

Best Practices for Recalls in Hospitals

September 2009 Draft

Developed by participants at the meetings of the California State Board of Pharmacy's Subcommittee to Evaluate Drug Distribution in Hospitals

Note: This draft will become a best practices guidance document (not law, statute or regulation) for recalls in hospitals. Interested parties are encouraged to review the information below and provide comments and augmentations will lead to development of an optimal list of actions to take to remove recalled drugs from all patient care areas in hospitals. These comments can be returned to: Executive Officer Virginia Herold at virginia_herold@dca.ca.gov

The best practices for hospitals to follow in response to recalls can be summarized as:

1. Pre-position the facility to receive early notice of recalls from multiple sources,
2. Identify if the facility has the product,
3. If so, quickly remove the product from all patient care areas,
4. Identify, assess, notify and treat patients who may have received the product,
5. Identify alternative products to maintain therapy,
6. Return the quarantined product,
7. Evaluate the process.

Best Practice Actions for Recalls:

A product recall includes any notice from a drug manufacturer, wholesaler and/or FDA to return a drug product or medical device due to suspected contamination or defect.

There are seven parameters that should be included in preparation and activated in response to any recall. These are:

- Training of staff
- Notification receipt of the recall
- Evaluation of the recall and determination of the action plan
- Communication of the recall
- Removal of the recalled drug
- Documentation of the recall action
- Followup and monitoring.

Pre-Recall Planning

Procedural:

The pharmacy department has direct authority and ultimate responsibility for implementation of the facility's recall policy and procedures.

The pharmacy department is to develop and implement written policies and procedures for the effective and efficient removal of recalled products from all patient care (inpatient and outpatient) areas and storage areas. However, policy and procedure development must be multidisciplinary in approach. At a minimum, representatives from nursing, medicine, pharmacy services and administration should be involved. The focus should encompass all patient care areas, including outpatient services.

1. Components of written procedures for recalls.
 - Include a duties or detail list with all steps needed during a recall so that any staff member can effectively carry out the steps. The procedures shall identify the specific roles and responsibilities of all personnel involved in the recall process in sufficient detail to ensure maximum compliance.
 - Ensure knowledge of drug recall procedures by developing facility-wide systems and providing periodic training at least annually.
 - Ensure personnel designated to receive, interpret and disseminate information on recalls are competent to perform such duties. Competency shall include, but is not limited to:
 - Knowledge of federal and state regulations governing drug product or medical device recalls.
 - Establishment of a centralized method to receive, interpret and disseminate information about recalls, especially Class 1 recalls.
 - Ability to discern the actual or potential clinical significance of the recall on patient care.
 - Ability to readily identify all storage and/or use areas for any recalled product.
 - Communication of all pertinent recall information to all impacted areas, including appropriate staff in a timely manner.
 - Establish timelines for completion of each task.
 - Ensure the recall process is capable of activation at any time.
 - Limit and identify the number of people pulling the product during a recall for better accountability and control. Specify who is responsible for checking which areas.
 - Establish a dedicated and trained recall team that knows all the policies, procedures and pertinent regulations.
 - ~~Identify individuals pulling products in each location.~~
 - Require individual departments to verify in writing or via a signature that they looked for the recalled product.
 - Identify avenues for notification for communication throughout the organization (email, fax inter-campus, interoffice mail, hospital newsletter – some of these methods are too slow but can serve as reminders).
 - Post flyers about recalls; for example, post flyers saying “bad heparin” with the lot numbers. This information will be shared with the nurses.
 - ~~Offer a reward. (One facility offered a reward if \$10 per vial of recall, that was increased by the administrator to \$100 per vial.)~~

- Recall notices are received by designated facility staff. All facility action is fully documented. Recall notices are centrally located and readily retrievable.
 - Recalled drugs identified as recalled and stored in the pharmacy must be clearly labeled as “recalled” and sequestered in a quarantine area to prevent inadvertent redistribution
2. Know drug storage areas in hospitals:
- Identify all locations where drugs are kept throughout the hospital: storage outside these areas shall be prohibited, with the exception of bedside storage.
 - Maintain control over drug storage everywhere in the hospital.
 - Set up an organized storage facility for drugs so there is just one place to go.
 - Allow no drugs in the hospital that were not purchased through the pharmacy. There should be no allowance for drugs to be brought in for patient use without the express knowledge and approval of the pharmacy department.
 - Minimize the number of and maximize the quality and authority of the individuals carrying out monthly inspections. Ensure that someone is authorized to do what is necessary to secure the drug supply throughout the facility.
 - Establish a redundant system approach for the identification, sequestering and removal of recalled products.
 - Establish a method to ensure all drug storage areas are checked, and then perform an audit. For example, if recall notices are faxed to all pharmacies and responses confirming that all recalled drugs have been removed are expected within 72 hours. After the faxes are received, consider double checking via audit of the drug storage locations.
 - Ensure that recalled drugs and devices are secured by the pharmacy in an area clearly designated as a quarantine area until disposed of as directed in the recall notice.
 - Medical devices should be inventoried and controlled in a manner that facilitates their rapid location by the manufacturer, model product or serial number.
3. Additional steps:
- Monitor subsequent product shipments to ensure recalled products are not shipped into the facility.
 - Establish a system by which patients who may have been affected by the recalled product and identified, notified and assessed for any adverse outcome.
 - Establish a system to monitor implementation on a regular basis to provide insight into opportunities for process improvement.
 - Designate an individual to identify a suitable replacement product that can be used in place of the recalled product.
4. Quality Assurance and Process Improvement:
Implement monthly reporting of recall activities. Such reports should include:
- The number of recalls received by the organization.
 - The number of recalls requiring action by the organization.
 - The amount of time from receipt of the recall notice until closure is attained.

- The number of patients affected or potentially affected, including any adverse outcomes.
 - The location and quantity of recalled product returned.
 - Identification of any problems encountered with the recall process.
 - Share these reports with staff to review and identify opportunities for process improvement.
5. Activities with drug wholesalers to improve recalls:
- Have a wholesaler representative dedicated to the hospital or hospital group. (Alternatively, designate one person as the hospital's liaison with the wholesaler.) This person can run reports and identify recalled drugs purchased by the hospital.
 - Require that all drug purchases be made under the control of the pharmacy.
 - Collaborate and communicate with the wholesaler on drug shipments and recalls, including shipments after a recall is announced.
6. Technology-based solutions:
- Maintain all stock in automated dispensing cabinets (Pyxis, Omnicell) to easily and quickly do an electronic lockout for recalls.
 - Implement an adverse drug reaction system that allows better tracking what occurred in relation to a recalled drug being administered to patients. Outcome: better communication with patients.
 - Obtain an electronic receipt of recall notices from multiple sources.

IMPROVEMENTS FOR THE SYSTEM:

1. Notification System for Recalls Needs Improvement:
- Have a more effective notification system that originates in one place, listing what the issue is, what should be done, what steps should be taken, etc. Having one notice from one source with all the relevant information would minimize confusion.
 - Recall notices should state whether the recall is a Class I, II or III recall. Also, notices should have clear instructions about what actions to take.
 - Recall messages are not always clear. Improve and simplify messages regarding recalls. Create recall notices with more uniform language or have the notice come from one source.
 - Establish a centralized method to interpret and disseminate information about recalls.
 - Have a centralized system or body in a hospital that would distribute recall information though email. This would create better accountability and better response time.
 - Improve coordination of recall notices especially for ubiquitous products.
 - Encourage wholesalers to take more responsibility in terms of communicating recalled lot numbers.
 - Encourage the FDA to develop a standardized format for recalls, including listing the reason for the recall, so adherence is easier to achieve.

- Recalled products repackaged under another name or brand by a different distributor should be recalled by all names, and a separate recall notice should be listed for the distributor.
2. Establish Tracking of Drugs Throughout the Hospital:
- Institute bar coding to better track drugs throughout the facility. Hospitals need to prioritize bar coding technology.
 - Electronic tracing or notification (e.g., secure email) of recall would be helpful.
 - Institute RFID or bar codes and advocate to have standardized methodology in the way the information is sequenced. This should apply to the entire lifecycle of the product.
 - Establish radio frequency identifiers as a way to track drugs (a non-line of sight read) this would be one way to carry e-pedigree. E-pedigree would be a way to better execute a recall.
3. Methods of Obtaining Recall Information:
- Recall notices can arrive at hospitals via fax, certified letter, standard mail, emails from manufacturers, wholesalers, or notices with invoices for other drugs. Listserves of the FDA (<http://www.fda.gov/Safety/MedWatch/default.htm> or the California Board of Pharmacy and other entities can provide recall information.
 - Redundant notification systems should be established: facilities are encouraged to subscribe to more than one listserves available for product recalls. Sole reliance on recall notification via the US Postal Service is not acceptable.
4. Administrative Policies
- ~~One department has to take responsibility for something that is the responsibility of the whole hospital. The emphasis needs to be placed on the CEO or president instead of the PIC; if so, a lot more action might have been taken.~~
 - Require that drugs be stored in specific locations and institute consequences when drugs are stored out of the area .
 - Expand policies to increase responsibility of other department heads during a recall.
 - Increase authority of PIC to better control where and how drugs are stored.
 - Increase accountability. All health care providers that are touching the drug are accountable.
 - At the site level, involve nurses, physicians, dialysis tech, therapists, and administrators in discussion about accountability. Pharmacists need more authority if held accountable.
 - Bring together management, California Hospital Association, Medical Board, Nursing Board. Other health care providers should be willing to accept citations and fines for their failure to follow the facility's recall procedures.
 - Increase accountability and collaboration among members of the health care team. There is a lack of consequences for other health care professions.

5. “Geographic” concerns:
- Have a better system to identify outpatient clinics that are on the facility’s license. This would help clarify what a PIC is responsible for.
 - The PIC should work with the hospital regulatory department to identify what is under the hospital license or clinic license.
 - The PIC should ensure that all recalled drugs are removed in both surveyable and on-surveyable patient care areas.
 - Establish an authorized storage area. If something is not in an authorized storage area, then it is stored unlawfully.
 - Outside medications from vendors or contractors should not be allowed in the hospital.

Examples of a recall plan and components of a recall plan

A designated “recall coordinator” within the pharmacy department will be responsible to coordinate any recall effort. This individual will alert the recall/alert team

1. Evaluation of the recall and determination of action plan

- The pharmacy recall coordinator, with oversight of the PIC, will develop an action plan (with time frames) based on the classification of the recall or the significance of a voluntary manufacturer recall.
- When a recall is issued, the recall coordinator will review the situation and activate a Recall/Alert Team within the pharmacy department.

2. Communication of the recall

- For class 1 recalls, the pharmacy recall coordinator shall communicate immediately to the PIC, pharmacy department manager, and hospital administrator on call.
- The recall coordinator shall notify pharmacy staff of recall notification by standardized communication methods.
- The pharmacy recall coordinator shall notify designated directors/managers and clinics of recall notification by standardized communication methods. This will include the anesthesiologist for medications that are stored in the surgery or recovery areas.
- The recall coordinator shall direct pharmacy staff to search their assigned drug storage areas.
- Designated directors/managers of departments with drug storage areas will communicate recall information to their staffs by standardized communication methods.

3. Removing the recalled drug

- The pharmacy department will reference its list of all approved medication storage areas throughout the facility.
 - Medications located outside of the pharmacy must be stored in designated storage areas approved by pharmacy.
 - All approved drug storage areas and potential drug storage areas, identified by staff, are inspected.
 - Recalled drugs that are found during the inspection process are immediately isolated from drug stock areas and returned to the pharmacy to prevent use.
 - All recalled drugs are quarantined within the pharmacy in a location that is distinctly removed from any medication routinely used for treatment, and clearly marked as quarantined.
 - The recall coordinator assigns pharmacy staff to inspect all areas within the pharmacy department to remove a recalled drug from stock.
-
- The pharmacy buyer or designee contacts the drug wholesaler to confirm that the wholesaler is aware of the recall and has taken steps to remove the recalled drug. (as an alternative, the facility and the wholesaler may develop a communication tool that identifies that the wholesaler has responded to the drug recall).
 - Reports for all automated medication cabinets (e.g., Pyxis, Omnicell) are generated to determine the location of potentially recalled medication. However such reports should not replace a physical inspection of each storage area.

4. Documentation of the recall action

- A readily accessible detailed report (Drug Recall Log) of the medication storage areas will be created and maintained within the pharmacy with specific drug recall information. The report will contain at the least, the date of the storage inspection, who inspected the area, and the results of the inspection.
- The recall coordinator will monitor the recall periodically to confirm documentation and insure that the inspections are completed within the time frame prescribed by the action plan.

5. Follow-up and monitoring

- The recall coordinator will notify executive leadership when the class 1 drug recall process is complete, and provide updates as necessary.
- A summary report of any class 1 drug recalls will be submitted to an appropriate committee (e.g., the Pharmacy & Therapeutics Committee).
- The pharmacy buyer or designee will confirm that the recalled product is not being shipped into the facility by the wholesaler or other sources for 30 days following the drug recall notice.
- The recall coordinator shall ensure adherence to the manufacturer's or FDA's recall guidelines for destroying or returning the recalled product to the designated shipping point.

- The recall coordinator shall ensure adherence to the manufacturer's or FDA's recall guidelines for destroying or returning the recalled product to the designated shipping point.
- Patient medication profiles are reviewed BY WHOM? to determine if patients may have received the recalled drug.
- If it is determined that it is likely that a patient received a recalled drug, the patient's primary physician is notified and provided with the specific recall information.
- The recall coordinator will audit the recall report periodically to confirm documentation and insure that the inspections are completed within the time frame prescribed by the action plan.

NOTES:

- 1) All pharmaceutical products for an institution must be received through the pharmacy services department unless specific approval is given by the director of pharmacy.
- 2) Encourage the use of technology (RFID, e-Pedigree or bar codes) to facilitate quick identification and storage of recalled drugs.

FDA Classification

Product recalls may be classified as I, II or III relative to the degree of health hazard presented by the product being recalled. The FDA uses a Health Hazard Evaluation to determine the classification.

- Class I – A situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious adverse consequences or death.
- Class II – A situation in which use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote.
- Class III – A situation in which use of, or exposure to, a violative product is not likely to cause adverse health consequences.