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Pharmacies and Recalls: Understanding the Impact—and Changes to Come

Hospital and retail pharmacies manage an average of 456 non-compounded prescription drug-related recalls* from the US Food and Drug Administration (FDA) each year. If you have pharmacy oversight responsibilities, you know that managing recalls puts a significant burden on operations, and may even require dedicated staff. But you may not understand exactly why recalls are currently so time-consuming and—more importantly—how the introduction of serialization under the Drug Supply Chain Security Act (DSCSA) and supply chain digitization has the potential to transform the recall process. Read on for a refresher on how recalls work today; a discussion of the current challenges; and a glimpse of how serialized product in the supply chain will be a game-changer.

Recalls today: Mass notification and costly remediation

Currently, manufacturers push out their recall notifications to the FDA, recall alert manager services, and direct distribution partners of the recalled products. At the same time, they issue a mass communication via a press release and a letter to media and product alert services. In turn, the recall alert manager services and distribution partners pass along the information to all of their dispensers. They do this regardless of whether the pharmacy has purchased the product or not, which means pharmacies spend a lot of energy processing recalls that may not actually impact them or their patients.

Pharmacies could receive 8-10 alerts for just one recall—for product they may or may not have purchased—from:

- **The Manufacturer.** If the product has been distributed direct from the manufacturer, the manufacturer alerts the dispensing pharmacy via email, fax, or mail indicating severity, the National Drug Code (NDC)/Lot, and instructions on how to respond.
- **The Wholesaler.** If the product has been distributed by a wholesaler, they send a " sub recall" on behalf of the manufacturer or repackager, alerting the pharmacy via email, fax, or mail indicating severity, NDC/Lot, and instructions on how to respond.
- **Recall Alert Management Subscription Services.** If pharmacies subscribe to services like RASMAS, they will receive additional duplicate notices, which adds to the number of alerts.

Once this flurry of alerts comes in, hospitals and pharmacies spend considerable time managing each recall, including:

- Logging the receipt of the recall notice in their system.
- Determining whether the recalled product was purchased by them or not by manually checking their inventory database and/or their shelves.
- If the recalled product was purchased, ascertaining its current location in order to gather it up and quarantine it in a secure location so it can't be used.
- Disposing of or returning the recalled product.
- Documenting this whole process.

On average, it takes 5 hours to respond to one recall, with an associated labor and lost productivity cost of $100 per hour. With 456 recalls per year, that's 2,280 person hours spent on recalls, and $228,000 per year in labor and lost productivity.

The average pharmacy spends 2,280 person hours a year on recalls—and $228,000 in labor and lost productivity.

Another potential cost? Patient safety

The inability for hospitals and pharmacies to immediately determine if they actually purchased a recalled product impacts more than their operational efficiency. It also has the potential to impact patient safety. While pharmacy staff are going through multiple recall notifications and checking shelves for products they may never have purchased, it

may take longer to address a recall for a product they did purchase and have potentially dispensed, which—depending on the severity, or class, or the recall—could have a significant impact on patient health.

Potential for Change: Serialization data

DSCSA requires that manufacturers begin serializing product in November 2018, and that beginning in November 2019, wholesalers ship only serialized product to their pharmacy customers. That means that your pharmacy will increasingly receive products with a unique product identifier ("serialized data") at each lowest saleable unit and sealed homogenous case on the scannable **2D barcode** that consists of four data elements:

- 1. National Drug Code (NDC)
- 2. Serial Number
- 3. Lot Number
- 4. Expiration Date in both a machine-readable and human readable format

If this serialized data is used in partnership with a digital information network, it has the potential to transform recall management:

- Upon receipt of the product, you will scan and check the data against a service to see if that specific product and lot number has already been recalled. This enables a protective measure before that recalled product enters inventory, and is

potentially dispensed to patients.

- Receive only relevant recall alerts—and just 1 per recall—in real time via a repository of recall notifications that are targeted by serialized data you have previously scanned in. This targeted approach reduces recall response time.
- For serialized products already on the shelves, a recall triggers a notification that you received a recalled product and lot at a certain location on a certain date.
- For larger pharmacies, there are additional advantages. For example, if you buy 100 bottles and parse out 10 bottles to each location, you can use the unique identifier on each bottle to see where each recalled bottle is located, and pull just those bottles off of the shelves rather than having to review all products on the shelves in each location.
- When you return the recalled product, you can electronically notify the manufacturer that you have the product and specify which serial numbers you are sending back.

Pharmacies that capture, store, and access product data on a connected data network can realize significant business value and operational efficiency in the form of faster recalls and inventory management—which ultimately benefit their patients, as well. Contact TraceLink to learn more.

* Per the FDA drug recall enforcement reports.

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I'd like to learn more about serialization solutions from TraceLink.