Dispensers and DSCSA:

Using Lot-Level Learnings to Prepare for the Serialized World

Special Edition of the 2016 Global Drug Supply, Safety and Traceability Report

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Introduction

The 2016 Global Drug Supply, Safety and Traceability Report revealed that dispensers—along with much of the supply chain—have struggled to comply with DSCSA lot-level requirements, and are concerned about readiness for the next wave of regulations.

According to the law, dispensers do not need to address additional requirements until 2020. However, other supply chain segments face significant new mandates between now and then – and the impact on dispensers will be unavoidable.

In this special edition, we first recap lessons learned from the lot-level experience of the report's 183 hospital and retail pharmacy survey respondents. Then, we look at data not included in the original report to consider how the compliance activities of trade partners—and dispensers' own operations—will require hospitals, pharmacies and health systems to take action for upcoming DSCSA challenges long before the official 2020 deadline arrives.

Lot-Level Lessons Learned

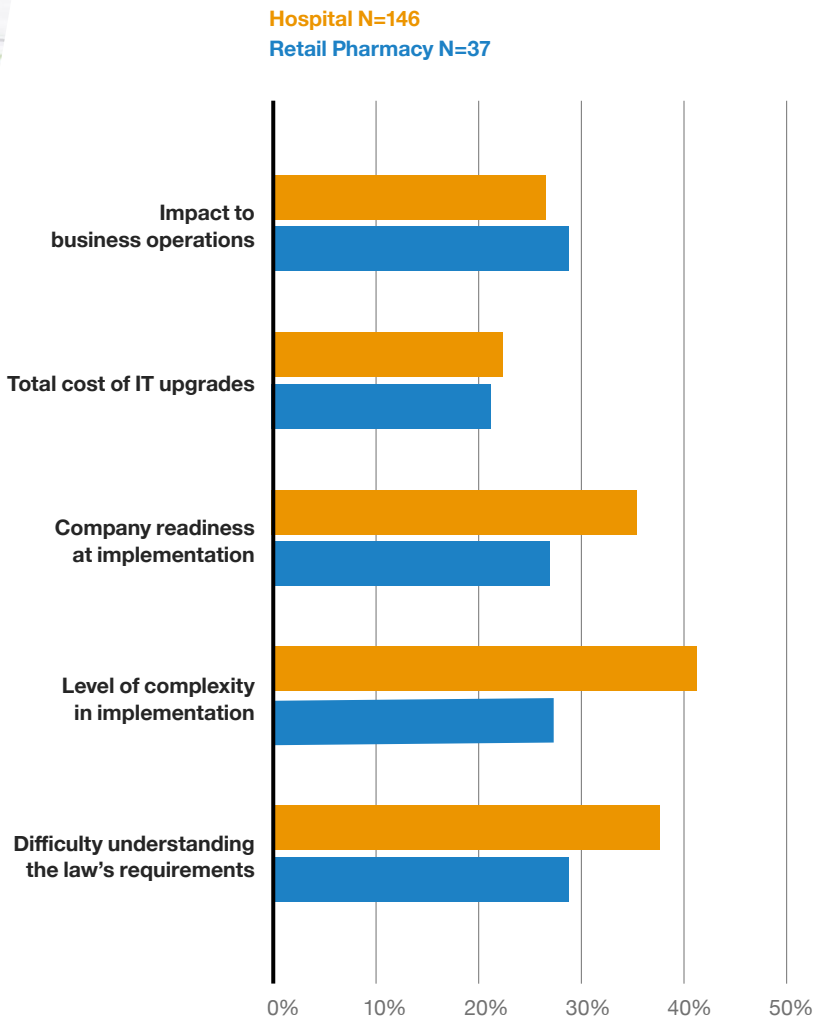
Lesson #1

More than one-fourth of dispensers underestimated the scope of lot-level compliance.

Achieving regulatory compliance requires assessing what it takes to get there. We asked hospitals and pharmacies to describe how well they estimated various aspects of lot-level compliance.

In nearly all areas, at least one-fourth of respondents underestimated what lot-level preparation would entail. In some cases, more than one-third missed the mark.

Percentage of Companies that Underestimated Lot-Level Compliance Needs



Lesson #2

To manage compliance data, dispensers used processes that can't be sustained in the long term.

As part of lot-level compliance, all dispensers need to receive and store Transaction History, Transaction Information, and a Transaction Statement (T3) for each product received.

In 2015, many dispensers took a patchwork approach to managing their T3, using a combination of manual and electronic methods, sometimes with newly purchased systems and other times with pre-existing ones.

This hodgepodge strategy is more a short-term fix than a long-term solution, as the entire supply chain progresses toward electronic-only T3 exchange.

Dispensers that made modifications to their supply chain management to achieve lot-level compliance

75% of hospitals

35% of pharmacies

65%

of dispensers that made modifications implemented a manual process as part of their data management

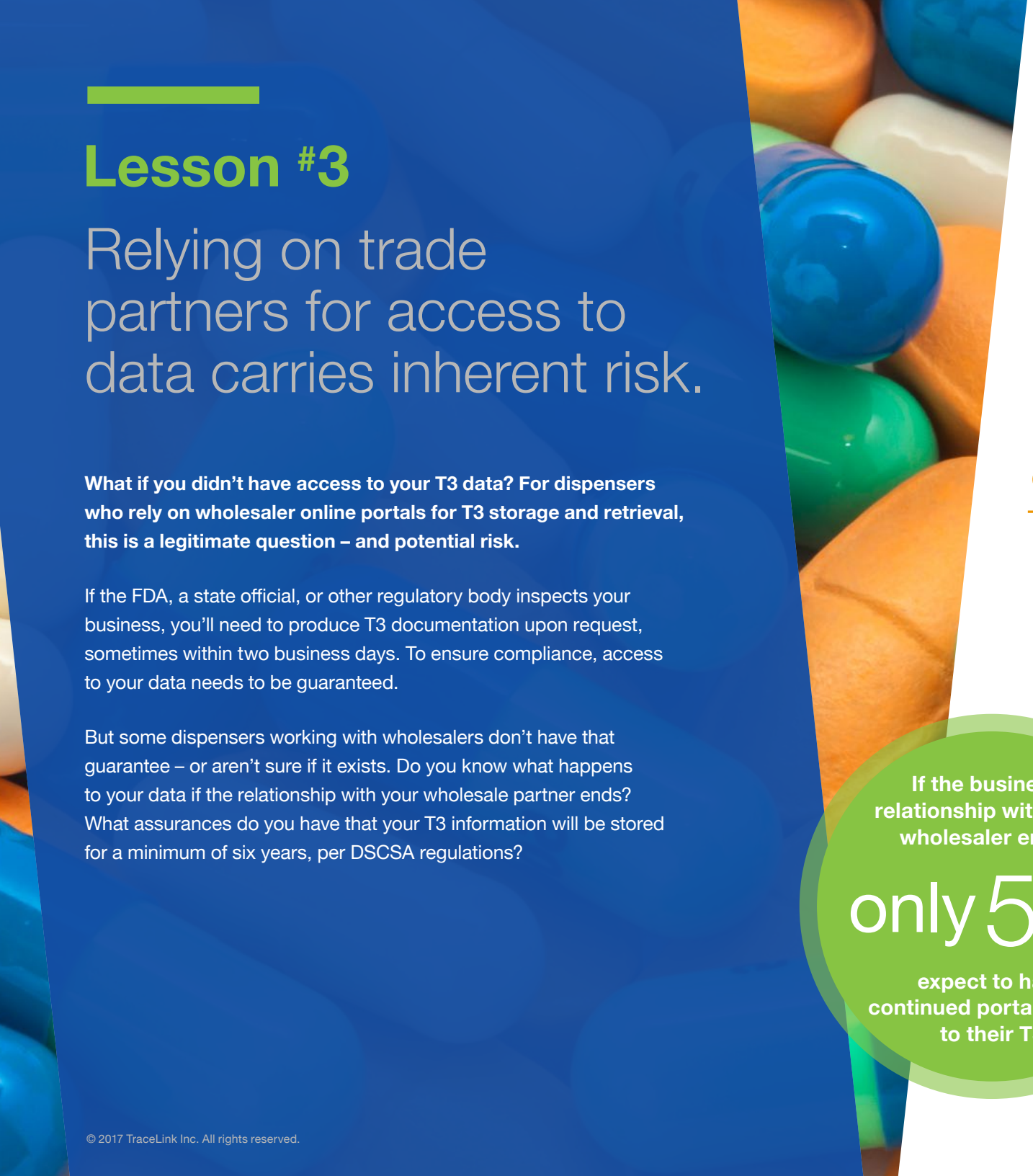
Lesson #3

Relying on trade partners for access to data carries inherent risk.

What if you didn't have access to your T3 data? For dispensers who rely on wholesaler online portals for T3 storage and retrieval, this is a legitimate question – and potential risk.

If the FDA, a state official, or other regulatory body inspects your business, you'll need to produce T3 documentation upon request, sometimes within two business days. To ensure compliance, access to your data needs to be guaranteed.

But some dispensers working with wholesalers don't have that guarantee – or aren't sure if it exists. Do you know what happens to your data if the relationship with your wholesale partner ends? What assurances do you have that your T3 information will be stored for a minimum of six years, per DSCSA regulations?



More than 1 in 4 dispensers who access T3 via a wholesaler portal have no expectations about how long that access will continue

If the business relationship with their wholesaler ends,

only 58%

expect to have continued portal access to their T3

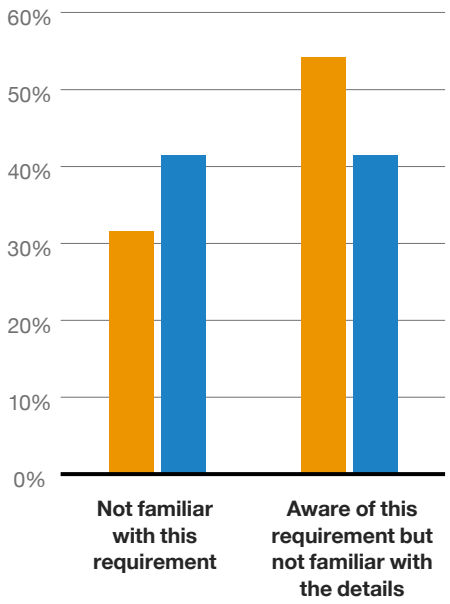
Lesson #4

Many hospitals and pharmacies don't know about upcoming requirements.

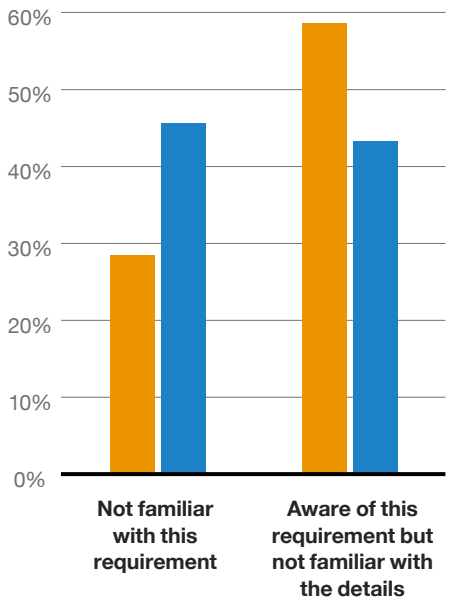
Dispensers have considerable gaps in knowledge when it comes to the next phases of legal requirements, working only with serialized product by 2020, and exchanging T3 electronically at the unit level for all products by 2023.

As evidenced by the survey responses, many dispensers don't understand the requirements of their own upcoming regulations. But they'll need a compliance plan for them, as well as the requirements coming from upstream partners as soon as November 2017.

Awareness of the 2020 Serialization Requirement



Awareness of the 2023 Electronic T3 Exchange Requirement



Considerations Beyond Lot-Level Compliance

Consideration #1

November 2017: Your business may feel the impact of a new deadline.

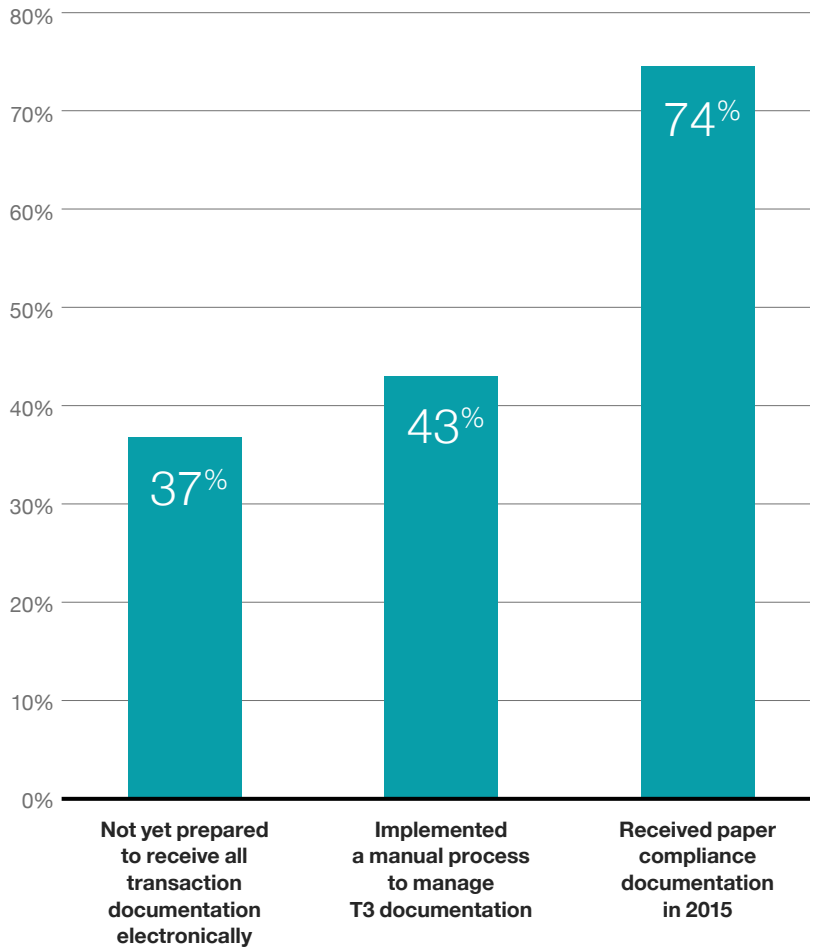
Although the next DSCSA compliance deadline for dispensers is 2020, make no mistake: On November 27, 2017, hospitals, health systems, and pharmacies will likely be affected by the new manufacturer serialization requirements.

By that date, manufacturers must send T3 transaction documentation electronically – so you can expect at least some of your suppliers to send electronic T3 your way by the November deadline.

Are you ready to receive it? Dispensers have no legal requirement for electronic T3 exchange until 2023, but you'll still need to manage T3 for current lot-level regulations, no matter how it arrives at your organization.

With electronic transaction exchange on the way, a heavy reliance on paper presents a risk to dispensers - and an immediate challenge. Based on our data, that challenge is widespread.

How Dispensers are Managing Lot-Level T3 Documentation



Consideration #2

Over the next few years, continuous change is the new normal.

If your hospital, health system, or pharmacy is already equipped to receive T3 electronically, you're in good shape for this November. But here's why you should be ready for other options.

1. **DSCSA requirements are rolled out gradually, so not all supply chain companies have to follow the same rules by the same deadlines.** Although wholesalers should be receiving T3 electronically from manufacturers as of November 2017, they won't yet be required to send documentation electronically.

   It's possible that a manufacturer will deliver T3 electronically, only for a wholesaler to transfer the information to paper before sending it down the supply chain to you.

2. **Some companies don't expect to hit their required deadline dates, and will comply some time afterward.**

As a result, dispensers are subject to constant change through 2023, and should be prepared to efficiently manage all T3 that arrives at their door, regardless of format.

Additionally, if your business receives product directly from a manufacturer, it's important to know whether they plan to transmit T3 electronically to you by November, if they don't already. In 2015, 31% of dispensers who received product directly from the manufacturer received T3 only by paper.

20%

of manufacturers plan to meet the electronic T3 requirement within a month of the deadline

15%

plan to meet the requirement after the deadline

26%

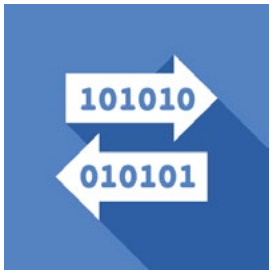
don't know how they will enable and deliver electronic T3

Consideration #3

Dispensers who conduct business as wholesalers must comply with an earlier deadline.

Hospitals and pharmacies that loan, borrow, or resell prescription drug product downstream are engaging in wholesaler operations, and must comply with the 2019 DSCSA deadline for resellers.

These dispensers must only loan, borrow, or resell product that's been serialized at the unit level – one year sooner than the 2020 serialization requirement for dispensers.



37%

of hospitals and pharmacies sold prescription product in 2015

1 in 4

of reselling dispensers sold product to 6 or more customers

Consideration #4

Millions of patients are depending on your compliance.

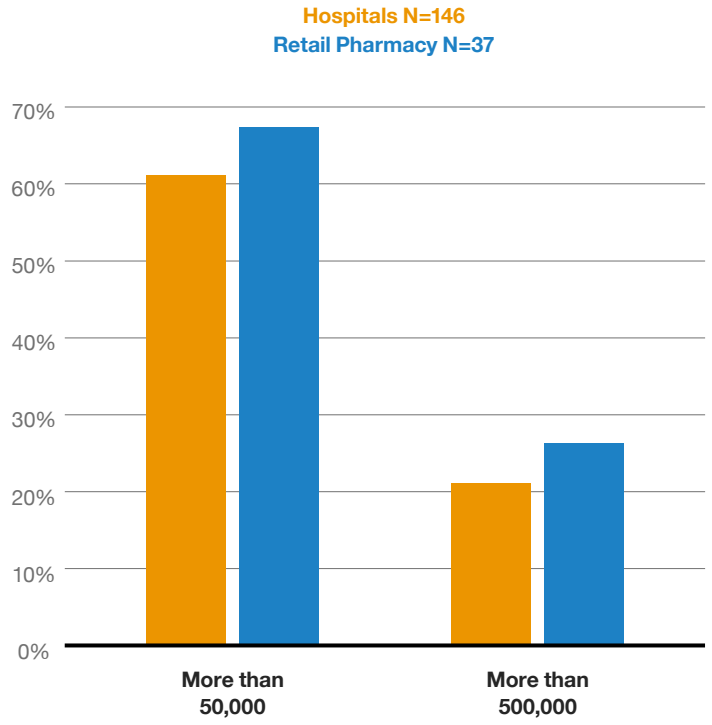
Behind the regulations, deadlines, and process modifications, it's important to remember that dispensers are the last line of patient safety within the supply chain. There's a lot at stake for every patient—and dispenser business—so getting the DSCSA requirements right is imperative. Remember, they were put in place to keep counterfeit and adulterated drugs away from patients.

The sheer volume of drug product you and your industry peers manage underscores the responsibility involved, and the large number of patients affected:

Volume and variety of product for all dispensers in 2015

- 81% dispensed more than 1,000 different prescription products.
- Nearly 1 in 3 dispensed more than 5,000.
- 49% of dispensers purchased more than 100,000 eaches.
- 10% bought over 5 million.

Prescriptions Filled Per Dispenser in 2015



Conclusion: Dispensers will experience ongoing change through 2023, but can take steps now to prepare for it.

As DSCSA continues to roll out between now and 2023, dispensers will consistently face change – from trade partner requirements and regulations, their own official deadlines, and more.

But there is a steady constant: The pharma supply chain is progressing toward an electronic-only future. It starts this November with the manufacturer deadline and culminates in an electronic unit-level traceability system in 2023. Preparing for this change can begin with a single mission: Start transitioning your operations today to be ready for an electronic, serialized world.

By phasing out paper and putting electronic systems in place, you'll begin the process of mitigating risk and future-proofing your business. Your hospital or pharmacy will be well-positioned for this November's manufacturer deadline, and have the foundation to manage every DSCSA regulation, trade partner consideration, and operational permutation for years to come.

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