



## RESOURCES

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# A Day in the Life of Handling Recalls



If you oversee pharmacy operations, you know how busy your team is each day with dispensing medicines, communicating with physicians, and other core tasks. When a drug recall is added into the mix, managing that recall can quickly derail pharmacy operations for the day.

View this infographic to:

- Get a glimpse into a day in the life of recall management.
- Understand the true cost of recalls to your bottom line and patient health.
- Learn why serialization is the right way to handle recalls.



## A Day in the Life of Handling Recalls

Understand the daily impact of fully responding to every recall today, and how the advent of serialization in the supply chain promises improvements—for your bottom line and patient health—for tomorrow.



**MEET PAUL.**  
He was hired as a Pharmacy Tech, but spends the majority of his time managing recalls.



It takes **5 hours** to respond to just one recall. The countdown starts now.

- 9:00 a.m.**
- Recall notifications have arrived overnight via email, mail, and fax.
  - Class I, II, and III recalls are mixed together, including for products not purchased.
  - Manual review of all notices for ones marked "Urgent," denoting Class I.



- 9:30 a.m.**
- Discover Class I recall.
  - Search in-store product database for match.
  - Product located in database; review details for lot level match.
  - In stock product and lot matches recalled product.



- 10:00 a.m.**
- Patient arrives to pick up a prescription.
  - Prescription is for the Class I recalled drug.



- 10:30 a.m.**
- Call patient's doctor's office.
  - Notify them about the recall and medicine change.
  - Patient is given a non-recalled medicine.



- 11:00 a.m.**
- Place the recalled drug bottles on a shelf in quarantine.
  - Label the shelf "Recalls—Do Not Use."



- 11:30 a.m.**
- Check the database for patients who have the recalled drug.
  - Find 35 impacted patients.



- 12:00 p.m.**
- Call those patients' doctors' offices to alert them of the recall.

**Did You Know?** Per the FDA policy, the physicians are the ones responsible for deciding whether the impacted patients are to be contacted.

- 1:30 p.m.**
- Create and post a flyer for other pharmacy staff about the recall.



- 1:00 p.m.**
- Write and send an email to the other pharmacists about the recall.



- 2:00 p.m.**
- Pack the recalled bottles for return.
  - Notify the distributor about the recalled meds being returned.



- 2:00 p.m.**
- Place a note in the pharmacy database to prevent further shipments of the recalled drug from being received.



- 2:30 p.m.**
- Review the 5 Class II recalls and the 8 Class III recalls.
  - Search database for product matches.



- 3:00 p.m.**
- Found Class II recall in database; review lot level details.
  - Lot level number was different. Not a match.

5 hour mark



- 4:30 p.m.**
- Write and send an email to the other pharmacists about the recall.
  - Create and post a flyer about the recall.
  - Place a note in the pharmacy database about the recall.



- 4:00 p.m.**
- Put Class III recall from inventory.
  - Pack the recalled bottles for return.
  - Notify the distributor about the recalled meds being returned.



- 3:30 p.m.**
- Found Class II recall in database; review lot level details.
  - Lot level number is a match.

### ALL RECALL CLASSES AREN'T THE SAME

The U.S. Food and Drug Administration (FDA) defines three classes of recalls to indicate the severity of the threat.

- CLASS I:** Most urgent; has the potential for serious health problems and even death. Rare, but should be responded to immediately.
- CLASS II:** Has the potential for temporary health problems and are seen as a lesser threat, although the risk of death or injury may still be there.
- CLASS III:** Unlikely to cause an adverse health reaction. Drug has been contaminated by a non-harmful ingredient.

However, notifications for all three recall classes are issued in the same way, without distinction, making it challenging for pharmacies to triage the ones most likely to endanger patient health.

### THE TRUE COST OF RECALLS



**456**  
Average number of annual non-compounded prescription drug recalls

**5**  
The person-hours to respond to each recall in a clinical/hospital pharmacy

**\$100/hour**  
In labor and lost productivity cost

**\$500**  
Average cost of a recall

**\$228,000**  
Maximum estimated financial impact per system based on response to 100% of recalled drugs

### SERIALIZATION: THE RIGHT WAY TO HANDLE RECALLS



The Drug Supply Chain Security Act (DSCSA) requires that wholesale distributors ship only serialized product by November of 2019. At that time, pharmacies will be receiving products marked with 2D barcodes of unique identifiers (UIDs), including a serial number.

Using an information sharing platform and 2D barcodes to exchange data, the recall management process will be simplified:



- As soon as a recall is initiated, **pharmacies will be notified immediately** via a targeted alert of any impacted purchases based on specific purchase history.
- When product is received, **pharmacies will be alerted to a potential recall** when they scan the 2D barcode.
- It will be very **clear from a recall notification whether a product was actually received/purchased** by the pharmacy.
- Alert fatigue will be eased since **you won't receive recall notifications for products that were not received/purchased**.

This will all cut recall management time in half, increasing operational efficiency and cost reduction.



## United States

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Learn more about the value of serialized data in pharmacy operations.

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