliance with the DSCSA requirements. We then compared these data to electronic Advanced Ship Notice (ASN) data we received on behalf of the pharmacy participants in the study. In some instances, printed records were analyzed rather than electronic ASNs as some suppliers (i.e. manufacturers, repackagers, and wholesale distributors) were unwilling or unable to supply the ASNs electronically. The data were analyzed for internal and external disparities. Internal disparities might be an instance where the printed, human readable data were different than the data obtained from scanning the 2D barcode. External disparities were those differences in ASN submitted data and 2D barcode data. We also kept records of those items scanned to expedite return of medications in the event of a recall or for other reasons.

At the onset of the study, we measured the general awareness of DSCSA Federal Requirements among dispensers who agreed to participate in the study. We discovered that awareness of DSCSA regulations was not widespread in general among pharmacists and they were completely unaware of any of the DSCSA requirements for dispensers. It seems that awareness and education of DSCSA legislation has been eclipsed by other pharmacy issues, primarily those

[2] From: https://www.fda.gov/media/106198/download, accessed 3/30/20

surrounding reimbursement and many pharmacies are struggling with merely staying in business. Preliminary discussions with small dispensers revealed that much education is still needed within the pharmacy community regarding dispensers' responsibilities related to DSCSA federal requirements. The Contractors measured small dispensers' initial awareness for those dispensers participating in the study using questionnaires given to the participants. Data from this pre-test was gathered to determine the current depth of understanding of the DSCSA requirements of small dispensers. Participants in the study were chosen from four (4) categories of dispensers including retail pharmacy, hospital pharmacy, specialty pharmacy, and long-term care pharmacy. These subgroups of the dispensing pharmacy environment represent the majority of small dispensers in the market and all four of these pharmacy sectors are well represented by small dispensers.

Small Dispensers have a good understanding of traditional labeling requirements for medications. Identifiers on properly labeled packages, bottles, and containers such as National Drug Codes (NDCs), Universal Product Codes (UPCs), Lot numbers, expiration dates, etc. are understood and used by pharmacists every day. Introduction of the serialized data and the 2D barcode was noticed, but not much attention was given to this new data. With some education these data could provide new value to dispensers including the ability to quickly check and record quantities shipped, store expiration dates, and record serial numbers for each item received. DSCSA requires the NDC, serial number, expiration date, and lot number be present in human readable form as well as incorporated and present in a (2D) barcode on the label of each package or smallest saleable unit. The pilot project sought to obtain the data present in the transaction information submitted to the pharmacy from the supplier and compare those data with the information present within the 2D barcode on each package. Discrepancies in barcodes and EDI data were recorded and reported in our findings to the FDA. Additionally, records of missing or unreadable barcodes as well as barcodes with missing data were captured and collated with these findings.

Table of Participants

Participating technology and retail services companies

Company	Key Personnel	Title
Providence Health Technologies, Inc.	Todd Barrett, R.Ph.	President
Hamacher Resource Group, Inc.	Dawn Vogelsang	President
Advasur, LLC	J. Randall Hoggle, BS, DPh, MBA	Managing Director

Participating Small Dispensers

Dispenser Type	State
Long Term Care Pharmacy	MS
Long Term Care Pharmacy	MS
Long Term Care Pharmacy	WI
Hospital Pharmacy	MS
Hospital Pharmacy	MS
Specialty Pharmacy	MS
Specialty Pharmacy	MS
Specialty Pharmacy	MS
Retail Pharmacy	MS
Retail Pharmacy	MS
Retail Pharmacy	MS
Retail Pharmacy	WI
Retail Pharmacy	WI
Retail Pharmacy	WI
Retail Pharmacy	WI
Retail Pharmacy	WI
Total	**17**
The Study was initiated with twenty-four (24) Participants. Seven (7) reported that they did not have the staff to continue to participate. We report this as a 30% Study fall-off.	

Pilot Overview & Scope

The primary focus of the pilot study was to identify and measure the ability of small dispensers to comply with the requirements of the new FDA DSCSA federal requirements. Secondly, PHT sought to identify awareness of the DSCSA requirements among dispensers, identify burdens in workflow changes needed to accommodate compliance, measure costs that might be incurred with compliance, determine adequacy and type of data received from suppliers, and measure

trending of data quality and data present on product shipped that might indicate when compliance benchmarks might be achieved.

Methodologies

Data Collection

A mix of small dispensers from the Long-Term Care, Specialty, Hospital, and Retail communities were asked to participate in the study. These sectors were identified based on anticipated volume of shipments and their willingness to adhere to the study guidelines. In total, seventeen small dispensers participated. The participants were asked to:

1. Provide an assessment via an individual survey of their DSCSA knowledge at the beginning and midpoint of the study
2. Provide both objective and subjective findings to help determine burden, costs, and daily workflow modifications
3. Provide a complete list of wholesale distributors to setup electronic receipt of shipped product (typically ASNs)
4. Scan 2D, and sometimes 1D barcodes on products received
5. Visually verify drug labeling against electronic barcode data by:
    a. Scanning the product as it comes into the pharmacy
    b. Analyzing the product barcode, comparing that information to the human readable package label, and record any discrepancies that exist in:
        i. Serial Number
        ii. Lot Number
        iii. Expiration Date
    c. When prompted by the software, take pictures of:
        i. Any non-compliant barcodes
        ii. The front of the container to capture product name and NDC
        iii. Any other surface or side containing serial number, lot number, and expiration date
6. Provide access where applicable for study representatives to provide on-site training, discuss best practices, and share knowledge

Manufacturers, wholesale distributors, or other suppliers providing trackable product to these small dispensers were contacted to supply electronic shipping information in the form of ASNs (EDI 856 formatted data). Wholesale distributors were asked to provide electronic EDI 856 information to our central repository as they shipped product to the Dispensers in the study. Throughout the study, product was analyzed for barcode and label adherence to the DSCSA. These data were provided to the FDA in a monthly report throughout the term of the study.

Our experience in coordinating with other trading partners to receive electronic submissions for participating pharmacies covered the spectrum from easy and straightforward to contentious. Some wholesale distributors had created infrastructure in preparation of the requirements to provide data to dispensers, while others simply would not submit data. As we began to setup receipt into our data repository, to ensure ample time was allowed for onboarding each wholesale distributor, the Contractors provided every opportunity to those wholesale distributors that demonstrated a desire to transmit data electronically, but needed additional time for technology setup and configuration.

A gap analysis was performed comparing received electronic ASN data and scan data retrieved from products received by dispensers. Comparisons were made to discover any missing data or data discrepancies.

Of the 31 wholesale distributors initially identified by the participating pharmacy dispensers, only five (5) were able to fully participate in the submitting electronic ASN data. Of those five, one (1) of these wholesale distributors only participated partially, stating that submitting the data electronically was cost prohibitive.

Executive Summary

Project Objectives

1. Assess ability for Small Dispensers to comply with the DSCSA requirements
2. Measure awareness of the DSCSA dispenser requirements among four Small Dispenser types
3. Assess current state of Small Dispenser readiness for 2020 & 2023 DSCSA requirements
4. Develop best practices model for Small Dispensers compliance
5. Simulate full scale workflow in pharmacies and measure impact
6. Measure percent of products received at each level of serialization compliance
7. Quantify amount of product unnecessarily quarantined; confirm quarantine procedures in place
8. Measure number of transactions flagged as errors and compare to subsequent transactions corrected rather than quarantined
9. Evaluate accuracy of scanned data vs ship notices
10. Calculate associated costs to implement systems

Key Outcomes and Findings

1. Small dispenser pharmacies were willing and able to comply with the DSCSA requirements outlined for dispensers. The data collection for the study was designed to be as straightforward as possible. Processes for data collection were incorporated into current pharmacy workflows wherever possible with a focus to reduce the additional burden on staff as much as possible.
2. There was no significant difference in prior DSCSA knowledge or awareness between the different dispenser types. Most pharmacists interviewed expressed a desire to be compliant but were unaware of the requirements and needed assistance in carrying out process implementation.
3. The midterm self-assessment survey showed 87% of participants were aware of the upcoming 2023 requirements, though none were prepared for the upcoming changes. At the end of the study, pharmacists and technicians were aware of the DSCSA dispenser requirements, the placement and content of 2D barcodes, and in some instances the

absence of required 2D barcodes. The study helped dispensers gain confidence that compliance could be achieved.

4. The average number of Suppliers per participant category are:
   (a) Independent Pharmacy: **3.9**
   (b) Small Specialty Pharmacy: **10.5**
   (c) Small Long-Term Care Pharmacy: **3.3**
   (d) Small Hospital: **1.5**
5. The average number of product shipment scans per participant category per month are:
   (a) Independent Pharmacy: **3030**
   (b) Small Specialty Pharmacy: **2592**
   (c) Small Long-Term Care Pharmacy: **6721**
   (d) Small Hospital: **567**
6. In developing the processes for implementation and execution of data collection for the study, we determined that it was best to standardize "Best Practices" for drug product procurement and inventory maintenance. The development of a Best Practices document allowed us to evaluate the structure and necessity of some of the processes that become second nature and automatic to most pharmacists over time.
7. Dispensers agreed to make those changes that improved workflow and improved scanning efficiency. However, most pharmacies found that the scanning, and more significantly the prompts to take pictures of non-compliant drugs, created significant barriers within their workflow. These barriers increased costs of labor required for documentation. We outline the estimated costs of data capture in item #10 below, and later in this report, in detail.
8. The non-compliance rate for barcodes when we began the study was reasonably high and, as predicted, improved as the study progressed. As non-serialized inventory within the supply chain was consumed, it was replaced with DSCSA compliant labeling. We detected a reverse in the trend of serialized product reaching our pharmacies the latter months of the study that we attributed to product being sold before dispensers could no longer accept it. However, it did not have a major impact on percentage of non-serialized product received by our dispensers.
9. The short timeframe for our study, did not reveal any instances where a product would require full quarantine. Our dispensers were asked to create processes in their pharmacies where suspect or illegitimate product could be quarantined. Quarantine procedures were reviewed with our dispensers.

10. During the first few months of the study, we realized a small amount of human error was introduced when separating compliant and non-compliant barcodes. This warranted a coding change to create a smarter barcode reading system. Rather than allowing users to qualify a compliant barcode, the system was updated to separate simple (1D) or complex (2D) barcodes. Complex barcodes, if parsed accurately were then labelled compliant. With this code change, human manipulation was reduced, and no errors were recorded that warranted quarantine of a product.
11. Data received via the electronic advance ship notices (ASNs) were of poor quality with many of the required data elements missing. Some products were even missing National Drug Code (NDC) records. Additionally, there were challenges in discerning whether a ship date should be present and added to the shipment notice upon transmission. Fields exists within the data for entry date and processing date, but no definition differentiating these was found. Many ASNs did not indicate the quantity ordered by the dispenser - only the quantity shipped. More detail of these findings is found later in this report.
12. While most manufacturers and labelers incorporated the assigned legacy NDC numbers into the Global Trade Item Number (GTIN) format, there was no assurance that this was universal, nor reliable.
13. It is anticipated that our dispensers could spend over $15,000 per annum to properly scan, identify, and verify each serialized product. Extrapolating industry wide for over 67,000 dispensers, the average cost of this endeavor would be over $1 billion annually.

Recommendations

1. Make available more continuing education programs for pharmacists
2. Provide detailed training and resource programs on FDA Guidance and upcoming regulations required for both dispensers and wholesale distributors
3. Work with Pharmacy Associations and Trade Groups to provide educational programs describing how FDA Guidance impacts decisions for pharmacy dispensers
4. Encourage suppliers to provide data in an electronic format to dispenser customers
5. Work with suppliers and manufacturers to standardize data elements within ASNs (EDI 856 formatted data)
6. FDA to instruct wholesale distributors that were unresponsive to requests for data submission comply by providing a way to track data submissions
7. Development of a GTIN to NDC crosswalk data index is imperative
8. Alternatives to scanning the incoming prescription product shipments should be evaluated to meet product lot level validation

Project Objectives & Outcomes

Compliance

Assess ability for small dispensers to comply with the DSCSA requirements

Small dispenser pharmacies were willing and able to comply with the DSCSA requirements outlined for dispensers. The collection of data for the study was designed to be as straightforward as possible. Processes for data collection were incorporated into current pharmacy workflows wherever possible and care was taken to reduce the additional burden on staff as much as possible.

PHT developed an easy to use, web-based application and integrated this software with a handheld scanner. Pharmacy managers or owners helped identify personnel at each pharmacy who would be responsible for scanning drug products as they were received from suppliers. Typically, an inventory receiving technician was given this responsibility. Visits were coordinated with each pharmacy and the designated scanning person and management received one-on-one training at each initial visit, and on subsequent visits as needed. A training manual was created to help with questions on software use and instructions on accessing collected data. Incorporated into the training manual were configuration barcodes that were used to reset and initialize the barcode scanners in the event of hardware failures or malfunctions. Follow up visits were scheduled to review scanning processes and determine if retraining or encouragement was needed.

Some pharmacists and technicians had a cursory awareness of the DSCSA “Track and Trace” federal requirements, but no real sense of detail or responsibilities given them within the federal requirements. During the study period, we provided continuing education programs for pharmacists’ awareness and responsibilities for DSCSA compliance. Anecdotally, during these continuing education seminars, we discovered that pharmacists not participating in the study were also unaware of much of the detail and corresponding dispenser responsibilities of the federal requirements. Even after the dispensers were made aware of their responsibilities, they had very little influence or control of the data received (or not received) from manufacturers or wholesale distributors.

The ability for small dispensers to comply with DSCSA requirements, or respond to an FDA audit, is tied directly to the willingness or ability of the wholesale distributor to provide proper data. In many cases, requests for electronic submission of shipment notices were made directly by the small dispenser to the supplier and the supplier would not submit data electronically. Staffing restrictions and restrictive costs make it almost impossible for small dispensers to manually verify shipping data from suppliers. Additionally, data made available by web portals, as offered by

some suppliers, requires manual verification by the dispenser and is not easily incorporated into daily workflows. Dispensers volunteering for this study willingly changed their daily routine to suit the needs of the study, and to ensure compliance and patient safety. As a result, dispensers scanned 130,035 drugs into the system. A breakdown of the scans by dispenser type is shown in Figure 1 below.

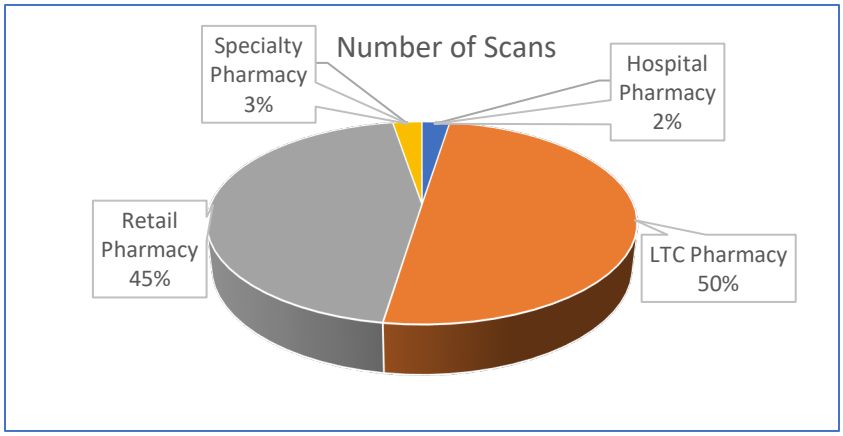

Figure 1 - Number of Scans by Dispenser Type

In comparison, of the 33 wholesale distributor or manufacturer suppliers that were contacted to provide electronic shipment data, only 12 were willing to participate, and only 5 managed to onboard with our track and trace system in time to provide the data desired for the study. Technical integration experts were required on both the sending and receiving teams to ensure quick onboarding. Figure 2 below shows the metrics for the suppliers that successfully onboarded.

Suppliers	Initial Setup (Business Days)	Subsequent Days Required to Onboard Suppliers	Comments
Wholesale Distributor 1 & Subsidiary	8	5-14	Multiple staff, defined procedure
Wholesale Distributor 2	12	3-14	Multiple staff, defined procedure
Wholesale Distributor 3 & Subsidiary	30	N/A All connections were set up with initial contact	• New staff and December Holidays extended initial timeframe. • All dispenser connections were set up with initial contact • Multiple staff, defined procedure
Wholesale Distributor 4	35	N/A All connections were set up with initial contact	• Unknown if a defined procedure exists
Wholesale Distributor 5	14	N/A	• Only one dispenser was onboarded. Wholesale distributor stated the ASN transmission via third party was too costly.

Figure 2 – Onboarding Metrics for participating suppliers

A few suppliers were able to complete the onboarding process in late January/early February of 2020. However, this was after our study deadline for onboarding and hence were not counted as onboarded.

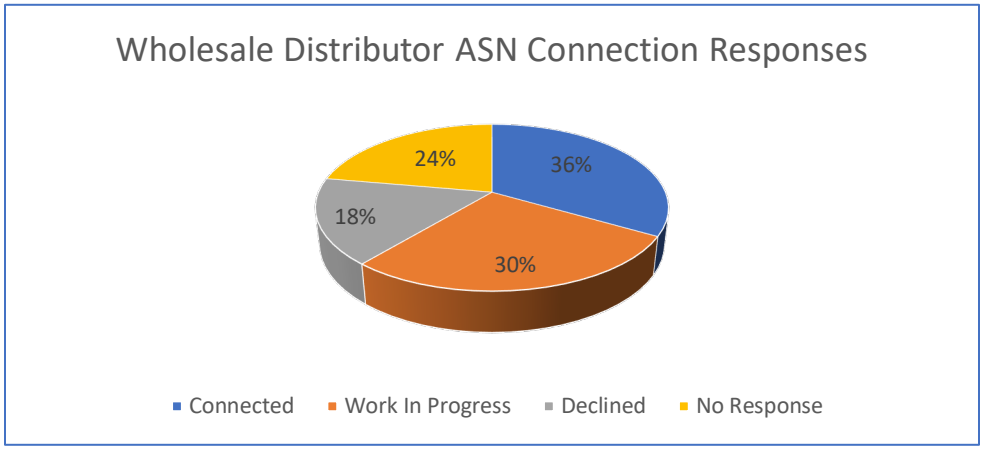

Figure 3 - Wholesale Distributor response to electronic T3 data request

Figure 3 shows most of the wholesale distributors were willing to participate. However, many lacked the needed technology, process or resources to complete timely onboarding. Those wholesale distributors that declined to participate stated their current offering (Invoice FTP, Web Portal Access, or paper invoice with T3 data) met current guidelines. Validation of potential compliance using these methods of data submission were outside the scope of the study. PHT recommends follow up with these suppliers to validate DSCSA compliance.

Measure awareness of the requirements to comply with DSCSA among four small dispenser segments

The study itself initiated some interest and educational opportunities among pharmacists. Pharmacists were mostly unaware but curious of the responsibilities of dispensers. Education of DSCSA requirements was required to explain why PHT wanted to conduct the study and why we wanted dispensers to participate in the study. Some explanation of the study was required for participation. An initial survey questionnaire was used to determine dispensers' level of knowledge of DSCSA regulations. There was no significant difference in DSCSA knowledge or awareness between the different dispenser types. Most of the pharmacists interviewed had a desire to be compliant but were unaware of the requirements and needed assistance in carrying out process implementation.

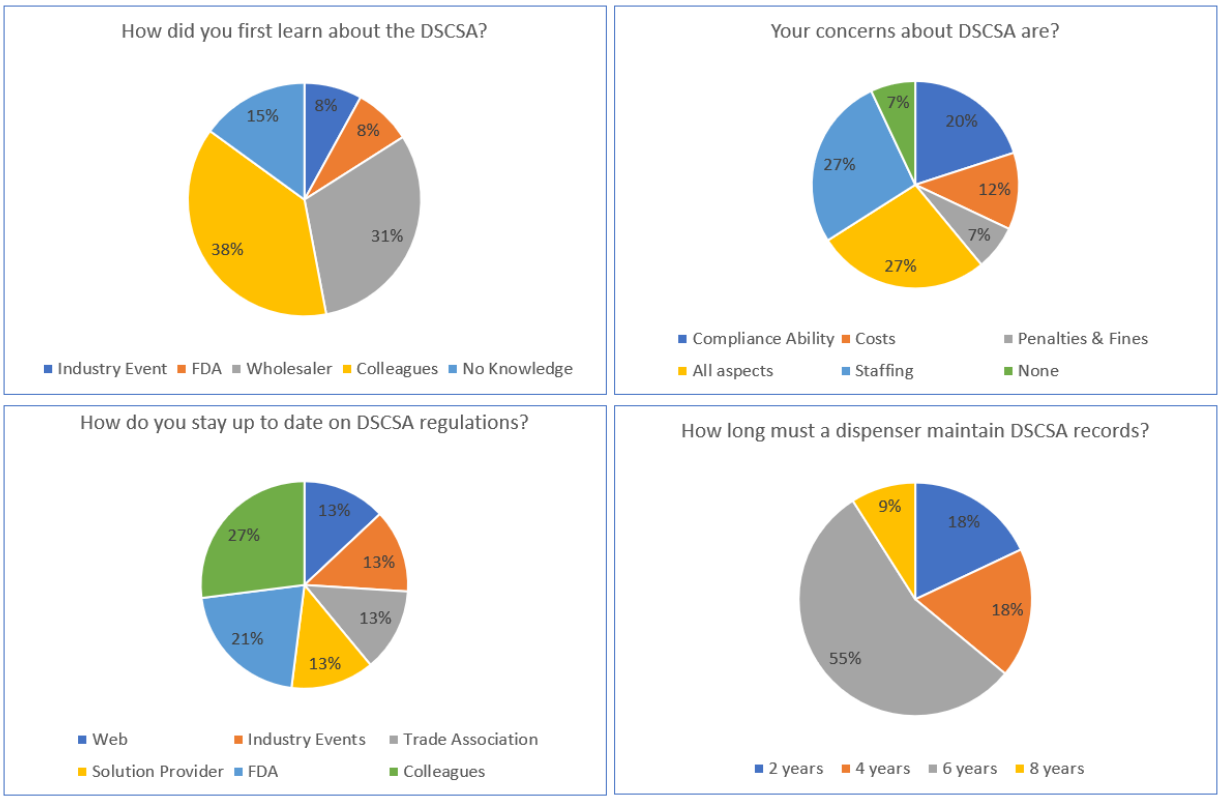

Figure 5 - Sample of survey results

To further support the dispensers' knowledgebase, a website landing page was created within the pilot study application where pharmacy personnel could access DSCSA information and frequently asked questions. A document outlining the timeline of major milestones was also distributed to aide as a quick guide.

Assess current state of small dispenser readiness for 2020 and 2023 requirements of DSCSA

Midterm study results demonstrated an improvement in knowledge and understanding of DSCSA dispenser requirements and a commitment to self-directed understanding of the regulations. The midterm self-assessment survey showed 87% of participants were aware of the upcoming 2023 requirements, though none were prepared for the upcoming changes. The study helped dispensers gain confidence that compliance could be achieved. PHT strongly recommends that a continued education, training, and resource program on the changing regulations be made available.

We were surprised to find a number of wholesale distributors were also not aware of, or preparing for, the upcoming 2023 Electronic Interoperability Guidelines. Some cited resource and/or financial constraints as their reason to not provide electronic data. For this reason, education of the small wholesale distributors is also highly recommended. A best practice methodology for achieving full compliance should also be developed and distributed.

Develop best practices model for small dispenser compliance

In developing processes for implementation and execution of data collection for the study, we determined that it was best to standardize “Best Practices” for drug product procurement and inventory maintenance. The development of a Best Practices document allowed us to evaluate the structure and necessity of some of the processes that become second nature and automatic to most pharmacists over time. The content of that document appears on the two following pages.

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Best Practices for Pharmacies (Dispensers) to Ensure DSCSA Compliance

1. Become familiar with and understand Dispensers' (Pharmacies') responsibilities and the associated timelines for DSCSA compliance
2. Read and understand DSCSA definitions, including those for "Suspect Product"[3]
3. Evaluate and select software/hardware necessary for DSCSA compliance
4. Designate key personnel responsible for DSCSA compliance
5. Designate space for order checking and other process components
6. Train and equip key personnel on DSCSA requirements, responsibilities, and timelines
7. Direct and monitor key personnel's in-service training of other personnel on operational components of DSCSA compliance
8. Develop, utilize and document ongoing personnel training processes
9. Develop, utilize and document means of evaluating and auditing compliance with DSCSA requirements by internal team and external partners
10. Develop, utilize and document processes for review of evolving related regulatory requirements and continuous improvement
11. Trading Partner verification against FDA database: https://www.fda.gov/drugs/drug-supply-chain-security-act-dscsa/annual-reporting-prescription-drug-wholesale-distributors-and-third-party-logistics-providers
12. Verify wholesaler VAWD accreditation. The NABP list of VAWD accredited wholesalers can be found here: https://nabp.pharmacy/programs/vawd/vawd-accredited-facilities/
13. Confirm supply chain partners have all requisite licenses and registrations, including state board of pharmacy and other licenses
14. Confirm that all wholesale distributors can comply with the requirements of the DSCSA before purchasing (or continuing purchasing). This includes provision and supplying of current ASNs, shipping DSCSA compliant product in compliance with current requirements. (EPCIS) and retention and timely provision of historical data upon request

[3] SUSPECT PRODUCT — The term 'suspect product' means a product for which there is reason to believe that such product— ''(A) is potentially counterfeit, diverted, or stolen; ''(B) is potentially intentionally adulterated such that the product would result in serious adverse health consequences or death to humans; ''(C) is potentially the subject of a fraudulent transaction; or ''(D) appears otherwise unfit for distribution such that the product would result in serious adverse health consequences or death to humans.

15. Develop, utilize and document processes for routine order verification upon receipt of orders from trading partners
16. Develop, utilize and document processes to only accept prescription drugs that are accompanied by three pieces of product tracing documentation, known as the 3 T's
17. Begin collecting required T3 data from suppliers for product received [4]
18. Develop, utilize and document means of maintaining records required by DSCSA for six (6) years
19. Develop, utilize and document means of identifying items that do not comply with DSCSA requirements
20. Develop, utilize and document means of quarantining items that do not comply with DSCSA requirements and returning those products when necessary
21. Develop, utilize and document means of notifying trading partners of receipt of items that do not comply with DSCSA requirements
22. Monitor timelines for new requirements for documentation and receipt of DSCSA compliant product (i.e. Serialized only product in November 2020)
23. Execute a written agreement with a third party to obtain and/or maintain T3 data for a period of six (6) years [5]
24. Confirm eligibility of returnable product. (i.e., saleable returns eligibly depend on dispensers' ability to associate returned product with documentation from when it was obtained).
25. Effective November 2023, dispensers should work with trading partners to comply with the requirements for submitting and receiving data from an electronic, interoperable database to monitor product transactions.

[4] The DSCSA states that dispensers "shall not accept ownership of a product, unless the previous owner prior to, or at the time of, the transaction, provides transaction history, transaction information, and a transaction statement"; and that they must maintain access to "transaction information (including lot level information, if provided), transaction history, and transaction statements, as necessary to investigate a suspect product, and maintain such information, history, and statements for not less than 6 years after the transaction

[5] The DSCSA states that "a dispenser may enter into a written agreement with a third party, including an authorized wholesale distributor, under which the third party confidentially maintains the transaction information, transaction history, and transaction statements required to be maintained under this subsection on behalf of the dispenser. If a dispenser enters into such an agreement, the dispenser shall maintain a copy of the written agreement and shall not be relieved of the obligations of the dispenser under this subsection."

We believe that posters or similar notices could be developed and then displayed within dispenser pharmacies to inform and remind pharmacy staff members of their obligations under DSCSA.

Impact

Simulate full scale workflow in pharmacies and measure impact

Dispensers agreed to make the required changes to improve the workflow to enable scanning. However, most pharmacies found that the scanning, and more significantly the requirement to take pictures of non-compliant drugs and packaging for NDC compliance, created a significant burden on pharmacy staff and process workflows. Scanning each item added time to the pharmacy order check-in process, but changes in process and benefits of capturing inventory data could outweigh the costs of scanning.

The cost to obtain the hardware and software to initiate scanning is defined below:

Item	Cost	Comments
Scanner	$225	
Camera	$100	
Computer		Required only if current system cannot be utilized. This was not required for any of our dispensers
Software One-time Cost	$500	
Software Annual Cost	$3,200	

Figure 5 - Hardware & Software Costs

Once the equipment was installed and the process of daily scanning began, our dispensers quickly notified us that the process had significantly increased the time required to process an incoming order. Some participants estimated that these new compliance tasks doubled the amount of time required to process orders received from a wholesale distributor.

Figure 6 shows the amount of time it took for dispensers to process an order.

Dispenser Types	Number of Items	Number of Suppliers	Number of Totes	Average Items per Tote	Lowest Tote Size	Highest Tote Size	Average Minutes per Tote	Average Minutes per Item
Average of All Types	**3340.2**	**4.3**	**67.4**	**46.8**	**2.0**	**184.6**	**31.97**	**0.73**
Retail Pharmacy Average	3030.2	3.9	62.9	43.8	2.6	143.5	30.9	0.72

LTC Pharmacy Average	6721.0	3.3	74.7	95.3	1.0	239.7	56.1	0.55
Specialty Pharmacy Average	2592.0	10.5	102.5	23.4	1.0	466.0	22.34	0.94
Hospital Pharmacy Average	567.5	1.5	44.0	12.6	1.5	26.0	10.75	0.89

Figure 6 - Time required to scan

If we follow the average time to scan a tote and assume that a small dispenser receives three totes day, then we can estimate that scanning would take about 1.5 to 2 hours. The employee costs associated with this calculation are just over $40.00 a day.

Average Cost of Pharmacy Technician	**Additional Benefits Cost**	**Total (2 hours)**
National Average: $16.35 per hour https://www.bls.gov/oes/current/oes292052.htm	Benefits add an additional 30%, bringing this to $21.26 https://www.benefitspro.com/2019/01/28/benefit-costs-broken-down-into-the-numbers/?slreturn=20191027105353	$42.52

Figure 7 - National Average Hourly Pay Rate for Pharmacy Technicians

Annually, our dispensers could incur costs of over $15,000 for scanning, identifying and verifying the serialized product. Industry wide for over 67,000 dispensers, the average annual cost of implementing the scanning of product could exceed $1 billion. The FDA should evaluate alternatives to dispenser scanning to document receipt as serialized data sets become a requirement for the 2023 Interoperable Database.

The FDA should also determine if serialized data within EPCIS is can be relied on as a trusted data source or would verification scanning against the serialized ship notice be required. Suspect or counterfeit product, errors within the T3 dataset, and inadvertent shipping errors are all causes for concern if product is not validated at receipt. These are discussed further in the following pages of this report.

Our pharmacists wanted to understand exactly what constituted a suspect product and what products required quarantine. Although some counterfeit or adulterated product is obvious upon visual inspection, much counterfeit product is not easily identified. Pharmacists were educated on FDA guidance of identification of suspect product, released December 2016. That guidance includes instructions on how to identify suspect product based on factors such as source,

demand, or appearance. Validation of drug product legitimacy is currently difficult unless it is visually obvious (e.g. misspellings, wrong colors on the packaging or product, etc.).

> *Suspect product is defined in section 581(21) of the FD&C Act as a product for which there is reason to believe it (A) is potentially counterfeit, diverted, or stolen; (B) is potentially intentionally adulterated such that the product would result in serious adverse health consequences or death to humans; (C) is potentially the subject of a fraudulent transaction; or (D) appears otherwise unfit for distribution such that the product would result in serious adverse health consequences or death to humans. Section 582 of the FD&C Act requires trading partners, upon determining that a product in their possession or control is a suspect product, to quarantine the product while they promptly conduct an investigation to determine whether the product is an illegitimate product. Illegitimate product is defined in section 581(8) of the FD&C 5 The portion of this guidance that describes when manufacturers should notify FDA of a high risk that a product is illegitimate is shaded in gray and is being distributed for comment purposes only. 6 See section 582(h)(2)(A) of the FD&C Act. Contains Nonbinding Recommendations and Binding Provisions 3 Act as a product for which credible evidence shows that it is (A) counterfeit, diverted, or stolen; (B) intentionally adulterated such that the product would result in serious adverse health consequences or death to humans; (C) is the subject of a fraudulent transaction; or (D) appears otherwise unfit for distribution such that the product would be reasonably likely to result in serious adverse health consequences or death to humans.* (Drug Supply Chain Security Act Implementation: Identification of Suspect Product and Notification Guidance for Industry, Dec 2016, US-HHS, FDA)

In accordance to these guidelines, because of the short period of time of the study and the small number of participants, no counterfeit or illegitimate drugs were found.

Serialization

Measure percent of products received at each level of serialization compliance

For most of the drugs shipped to our dispensers, label and barcode compliance tracked favorably to DSCSA Federal Requirements. Figure 8 shows the monthly trend of compliant vs non-compliant barcodes.

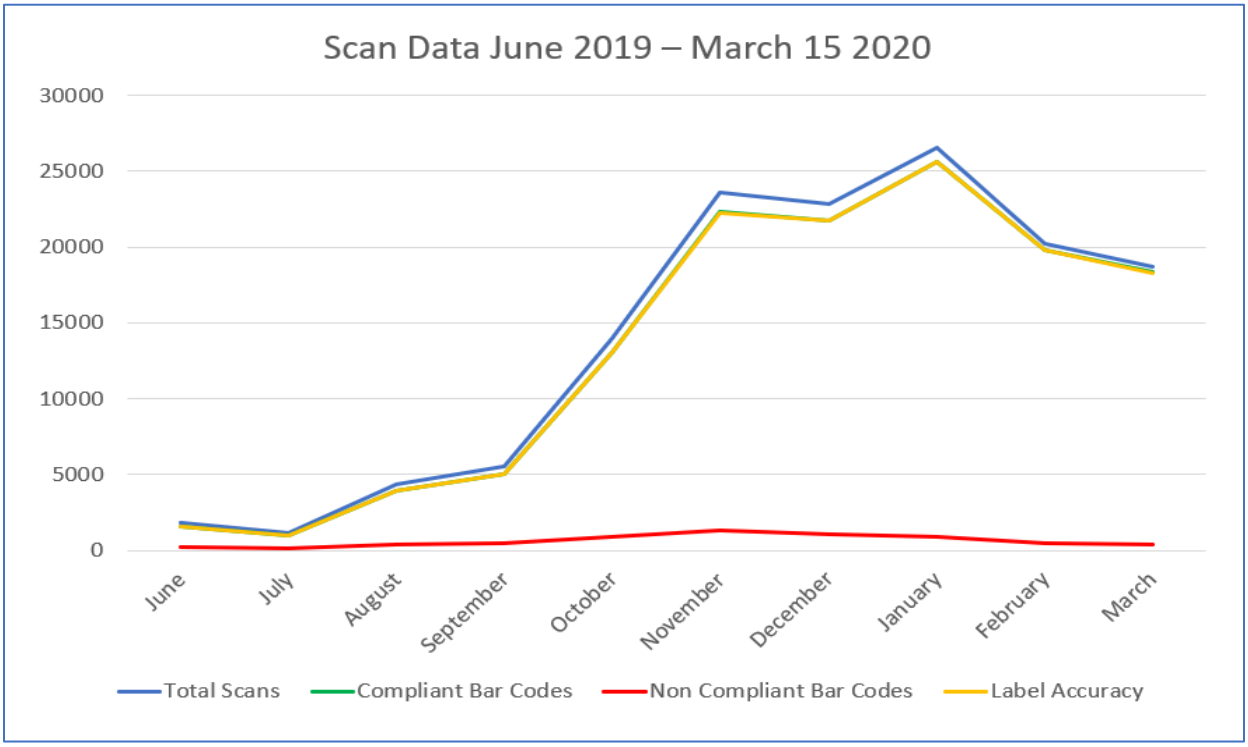

Figure 8 - Compliant vs Non-Compliant Trend

During our study we identified and labeled a change in participant behavior that we called burnout. Burnout was identified and measured when the number of shipped medications dropped, instead of stabilizing, as enrollment was complete. Validating the accuracy of the human readable data against the scanned 2D barcode required human intervention that was labor intensive. This extra labor requirement caused burnout among the scanning technicians. This was a significant finding which reinforces the need to find alternative ways to meet lot level validation for incoming shipments and future interoperable data submission requirements.

The monthly barcode compliance rate trended as predicted. As old inventory was consumed in the supply chain, it was replaced with DSCSA compliant labeling. Though we did notice a small amount of old inventory sell-off occur in the latter months of the study, it did not have a major impact on the percentage of non-serialized product received by our dispensers.

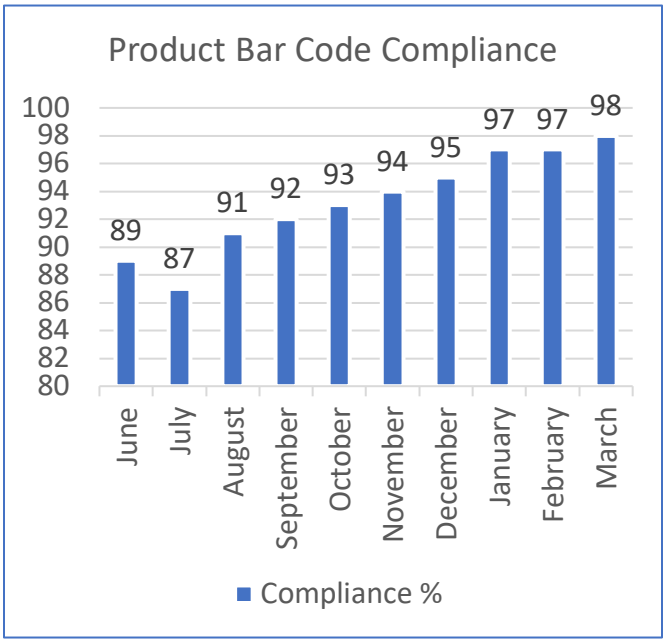

Figure 9 Compliance Trend by Month

During the study we encountered 849 distinct products having both simple and complex 2D serialized barcodes. Of these medications we saw the transition of 250 drug labels from simple to complex serialized barcodes. At this time, there are still 65 items representing over 40 labelers and/or manufacturers received by our dispensers where we have not yet observed an example of a barcode transition. That is, there was no evidence that some manufacturers' products were transitioning to serialization. Expiration dates were examined on these medications and used to interpolate how long they may have been in the supply chain. We discovered some of these recently shipped items with simple (1D) barcodes have expiration dates in excess of two years from the date shipped to the dispenser, seemingly reflecting rather recent manufacturing dates and distribution.

All compliant barcodes did, in fact, have all the required characteristics of a DSCSA approved barcode. Lot number, serial number and expiration date were present. No duplicate serial numbers were detected. Duplication of serial numbers is possible and instances of those could exist outside of the dataset we collected. We did not verify serial numbers with manufacturing as it was outside the scope of this study. Data from serial number verification through the entire supply chain, from manufacturing to dispenser, would produce valuable data if incorporated into subsequent studies.

Internal accuracy of data within labels was also tested. The human readable portion of the label was compared to results of barcode scans and compared for accuracy. Our dispensers found a 99.8% label accuracy rate. The tiny fraction noted as inaccurate were attributed to either human error or to non-standard expiration date formats.

Crosswalk

A medication's NDC is a required marking on all prescription packaging shipped within or into the United States. A Global Trade Item Number (GTIN) is a GS1-assigned number used for tracking trade items and is used internationally. GS1 states that for US prescription medications, it is best practice to assign a GTIN that embeds the NDC within it. However, because GTINs and NDCs were developed separately, there is a possibility that instances might occur where this may not occur. PHT anticipated this possibility and developed a GTIN to NDC crosswalk to validate each product's NDC and GTIN within our dataset. However, we would draw attention to the fact that our crosswalk development was limited to only those GTINs and NDCs documented within this study. Their remains an extremely large set of GTINs and NDCs which do not, at this time, have a crosswalk.

PHT began the process of creating a crosswalk for the products that our dispensers had scanned. With the help of the Advasur 360 Harmonized Product Code Software and our end users, we were able to collect and analyze over 5,000 distinct product codes. This required having our study participants take pictures of the front packing where the Rx label and NDC could be found. Figure 10 shows that the manufacturers are adhering to this requirement and for the overwhelmingly majority of the products, an NDC is present within the 2D barcodes, product code. In our study we didn't observe any GTIN's without properly embedded NDCs.

Number of product codes collected and analyzed	Number of products exempt from DSCSA requirements	Number of products where NDC is present in the product code	% Compliance
5,137	62	5,051	**100%**

Figure 10 - NDC present in Product Code

Barcodes

Readability and format and the impact to workflow

During the study, we identified several anomalies that were initially thought to be labeling errors. Some manufacturers or labelers were creating barcodes with non-standardized data formats embedded within the barcode. GS1 provides a DataMatrix formatting guide for encoding data within the GS1 DataMatrix barcode[6]. The use of non-standard data formatting caused parsing errors making the data difficult to analyze. If a non-standard format was used in the 2D barcode, the system would label the barcodes as non-compliant, as illustrated in Figure 11 below:

[6] From: https://www.gs1.org/docs/barcodes/GS1_DataMatrix_Guideline.pdf, accessed 4/2/20

Barcode Type	Product Code Type	Count	Barcode Sample	Product Code Sample
Complex	GTIN_14	1,073	01691170009221000000000079219%172103311004173	69117000922100
Complex	GTIN_8	3	010032724103803721138085113215517210930l0PA0969J	0PA0969J
Complex	SSCC	5	00368001154000z80280607202060493184	368001154000z80280
Complex	Unknown	104	1720120010Y02209%3012	null
QR_CODE	Null	47	https://.....	null
Simple	Null	428	428031600 or 03B792	null
Simple	GSIN	1	21003120000595170	21003120000595170
Simple	GTIN_12	3,624	303780018013	303780018013
Simple	GTIN_13	8	4042809613896	4042809613896
Simple	GTIN_14	181	0130382903064244	30382903064244
Simple	Unknown	4	1722071910ht923101 L302221 Rev. 09/18	22071910ht923101 02221 Rev. 09/18
Unknown	Null	383	NULL	NULL

Figure 11 - Non-compliant barcode issues

The item circled depicts the traditional UPC-A barcode. The large number of complex barcodes that were not compliant did not parse correctly. The scanning software was designed using GS1 formatting guidelines to parse the complex 2D barcode. Barcode formatting issues include but are not limited to:

- Transposing digits read by the scanner. In a couple of isolated incidents where the scanner was connected to a computer involved in several other tasks, the scanner would overrun the processor and cause digits to be transposed.
- Readability issues. Some barcodes had to be scanned multiple times before data were obtained from them. Others could not be read at all.
- Placement of multiple 2D barcodes on packaging was confusing to technicians scanning the items, causing scanning of the wrong barcode where multiple barcodes existed (e.g. QR Code)

Even for compliant barcodes, some manufacturers did not follow the GS1 prescribed YYMMDD format for expiration date. Instead they utilized a MMYYYY format. Although only a tiny fraction of the data set, this non-adherence to the GS1 standard required a system change to ensure these barcodes were not omitted from our dataset.

Quarantine

Quantify amount of product unnecessarily quarantined; confirm quarantine procedures in place

During the limited timeframe of the study, our dispensers did not identify any product that would require quarantine. The dispensers in our study received product primarily from established, well known wholesale distributors, reducing the potential for receipt of suspect product. Regardless, our dispensers were asked to create a process within their pharmacies for quarantine of suspect or illegitimate product.

Prior to the study, none of the study participants were able to produce Standard Operating Procedures (SOPs) for handling or processing suspected Illegitimate or quarantining product. Quarantine procedures were reviewed with our dispensers and we included guidelines for developing procedures in our Best Practices Guidelines (previously discussed).

Exception handling (Human Error)

Compare the number of transactions flagged as errors and corrected to those eventually quarantined and not available for dispensing

During the early months of the study, we realized the amount of human error introduced while recording compliant and non-compliant barcodes warranted a smarter barcode reading system. Instead of allowing users to qualify a compliant barcode, the software was updated mid-study to label barcodes as simple or complex. Complex barcodes, if parsed accurately, were then labelled compliant. A script processed and validated the scans already completed to ensure the integrity of the system. Users were then asked to take pictures of non-compliant or simple (UPC-A) barcodes that were scanned. With the introduction of this new software code, human interaction was limited, eliminating recording errors that triggered improper quarantine of a product.

Evaluate accuracy of scanned data vs ship notices

As noted previously in the report, contacting and onboarding suppliers for electronic T3 transmissions was more challenging than originally anticipated. Working through the labyrinth of suppliers, their subsidiaries, and account executives to finally reach an EDI integration employee could take anywhere from 3 to 30 days.

The major wholesale distributors with internal IT teams designated to process EDI transmission requests were the easiest with which to work. However, we found it is very unlikely that small dispensers have the technical expertise or time to pursue integration of electronic ASN receipts. Although some wholesale distributors indicated that T3 data was available via a web portal on their website, we found that data difficult to find and could not be effectively integrated into our system. Our dispensers were mostly unaware of T3 data availability on any web portals for those suppliers stating that they provide that service. Though this may have been something communicated or signed via contract, our dispensers were mostly unaware of it. Many wholesale distributors were also not able to send historical transmissions when requested, though it is unclear if this was a data issue or a technical limitation on their EDI service.

For the handful of wholesale distributors that were able to participate in the study with our dispensers, an evaluation of their ASN data was made against the scan data from the dispensers. It was immediately evident that without serialized data in the ASN, matching to a serialized scan would be an onerous task.

Ship Notice Compliance

We used guidance provided by the FDA to check for errors in ship notice transmissions. Required data elements tracked for compliance included:

- Transaction Statement - the transaction set does not contain a transaction statement attesting to compliance with the DSCSA.
- Transaction Date - the transaction set does not contain a transaction date.
- Shipment Date - the transaction set does not contain a shipment date.
- Seller - the transaction set does not contain a seller.
- Buyer - the transaction set does not contain a buyer.
- Owner - the item's historical information does not contain its previous owners.
- Owner Transaction Date - the item's historical information does not contain the dates at which its previous owners took ownership of the item.
- Quantity - the item did not indicate the quantity shipped.
- Name - the item does not contain a name/description.
- NDC - the item does not contain an NDC.
- Lot Number - the item did not contain a lot number.
- Strength - unable to determine the strength of the item due to truncation or abbreviation.

- Form - unable to determine the dosage form of the item due to truncation or abbreviation.
- Container Size - unable to determine the container size of the item due to truncation or abbreviation.

Not a current requirement, though incorporated into our testing:

- Expiration Date – the item did not contain an expiration date.

These data have standardized formats derived from: the FDA Standardization of Data and Documentation Practices for Product Tracing Guidance for Industry[7]. Most transactions analyzed did not contain the data in the format specified in the guidance.

Standardization of Data

Wholesale distributors, dispensers, and repackagers generally must not accept ownership of a product unless the previous owner provides the transaction information, transaction history, and a transaction statement prior to, or at the time of, the transaction. As required by section 582(a)(2)(A), FDA issued a draft guidance that established initial standards related to the methods for the interoperable exchange of product tracing information. In this guidance, we provide recommendations for standardizing the product tracing information that trading partners are required to exchange. Certain transactions that may involve the exchange of product tracing information that is different from what is described in the statutory definitions of transaction information, transaction history, or transaction statements are also addressed in this guidance.

During our study, it became apparent that much of the data received via some electronic ASNs did not contain the necessary data elements. Many of the issues described in the following pages are quantifiable within the study data set. Additionally, issues were found from non-participating dispensers and are therefore anecdotal and are not quantified within the study data.

Because of the limited timeframe within the study, the longstanding relationships between dispensers and suppliers, and the responsiveness of suppliers to questions from dispensers, any items that may have been identified as suspect were typically promptly resolved and product was not quarantined. However, there remains a gap in the process of documenting the notification of suspect product to wholesale distributors and the resulting resolution of suspect product notices.

[7] From: https://www.fda.gov/media/111451/download, accessed 4/01/2020

We believe some errors may not require a formal FDA complaint or claim but may be inadvertent and resolved between trading partners quickly. (i.e. errors in quantities shipped, incorrect date stamps, etc.).

A total of 28,936 trackable drug item statements were collected over the study period.

Identified issues included:

1. Identifying product as Over the Counter (OTC) or trackable
    a. Most shipment notices do not contain a flag identifying items as OTC and consequently exempt from DSCSA tracing requirements.
2. Missing Seller or Buyer
    a. The shipping notice does not list a buyer. This occurs mostly on OTC items and causes processing issues for the application.
    b. The ship notices contain some Seller/Buyer information but may be missing details such as Street or City. These are required within the guidelines.
3. Inability to quantify a measurement larger than the lowest saleable unit such as Case or Pack
    a. Many shipments are by case or pack, but the lowest saleable unit is not quantified in the electronic shipping notice.
4. Product Descriptions were the most difficult to analyze using an algorithm. All wholesale distributors use this nonstandard field as “free text” and include all information including product name, strength, dosage and container size in this one field. No standardized method for describing or ordering these fields exists. Identifying and resolving these apparent or actual discrepancies required manual review by a pharmacist, each review averaging 30-40 minutes per day. Additionally, partial names and abbreviations with drug product descriptions (or incomplete descriptions) caused questions as to the proper identification of the product.
5. Some products were missing an NDC. Most of these were found to be OTC products, but some Rx products lacked an NDC identifier.

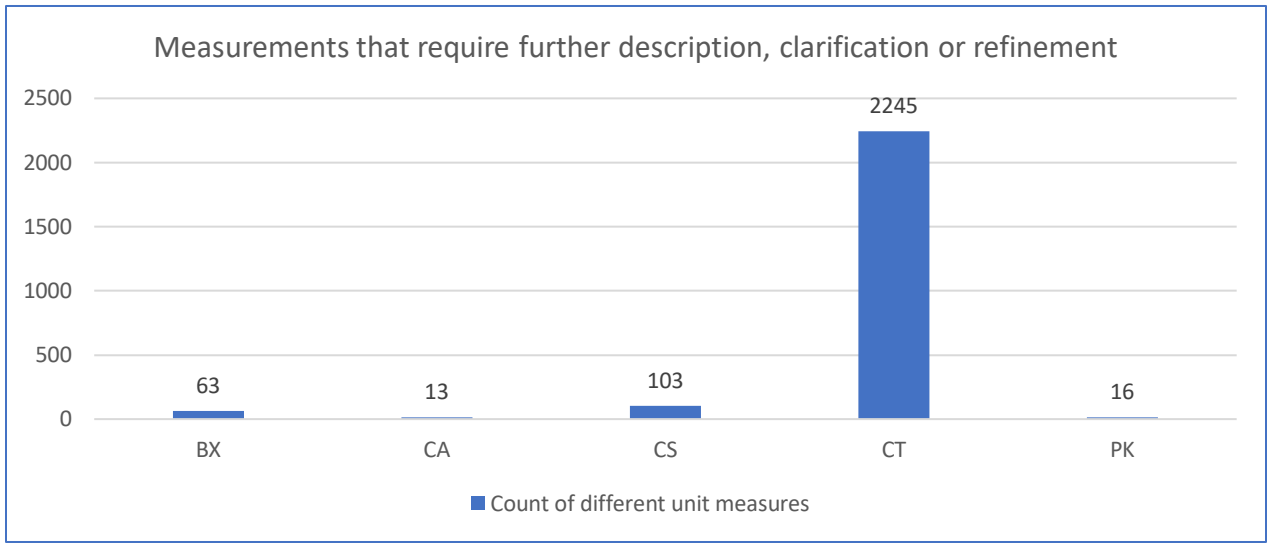

Figure 12 - Quantity Units other than EACH

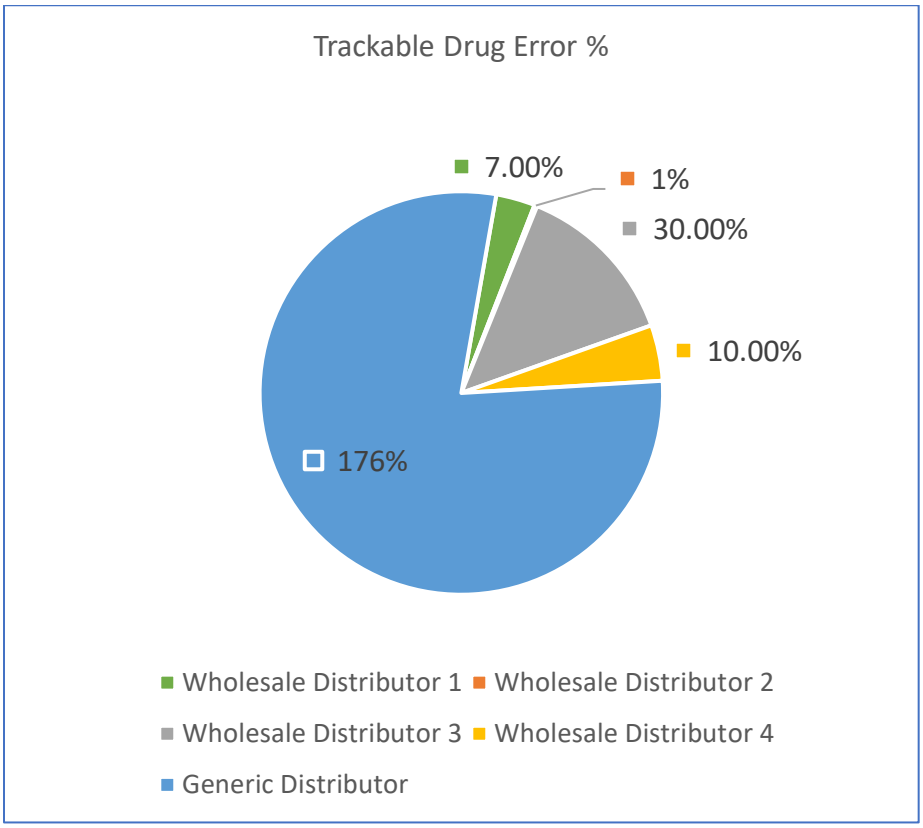

Figure 13 - Errors by supplier

6. There is a requirement within DSCSA for orders with dates of shipment more than 24 hours after the transaction is processed to be recorded and added to the T3 data separately. Currently, there is no mechanism for downstream trading partners to recognize if this date was in fact required.

7. It was sometimes time consuming and cumbersome to determine when a labeler or manufacturer was in possession of the item, and if the OWNER / OWNER TRANSACTION DATE was required. This can occur when a dispenser places an order with a distrbutor on one day, the order is fulfilled the next day, and the order is shipped yet on the following day. There is no industry standard to determine which date will be recorded as the TRANSACTION DATE.

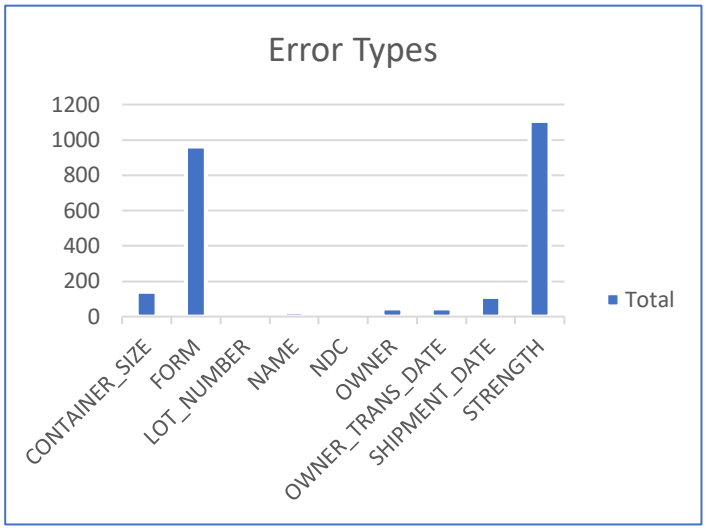

Figure 14 - Cumulative errors

8. Perhaps some wholesale distributors have a lot number exemption, as they buy directly from the manufacturer. However, we are not aware of the timeframe for this exemption and if it applies to all primary wholesale distributors. Without lot number and serialization present, drug tracing is impossible.

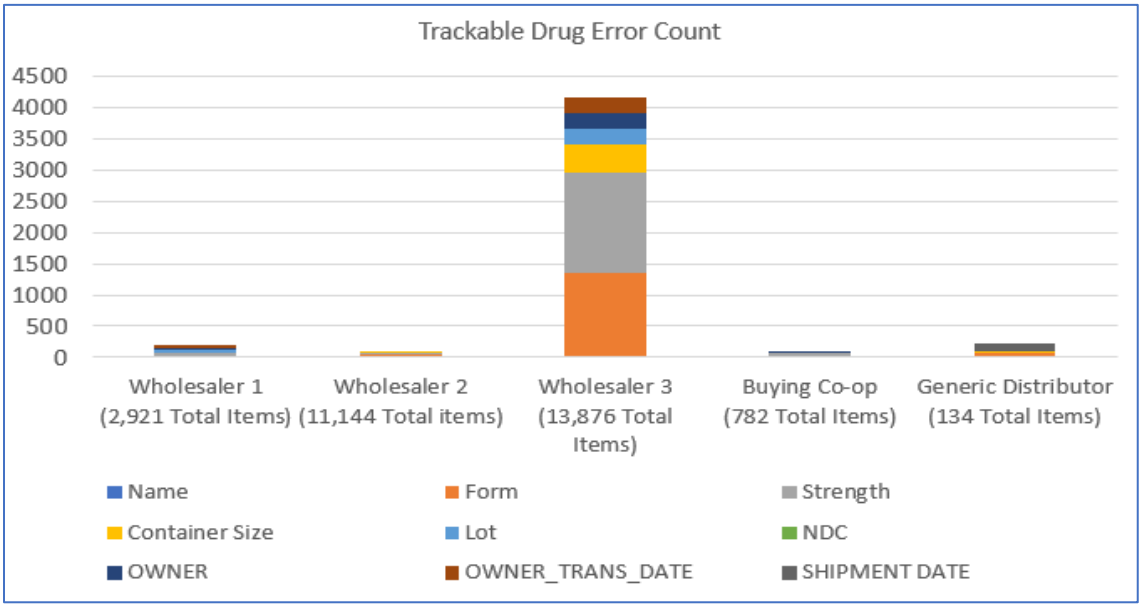

Figure 15 - Error comparison by supplier

9. Though the electronic advance ship notice contains fields for both ordered quantity and shipped quantity, some suppliers have chosen to populate only the shipped quantity. This again leaves a gap in the T3 data making human intervention necessary to check the number ordered against the quantity shipped. Over 50% of items in our shipments did not contain a recorded ordered quantity.

Scan and ASN Match Criteria

Unfortunately, due to the lack of participation by some wholesale distributors, not all scanned data were matched directly with the electronic ASNs. Also, as the ASNs are not serialized and a large number contain lot number exemptions, the data were matched using other criteria. The primary match between the ASN and scan data is the NDC. The ASN data contains an NDC value, whereas the scan data contain a 2D barcode with a product code included. In most instances, the NDC is embedded within the GTIN. There are several ways to match these two fields. The Scanned Product Code can be converted into 3 different derived values, based on the formulas below. These 3 derived values can then be compared to the ASN NDC.

If one of the derived values matched the ASN NDC, we constituted a match. However, this match does not indicate a match between a scanned item and an ASN item, it is only a match of the ASN NDC and Scanned Product Code fields. To establish a unique match between the ASN and scanned record, further matching criteria was utilized. Nine different matching sets were sequentially applied to yield a match. The first match routine (match 01 & match 02) yields the lowest margin of error and highest statistical relevance.

Match Type Relationship	**Matching Routine**	**Match Results**
Match 01	One Scan to One ASN Qty	ndc = ndc AND scan asn po/invoice # = asn po/invoice #
Match 02	Many Scan to One ASN Qty	ndc = ndc AND scan asn po/invoice # = asn po/invoice #
Match 03	One Scan to One ASN Qty	ndc = ndc AND scan po/invoice # = asn po/invoice #
Match 04	Many Scan to One ASN Qty	ndc = ndc AND scan po/invoice # = asn po/invoice #
Match 05	One Scan to One ASN Qty	ndc = ndc AND buyer = buyer AND seller = seller AND shipment <= scan created AND same day
Match 06	Many Scan to One ASN Qty	ndc = ndc AND buyer = buyer AND seller = seller AND shipment <= scan created AND same day

Match 07	One Scan to One ASN Qty	ndc = ndc AND buyer = buyer AND seller = seller AND shipment <= scan created AND within 1 day
Match 08	Many Scan to One ASN Qty	ndc = ndc AND buyer = buyer AND seller = seller AND shipment <= scan created AND within 1 day
Match 09	One Scan to One ASN Qty	ndc = ndc AND buyer = buyer AND seller = seller AND shipment <= scan created AND within 2 days
Match 10	Many Scan to One ASN Qty	ndc = ndc AND buyer = buyer AND seller = seller AND shipment <= scan created AND within 2 days
Match 11	One Scan to One ASN Qty	ndc = ndc AND buyer = buyer AND seller = seller AND shipment <= scan created AND within 3 days
Match 12	Many Scan to One ASN Qty	ndc = ndc AND buyer = buyer AND seller = seller AND shipment <= scan created AND within 3 days
Match 13	One Scan to One ASN Qty	ndc = ndc AND buyer = buyer AND seller = seller AND shipment <= scan created AND within 4 days
Match 14	Many Scan to One ASN Qty	ndc = ndc AND buyer = buyer AND seller = seller AND shipment <= scan created AND within 4 days
Match 15	One Scan to One ASN Qty	ndc = ndc AND buyer = buyer AND seller = seller AND shipment <= scan created AND within 5 days
Match 16	Many Scan to One ASN QTY	ndc = ndc AND buyer = buyer AND seller = seller AND shipment <= scan created AND within 5 days
Match 17	One Scan to One ASN Qty	ndc = ndc AND buyer = buyer AND seller = seller AND shipment <= scan created AND lot = lot AND expiration date = expiration date
Match 18	Many Scan to One ASN Qty	ndc = ndc AND buyer = buyer AND seller = seller AND shipment <= scan created AND lot = lot AND expiration date=expiration date

The results of the queries with the above criteria are considered potential matches. They include all the data from the ASN record and all the data from the scan record that potentially match. Over 60% of items were matched successfully.

Supplier Types	Number of Scans	Percentage
Buying Co-op	**146**	**0.44%**
unmatched	51	34.93%
matched	95	65.07%
Generic Distributor	**66**	**0.20%**
unmatched	45	68.18%
matched	21	31.82%
Wholesaler	**32,976**	**99.36%**
unmatched	8,824	26.76%
matched	24,152	73.24%
Grand Total	**33,188**	**100.00%**

Dispenser Types	Number of Scans	Percentage
Hospital Pharmacy	**1,124**	**3.39%**
unmatched	521	46.35%
matched	603	53.65%
LTC Pharmacy	**16,534**	**49.82%**
unmatched	4,416	26.71%
matched	12,118	73.29%
Retail Pharmacy	**14,535**	**43.80%**
unmatched	3,624	24.93%
matched	10,911	75.07%
Specialty Pharmacy	**995**	**3.00%**
unmatched	359	36.08%
matched	636	63.92%
Grand Total	**33,188**	**100.00%**

Figure 17 - Match vs Unmatched scans & ship notices by dispensers and suppliers

The number of unmatched scans were further broken out to understand why the match did not occur:

Unmatched Scans	Scans
Not matching using any match criteria	4,388
partially matched - quantity discrepancy	4,532
more scans than ASN qty*	2,093
less scans than ASN qty**	2,439
Grand Total	**8,920**

* In cases where there are more scans than shipped items, this could be attributed to dispensers scanning the same package more than once (either by mistake or scanning the same product multiple times thinking the barcode is the same) or the supplier sent more than ordered.

** In cases where there are less scans than shipped items, this could be attributed to dispensers not scanning all packages received

Figure 18 – Qualifying partially matched scans

In cases where there are more scans than shipped items, this could be attributed to dispensers…

Even with the above logic applied, approximately 28% of the electronic ship data could not be matched to incoming product scan data.

Dispenser Type	ASN's	Percentage
Hospital Pharmacy	314	3.06%
LTC Pharmacy	3448	38.19%
Retail Pharmacy	5477	58.00%
Specialty Pharmacy	58	0.74%
Grand Total	**9297**	**100.00%**

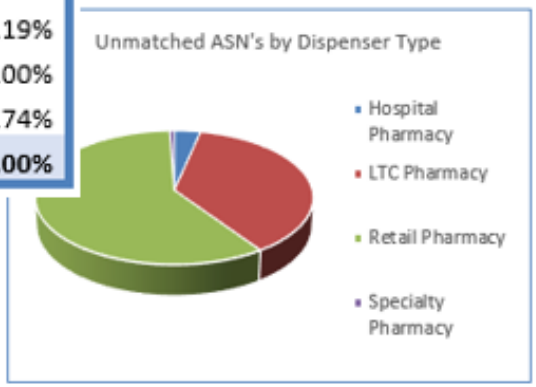

Figure 19 - Unmatched Scan Percentages

Given the limitations of available data, only 60% of the drugs were able to be matched. With the availability of enhanced data architecture and embedded serialization, tracing a product through the entire supply chain will be much easier.

Pharmacy Vendor Data System Readiness and Capabilities

Integration into other systems; systems' ability to identify product status; measure of time and resource impact of product flows prior to data flows; calculate associated costs to implement systems.

Our team had extensive conversations with six pharmacy information system vendors to determine their status and the impact of upcoming DSCSA regulations and guidelines to their systems and processes. Pharmacy systems were not initially designed to manage input of DSCSA T3 information. Lot level, and eventual package level, tracking of products as they enter and leave a pharmacy requires significant system changes. Most systems only track the distribution of distinct medicines to patients, not distinct packages to individual patients. Some system vendors have explored developing tools and capabilities to serve as a central repository of drug pedigree information and support retail pharmacies compliance with the Drug Supply Chain Security Act (DSCSA).

One such solution uses cloud-based technology to capture Transaction Information, Transaction History, and Transaction Statement from a pharmacy supplier's electronic data interchange (EDI) purchasing process or from scanned paper copies of the suppliers packing slips and invoices. Though some vendors have given the 2020 and 2023 solutions some thought,

they are not fully prepared to pursue a comprehensive solution. There is a myriad of responses from building a coherent solution, to allowing a third-party system designed for traceability to integrate via a common interface with the pharmacy system. With the current COVID-19 issues, much of this dialogue has been sidetracked. No consideration has been given at this point of developing a 2D barcode capability that reads, captures, and stores serialized product information.

Although the ASAP (American Society for Automation in Pharmacy) has included educational sessions on DSCSA, this has not been the center of focus nor has standardization been explored/revealed at the time of this research.

Next Steps

It is evident from this study and from conversations with dispensers and wholesale distributors, that the US pharmaceutical supply chain has opportunities for more development before a full-scale interoperable tracing system can be implemented.

Both small dispensers and small wholesale distributors sometimes lack technical and financial resources to help them maneuver the labyrinth of trading partners and guidance.

The FDA could potentially provide consolidated guidance via a certified trading partner and website to eliminate confusion among multiple websites and blogs that now exist.

Small dispensers should be further educated on regulations and consequences of non-compliance. The FDA should further require wholesale distributors to provide audited T3 data to ensure adherence to standards and compliance to guidelines.

Gaps continue to exist in the US pharmaceutical supply chain through physician dispensing and other non-traditional dispensers. Entities such as these are exempt from FDA DSCSA federal requirements. These gaps must be addressed to ensure counterfeit or illegitimate product doesn't enter the supply chain.

Simple scanning technology or automated processing of received drug orders must become mainstream in dispensing pharmacies for an established serialized tracing system.

Complete and clean data from wholesale distributors must be submitted to dispensers. Adherence to submission of quality data and standardization of data formats in the industry must be maintained before interoperability can be meaningful.

Electronic interoperability standards must be developed to create a framework for supply chain partners to participate in sharing drug product data. The DSCSA regulations must be supplemented by further guidance from the FDA to allow technology vendors a clear understanding of technical requirements of the software needed for present and future compliance.

We concluded that small dispensers do have the potential to comply with the FDA DSCSA legislative requirements. This is an unfunded compliance mandate given to small dispensers and as such, it is important to remove administrative burdens, where possible. Small dispensers exist as the last link the in US pharmaceutical distribution chain and therefore are burdened with ensuring product integrity as the drug reaches the consumer.

Small dispensers are best able to comply with DSCSA legislation and federal requirements surrounding the legislation if their upstream trading partners are fully compliant. Non-compliance of manufacturers, 3rd party logistics providers, repackagers, and wholesale distributors cannot be corrected at the dispenser level. Each noncompliant or suspect item received requires a review and investigation by a pharmacy technician or other team member. The current U.S. pharmacy reimbursement systems to not allow for dispensers to bill any party for this time and they must therefore absorb any and all incremental labor costs.

The pharmacists participating in the study were willing and able to comply with the federal requirements but did find that compliance with this legislation would be costly in labor and equipment. Small dispenser pharmacies are relatively low margin businesses and don't enjoy economies of scale of larger organizations, so they must outsource much of the technology development and much of the compliance programs they implement. DSCSA legislation adds to those costs.

We believe that small dispensers will be key to the successful implementation of FDA DSCSA legislative requirements and should receive key communication, coaching and resources to help facilitate prompt adoption and implementation of needed operational changes.