# Best Practices for Recalls in Hospitals

*Developed by participants at the March 2, 2009, Meeting of the Board of Pharmacy Subcommittee to Evaluate Drug Distribution in Hospitals*

Note: This is an early draft of what 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 ensure the effectiveness 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

## Best Practice Actions for Recalls:

Procedural:

- Develop 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.
  - Limit the number of people pulling the product during a recall for better accountability and control.
  - Establish a dedicated and trained recall team who knows all the policies, procedures and pertinent regulations
  - Identify individuals pulling products in each location.
  - Require individual departments to verify that they looked for the recalled product.
  - Identify avenues for notification
  - Have a centralized method to receive and interpret and disseminate information about recalls, especially Class 1 recalls.
  - Post flyers, for example on facility posted flyers saying "bad heparin" with the lot numbers. This information was 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.)

Know Drug Storage Areas in hospitals:

- Identify all locations were drugs are kept.
- 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.
- 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 method to close the loop and perform an audit. (For example, recall notices were faxed to all pharmacies and responses confirming that all drugs were removed were expected within 72 hours. After the faxes were received, an individual conducted site visits to double check.)

Wholesalers

- Have a wholesaler representative dedicated to the hospital or hospital group. (Alternatively, why not have one person be hospital's liaison with the wholesaler.) This person can run reports and identify recalled drugs purchased by the hospital.
- Drug purchases made under the control of the pharmacy.
- Collaborate and communicate with the wholesaler

Technology-Based:

- Maintain all stock in cabinets 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. Outcome: better communication with patients
- Obtain an electronic receipt of recall notices

IMPROVEMENTS

Notification System for Recalls Needs Improvement:

- Recall notices should state whether this is a Class I, II or III recall. Also, notices should have clear instructions about what actions to take.
- Message is not always clear. Improve and simplify messages regarding recalls.
- To avoid confusion, create recall notices with more uniform language or have notice come from one source.
- 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.
- 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

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.

Staffing/Lines of Authority:

- 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.
- Increase accountability and collaboration among members of the health care team. There is a lack of consequences for other health care professions.

"Geographic"

- 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.
- 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.