RESOURCES



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 U.S. 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—you might not how the introduction of serialization under the U.S. Drug Supply Chain Security Act (DSCSA) and supply chain digitalization 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

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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 various sources, including:

- **The Manufacturer.** If the product has been distributed directly 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 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.
- Ascertaining current location of recalled product to gather it up and quarantine it in a secure location so it can't be dispensed.
- Disposing of or returning the recalled product.
- Documenting this whole process.

On average, it takes 5 hours to respond to a single recall, with an associated labor

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and lost productivity cost of $100 per hour. With 456 recalls per year, that’s 2,280 hours spent on recalls, and $228,000 per year 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.

For example, while pharmacy staff are searching their shelves looking for a product involved in a Class I recall, other product involved in lower priority Class II and Class III recalls will sit on shelves where it could potentially be dispensed. Now imagine if the pharmacy finishes their investigation and discovers they never actually purchased the product in the Class I recall—that's hours or even days that the Class II and Class III product were left untouched, posing significant patient safety risks.

Potential for change: Serialization data

As of Nov. 27, 2025, all manufacturers, distributors, health systems, and retail pharmacies will be required to exchange serialized product data in compliance with DSCSA. That means that wholesale distributors and pharmacies will increasingly be receiving products with a unique product identifier (“serialized data”) at each lowest saleable unit and sealed homogenous case on the scannable **2D barcode**. This barcode 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 wholesalers, health systems, and pharmacies could easily crosscheck recall data and instructions against the serialized data captured for DSCSA compliance, they

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could to transform the end-to-end recall management process. Just imagine if:

- Staff could scan product on receipt and check the data against digitalized recall notices to see if that specific product and lot number has been recalled. This would prevent them from receiving recalled product into inventory, where it could potentially be dispensed to patients.
- Organizations received only relevant recall alerts—and just one per recall—in real time via a repository of digitalized recall notifications. This would tremendously reduce the amount of recall noise.
- Site leads could determine whether they had received deliveries with product involved in a recall with a quick report generated by their compliance solution. And that same report would precisely identify which sites received the recalled product, the quantity of recalled product received, and the date of the delivery. This would reduce the number of aimless shelf walks and speed the initiation of product searches.
- Digitalized recall data could be shared via API with other critical inventory systems like medication management systems. This would enable staff to find and retrieve recalled product even faster, giving them more time to perform other critical duties.
- All recall coordination and communication happened on a single digital platform. Not only would this limit miscommunication stemming from lost emails and missed phone calls, it would also enable recall activity to be captured instantly and reported back corporate to improve visibility and generate audit trails.

This is no longer just a concept. TraceLink's Digital Recall solutions provide wholesale distributors and pharmacies with all of these capabilities and more, enabling them to realize significant business value and operational efficiency from their DSCSA compliance investment. Get in touch to schedule an assessment—we're happy to look at your current recall process and identify opportunities for improvement.

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* Per the FDA drug recall enforcement reports.

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