STATE BOARD OF PHARMACY

DEPARTMENT OF CONSUMER AFFAIRS
SUBCOMMITTEE TO EVALUATE DRUG DISTRIBUTION WITHIN HOSPITALS
MINUTES

DATE:	September 17, 2009
LOCATION:	Department of Consumer Affairs 1625 N. Market St. First Floor Hearing Room Sacramento, CA 95834
BOARD MEMBERS PRESENT:	Kenneth Schell, Pharmacist Member, President Randy Kajioka, Pharmacist Member
STAFF PRESENT:	Virginia Herold, Executive Officer Joshua Room, Deputy Attorney General Kristy Schieldje, Senior Staff Council Robert Ratcliff, PharmD, Supervising Inspector Tessa Fraga, Administrative Analyst
CONSULTANTS PRESENT:	Val Sheehan, Meeting Facilitator Carmen Fraser, Senior Consultant

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The meeting was called to order at 9:15 a.m.

1. Welcome, Agenda Overview, Introductions

Val Sheehan, Meeting Facilitator, introduced herself and Senior Consultant, Carmen Fraser and welcomed the group to the subcommittee meeting, the third in a series of meetings. Ms. Sheehan then introduced Board of Pharmacy staff and board members who were in attendance.

Board President Ken Schell gave opening remarks and noted that the goal of these was to improve patient care by receiving the best input from pharmacists and others concerned with drug distribution in hospitals. These meetings provide an opportunity review and discuss pharmacy law with an eye towards making updates or changes as necessary. He reiterated the need to have an open and frank discussion and "get issues out on the table" so that they can be addressed in the best way possible to protect and enhance the health and safety of the public.

Ms. Sheehan then asked all meeting participants to introduce themselves.

Ms. Sheehan reviewed the proceedings and outcomes of the previous two subcommittee meetings held on March 2, 2009 and June 2, 2009. Ms. Sheehan also reviewed findings from a drug management survey completed by fourteen meeting participants at the June 2nd meeting. Ms. Sheehan acknowledged that while the sample size was small, the preliminary results still offer useful information.

One of the questions on the survey addressed the issue of contracted service providers bringing outside drugs into the hospital setting. One participant commented that patients and researchers can legally bring in their own drugs. FDA-approved drugs, drugs for premarket analysis, anesthesia services, organ procurement, and ambulance services represent other channels for drugs to get into hospitals. Ms. Sheehan noted that seven survey respondents indicated they had a policy banning outside contractors from bringing drugs into the hospital. However, in a related survey question about whether professional or other staff can bring in drugs for administration to patients, thirteen out of fourteen responded "no." Another participant thought the question had perhaps been misunderstood because national regulatory standards state that the pharmacist needs to be responsible for all drugs. Participants discussed the discrepancy between pharmacists being accountable or responsible for all drugs in a hospital without having the authority to control whether or not drugs were being brought into the hospital. There was agreement that a broader set of responses to the survey was needed to get a better understanding of actual practices in hospitals.

Ms. Sheehan presented results of the evaluations of the first two subcommittee meetings noting that participants rated the meetings very favorably. 93% rated the March 2, 2009 meeting as excellent or good, and 82% rated the June 2, 2009 meeting as excellent or good. Meeting participants stated they gained and benefited from:

- good and valuable information;
- opportunity to dialogue with regulators; and
- peer learning and brainstorming.

Ms. Sheehan reviewed today's meeting agenda and reminded participants of the meeting ground rules - open dialogue, collaboration, solution-oriented - as well as meeting courtesies. She noted the meeting was being recorded and that meeting minutes will be posted on the Board's website. She asked if there were any questions and reiterated the opportunities for public comment throughout the meeting.

2. Discussion and Group Presentation of Drug Recall Best Practices for Wholesalers and Manufacturers

Ms. Fraser noted that an important purpose of this series of subcommittee meetings was to provide information on drug recall practices from different perspectives. She mentioned that at the first meeting, regulatory agencies (FDA, CDPH and BOP) outlined their role in the recall process. At the second meeting, directors of four hospital pharmacies discussed policies, procedures and systems related to drug distribution and management in their facilities. At today's meeting, another key player in the recall process, drug wholesalers, as well as a major health service provider discussed how they manage recalls.

Presentations were given by:

- Marjorie DePuy, Director, Industry Relations, HealthCare Distribution Management Association
- Larry Hunley, Distribution Center Manager, McKesson Supply Solutions
- Amy Gutierrez, PharmD, Director of Pharmacy Affairs, Los Angeles County Health Services
- Elizabeth (Betty) Gregg, Manager, Recalls and Licensure, Cardinal Health

Marjorie DePuy – HDMA

HDMA represents thirty-two primary full-service healthcare distributors who deliver healthcare products to 145,000 healthcare settings in the country. One hundred seventy-seven manufacturer members are also represented. HDMA's strategic objectives are to:

- Protect patient safety;
- Create and exchange industry knowledge and best practices; and
- Advocate for standards, public policies and business processes that produce safe, innovative healthcare solutions.

Ms. DePuy outlined drug recalls from a distribution perspective saying that 1) the manufacturer initiates recall/market withdrawal, 2) HDMA members have recall/withdrawal procedures in place, and 3) distributors facilitate communications/product return as instructed. All parties have the shared goal of swift identification and quarantine of recalled product and operate under FDA guidance and oversight. She noted that most distributors and hospitals deal with hundreds of recalls each year.

Ms. DePuy highlighted HDMA's *Product Recall & Withdrawal Notification Guidelines,* developed by a Returns Task Force composed of 25 – 30 manufacturers, distributors and returns processors. This document includes:

- General recall regulations, responsibilities and guidelines
- Instructions for drug recall notice form
- Three sample drug recall notice forms: Wholesale, Retail, Consumer

Ms. DePuy outlined recalls from a company perspective saying that individual companies determine the most effective practices. Companies focus on continual assessment and improvement to secure the supply chain.

Audience members had questions about recall timelines and Ms. DePuy responded that HDMA doesn't set specific timelines for its members. A participant stated that recall timeline standards among all stakeholders would be helpful. The participant also asked whether it was within HDMA's purview to set timeline standards for its members. Ms. DePuy responded that from the Association's standpoint, it didn't make recall-related timeline recommendations to its members, but suggested that the group come back to the question following Mr. Hunley's presentation.

Larry Hunley – McKesson

Mr. Hunley covered the following agenda items during his presentation:

- Pharmaceutical Recall Profile
- Process Overview
- Inventory controls
- Communication
- Product Quarantine Developments.

Mr. Hunley stated that McKesson is involved in a significant number of recall events each year. He presented information on the number of recall/withdrawals in 2007, 2008 and 2009 broken down by the level of notification to wholesaler, retailer/hospital or consumer. The same product can have multiple events whether through added lots or a change in the notification level. He noted that recalls are increasing and in particular to the consumer/patient level of notification. The manufacturer's recall provider, a third party such as Stericycle or Genco, manages most recalls.

Mr. Hunley described MeKesson's overall recall process. If they receive advance notification, MeKesson immediately quarantines product and lots even if some recall items are pending. Audience members had questions about timing of recall notification. Mr. Hunley stated that the manufacturer determines who issues the recall notification (manufacturer or distributor) however, McKesson notifies its retail customers by both paper and electronic mail in any case. In response to a question whether McKesson makes a distinction about timing of notification to customers depending on its receipt of paper or electronic alerts from manufacturer, Mr. Hunley stated that McKesson is required to notify customers upon receipt of the first recall notice from a manufacturer, whether it is a mail or email notice. A comment was made that during the heparin recall some hospitals received notification from the manufacturer before the wholesaler. Mr. Hunley acknowledged that situation and stated that he wasn't sure whether McKesson was getting notified sooner than the large customers of the manufacturers.

Audience members had several questions about lot numbers and the accuracy of the recall process. Mr. Hunley stated that when a recalled product lot number has been entered into McKesson's SAP system, it cannot be picked and is quarantined in another part of the warehouse. If a recalled product is returned, it is not saleable and is blocked from going back into circulation. For returns, whether recall-related or not, the item is either scanned or

the lot numbers are entered manually if there are no bar codes. If a recall is issued and recalled product is en route, McKesson immediately notifies all customers who would receive it. However this process is not lot-specific.

When ordering drugs, customers go through a portal on McKesson's website, and recall notifications can be seen there. However it is possible for customers to not see the notification if they do not remain on that specific page.

Participants wanted clarification about McKesson's process for blocking a recalled product. Mr. Hunley outlined that if there is a recall notice at 8am, no order placed after that would have recalled product. It's possible that orders received within the previous 12 hours would have recalled product on the trucks that have already left the warehouse. If so, McKesson immediately notifies customers by telephone that a recalled product has been shipped. A participant commented that FDA has specific regulations about the handling of recalls, and 21 CFR Section 7 has information about timeframes.

Mr. Hunley stated that about a year ago his office introduced a system to better handle recalls. A designated staff person works with the inventory department to quarantine the product and identify lot numbers. Before each order is picked, a manager runs a query from the SAP system showing all recalled items and lot numbers. It is not possible for a recalled item to be included in an order's pick slot. Every order is verified and signed off by a manager. Mr. Hunley stated that McKesson monitors the recall process in its distribution center, and it is error-free.

One participant commented that it would be highly useful if recalled product could be identified by lot number, time and quantity so that customers can better track and reconcile their drug supplies. Mr. Hunley agreed that an e-pedigree system of tracking and tracing by lot number would be ideal.

Amy Gutierrez, Los Angeles County Health Services

Dr. Gutierrez gave an overview of Los Angeles County Health Services, but also highlighted a pilot project with their wholesaler, Cardinal Health, focused on more effective drug recall practices. Los Angeles County Department of Health Services is the second largest public health system in the country. It employs 22 licensed pharmacists, fills its own prescriptions and spends $160 million in pharmaceutical products each year. The LA County System features multidisciplinary collaboration among specialty medical expert panels as well as pharmacy and medication safety committees to develop best practices. Dr. Gutierrez chairs the Pharmacy and Therapeutics (P & T) Subcommittee.

Dr. Gutierrez stated the LA County System's previous recall notification process included reporting to LA County Board of Supervisors and receiving a paper recall notice from the wholesaler (Cardinal). They were not satisfied with the existing system and felt that the paper process was unreliable. It was challenging to get notifications to facilities, some notifications were getting lost and recalls weren't being acted upon in a timely manner.

The LA County System issued a new policy in August 2008. The first component of the new policy was to work with Cardinal to devise a better system through a *Wholesaler Collaboration Pilot Project*. They arranged with Cardinal for all pharmacists in the LA County System to receive advance recall notice by email. In the email notice, the wholesaler lists which accounts purchased the recalled product, when the order was placed as well as the type of notification by class. Dr. Gutierrez noted that after the inception of this program, they received more notices from Cardinal than from the MedWatch system through FDA.

The second component of the new policy was a centralized reporting process within the LA County System about actions taken as a result of the recall. Facilities throughout the LA County System use a form to notify the central committee about action taken within seven days of a recall. If it is a Class I recall, they require immediate notification from the facilities. The System's core P & T Committee reviews these forms monthly and decides whether further action needs to be taken.

Dr. Gutierrez stated that many notices from Cardinal were coming as "unclassified retail level." Ms. Gregg commented that the FDA often releases recall notices that have not yet been classified, therefore Cardinal release the notices as unclassified. However at its distribution center, Cardinal treats them as Class II. LA County is now getting notices from Cardinal for recalled products even if they haven't purchased the products.

Ms. Herold expressed concern about the lack of a centralized recall notification system and the inconsistency and unreliability of recall notices. Ms. Gregg stated that Cardinal, as a wholesaler, is never certain it is getting all recall notices from the manufacturer. Manufacturers track by lot number; therefore if a wholesaler didn't purchase that particular lot, they would not receive the recall notice. In addition, the number of FDA MedWatch notices is far fewer than the notices from manufacturers. MedWatch notices often lack the information that is needed for a wholesaler to initiate a recall; Cardinal often calls manufacturers for clarification. Subscription sites have proven to not be very helpful in this process.

A participant commented that while the discussion has focused primarily on hospital based drug distribution, she was concerned about the issue from a broader public health perspective. She asked how independent pharmacies are receiving information about recalls and whether procedures exist to ensure that their patients are not buying recalled drugs? Ms. Gregg responded that such pharmacies would receive retail- and/or consumer-level notifications.

A participant asked whether Cardinal has an internal Cardinal-led recall process if it notices something wrong with a product. Ms. Gregg responded that the product would first be quarantined, and calls would be made to the manufacturer. In such a case, Cardinal would not notify its customers before the manufacturer issued a recall.

Participants expressed concern about the disparity between the number of FDA-issued recalls and the number of wholesaler-issued recalls. Dr. Gutierrez added that the LA County System does not rely on FDA for recall notices because they are often inconsistent, inaccurate or delayed in classification. She noted that food-related FDA recalls are much more numerous than drug-related recalls. From a provider perspective, Dr. Gutierrez stated that knowing about a recall can be more challenging than knowing what to do about it.

Dr. Gutierrez reported that the LA County System was able to evaluate the effectiveness of its new policy because of a March 31, 2009 consumer-level recall of Digoxin. By the end of that day, Cardinal provided a list of all impacted LA County facilities whose pharmacy, medical and nursing directors were affected. By the next morning, all the Digoxin in the LA County System had been sequestered. By the next day, through NDC numbers from a central database, all patients who took Digoxin were identified. By the fourth day a bilingual (English/Spanish) patient notification letter was mailed to all affected patients. To supplement the letter, phone calls were made to patients, and patient charts were updated with this information. Overall, the new notification system was a success.

A participant asked whether patients in one-time use or limited use settings in procedural areas are identified or have received recalled items, even though they may no longer have access to the drug. Given the patient has a right to know, how far retrospectively is LA County required to notify? Dr. Gutierrez responded that there are no lot numbers for inpatient or outpatient services, so it is a challenge.

Betty Gregg – Cardinal Health

Ms. Gregg gave a brief overview of Cardinal Health's current recall process, its trial project with LA County and UCSF, and future recall processes. Prior to working with Cardinal, Ms. Gregg was a hospital pharmacist for many years and therefore understood the concerns participants were expressing.

Current process: Cardinal receives multiple recall notices, but many arrive without enough information to adequately process the recall. To process recalls, Cardinal needs lot numbers. Without lot numbers there is a risk of pulling all of the product, not just the recalled portion, which could add to market shortages. Within half an hour of receiving a recall notice, Cardinal's corporate office is able to notify its distribution centers. Distribution

centers are required to quarantine the product by the end of day. Cardinal creates a daily recall list, and distribution centers are required to check so that recalled product does not get into live inventory. Cardinal's customers will receive a notification within the first twenty-four hours.

Trial Project with LA County and UCSF: After the heparin recall, Cardinal was asked to pilot test a better notification system. This involved sending an email alert to customers in addition to the speedy-gram printed notice. Customers were responsible for providing and updating the email contact list for Cardinal to use. Ms. Gregg noted that LA County and UCSF are now getting notification sometimes twelve to twenty-four hours in advance of customers who are not involved in the trial project.

Ms. Gregg reiterated the three levels of recall notices, and noted that, unlike the Digoxin example described by Dr. Gutierrez, a wholesaler-level recall would not affect customers. An example of a recall that would only go to the wholesaler level would be a minor packaging issue or something that has minimal effect on patient safety. One participant commented that a wholesaler recall could affect market availability depending on their share of the market. Customers may need to know about wholesaler recalls because they have to plan for shortages. In addition, manufacturer's field corrections can have the same impact on market availability.

Ms. Gregg noted that the FDA has been doing more effectiveness checks lately and in particular the last six weeks.

Future recall process: Cardinal would like to develop an electronic notification system for recalls. Two aspects of importance are: 1) whether such a system meets FDA requirements and 2) the degree of customer ownership of the process in terms of participation. Cardinal is now in a fact-finding stage to see how the proposed system would work from corporate, distribution centers' and customers' standpoints. Cardinal expects the new recall notification system to be activated in the summer of 2010.

One participant asked why the number of recalls has been escalating over the last few years. Ms. Gregg noted the lack of good manufacturing standards and practices as well as assay findings of sub- or super-potency or contamination. Another participant commented that the manufacturing of drugs outside the country could be a contributing factor. Within five years, it is estimated that 85% of pharmaceuticals will be manufactured off shore. Other participants noted that a lack of FDA enforcement could be part of the problem. Ms. Herold noted that in October 2008 a Federal FDA study was released which concluded the recall system works and that there is no intention to modify existing procedures. This was the opposite of what California concluded. Ms. Sheehan noted that California has the opportunity to play a leadership role in closing the gaps in the system.

A comment was made that manufacturers should be part of this meeting process; manufacturers need to be sensitive to how their recalls affect the health care system. Another participant commented that other players such as physician-owned and operated entities also need to understand the system. The medical and dental communities need to be brought into this process as well.

3. Discussion and Possible Action to Develop Drug Recall Best Practices for Hospital Pharmacies

Virginia Herold, Board Executive Officer, thanked wholesalers for their input and the efforts they have made to correct deficiencies in the recall process. She then presented a draft best practices document and requested feedback from meeting participants. While hospitals would not be mandated to follow these best practices, Ms. Herold emphasized that hospitals should consider following them. This document was developed based on input received during the first two meetings as well as suggestions submitted to the Board directly. The underlined text generally represents the additions to the document since it was first presented at the June 2, 2009 meeting. Meeting participants had several questions and comments (summarized below). Ms. Herold stated that the revised document would be circulated again, finalized and brought back to the Board in October. Dr. Schell and Ms. Sheehan thanked Ms. Herold for her work in assembling the various comments and creating this document.

Ms. Herold summarized the main best practices in a recall process and elaborated on them by reviewing the document:

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.

One participant wanted some type of measurable objective (for example: "a successful recall is defined as…") so that hospitals can know whether they are successful. She thought a hospital could follow all best practices and still be perceived as doing a successful recall. Ms. Herold stated that the specifics regarding timelines have to be decided upon at a facility level otherwise it could be perceived as too much regulation. Kristy Schieldje, Board Counsel, added that such language could be interpreted as prescriptive and perceived as regulatory and would require a full APA process and noticing.

A participant asked whether the document addressed hospitals only or other providers. Ms. Herold stated that the subcommittee's immediate task was to address hospital-based issues of concern. While it's clear there are other issues of concern, the purpose of this document at this meeting at this time is to find a collective consensus for best practices. She added that other pharmacy law-related issues and concerns could be brought forward at the Board's October meeting.

A participant commented that the word "product" should be defined as "drugs and devices." There is a concern that some devices are "just appearing" in the hospital without the pharmacy director's knowledge. FDA classifies drugs differently from devices. Participants reached consensus that "pre-filled drug-containing devices" would be good language. 42 CFR §482 addresses whether devices used to deliver medications are recalled products. Ms. Herold clarified that the federal definition of devices will be used.

A participant commented that the term "hospital" needs to be defined. Some pharmacists do not have authority over outpatient facilities (such as an outpatient dialysis unit) owned by a hospital but not under the hospital license. Dr. Schell acknowledged this as an area of conflict because such facilities may be using the license to purchase drugs but are not under control of the hospital pharmacist. Loriann DeMartini, Chief Pharmaceutical Consultant, California Department of Public Health (CDPH), Center for Healthcare Quality (licensing and certification), clarified that CDPH, under its state or federal authority, only looks at services that are on the hospital license. The CDPH license is issued annually and is clear about physical location. The hospital must specify services provided at different locations, and this is used to establish boundaries of oversight. One participant commented that actual practice and the license do not always match. Dr. DeMartini suggested that such facilities work directly with the CDPH District Manager and stated she would be willing to help facilities to clarify their licenses. Dr. Ratcliff referred to Title 22 which states the PIC is responsible for purchase of all drugs in the institution. Whether or not another department purchases the drugs, in its inspection and enforcement efforts, the Board of Pharmacy will hold the PIC responsible. Ms. Herold clarified that the consolidated license will define the community to whom the Best practices document applies.

A comment was made that if the hospital pharmacy takes the lead in setting recall policies then hopefully those are followed by materials management departments for devices. There are many non-pharmacy hospitals in the state, and they also need best practices procedures. This best practices document could serve as a model for a system-wide improvement in recalls. Ms. Herold agreed.

A comment was made about the challenge of knowing about the drugs in ancillary storage areas and that this is more of an administrative leadership issue. All hospitals already have a policy that the PIC predetermines what the storage locations are; compliance is much more of an issue.

A participant asked whether this document is an optimal best practice or a minimum standard. Ms. Herold responded that if it becomes a minimum standard, this would be the result of a statute or regulatory change. The Board has not indicated it would undertake a legislative process and instead formed this subcommittee to address best practices. She added that pharmacists are accountable now whether or not there is a Best practices document. The intent is to have a collective sharing to avert another crisis; whether FDA or CDPH does this too is at their discretion. Mr. Room added that the document would not have the force of law. While it is an optimal compliance mechanism, neither is it a defense or safe harbor if recalled product is found. It could be evidence of good faith, but it's not a legal document.

Comments pertaining to Item 2. Know Drug Storage Areas in Hospital:

- A comment was made about clarifying the use and interpretation of the terms "quarantine" and "sequester." For a product to adequately be quarantined it must meet three FDA parameters of separation, barrier, and notice by labeling. Ms. Herold stated the intent was quarantine and that the product needs to be labeled as well as set aside.

- There was consensus to strike the 3rd bulleted statement.

- A participant disagreed with the 4th bulleted statement (first sentence) referring to not allowing drugs not purchased through the pharmacy. Participants agreed the 2nd underlined sentence is more acceptable.

- Under the 7th bulleted statement, rather than specify "72 hours", use language such as "immediately" or "as timely as is reasonably feasible." Because recall timeframes depend on the class of recall, insert language defining these terms as well as examples of expected timeframes.

Comments pertaining to Item 3. Additional Steps:

- Under the 1st bulleted statement, add "or quarantined if they are shipped into the facility."

- Under the 4th bulleted statement, change "an individual" to "a process."

Comments pertaining to Item 5. Activities With Drug Wholesalers to Improve Recalls:

- Add the statement: "establish electronic communication with all wholesalers." A suggestion was made to set up a pharmacy group email box so notifications don't get detained in the email boxes of vacationing employees or those who are quitting. There should be one email account for the hospital so that the PIC receives recall information from all wholesalers regardless of who from the hospital ordered or purchased the drug or device. A participant commented that the same principle should apply to wholesalers; wholesalers should demand of their suppliers/manufacturers that they receive all recalls so that they can be aware of potential shortages.

Comments pertaining to Item 6. Technology-based Solutions:

- A comment was made that there is not enough information to know whether subscription services are effective.

- A wholesaler/distributor participant stated that based on recall notices sent by customers and manufacturers, they are compiling their own email notification services for pharmacy customers. They work with small regional suppliers too, but the notification is being sent to everyone.

Comments pertaining to Improvements for the System:

Item 1: Notification System for Recalls Needs Improvement: Ms. Herold stated that issues related to FDA's delay in classifying a recall would be handled separately in a letter to the FDA. A participant asked about unclassified recalls and where to obtain additional information to make a decision about what action to take. Another participant responded that drug manufacturers are cooperative to the extent they can be, but they don't always have the information; his facility involves medical staff in making a decision. Ms. Herold added that it is important to include the participation of the pharmacist.

Item 2: Establish Tracking of Drugs Throughout the Hospital: Ms. Herold stated this is self-explanatory.

Item 3: Method of Obtaining Recall Information: Ms. Herold acknowledged this could be revised based on today's discussion.

Item 4: Administrative Policies: Ms. Herold stated that this is related to knowing the hospital's CEO and making sure the PIC has the authority to carry out their mandated responsibilities.

Item 5: Geographic Concerns: Ms. Herold stated this item can be blended into Item 2.

Comments pertaining to Example of a Recall Plan and Components of a Recall Plan:

Ms. Herold asked the group for feedback on the Examples of a Recall Plan. Some participants thought it seemed duplicative, while others thought it was a good idea to include as a prototype. Ms. Herold suggested organizing the Best practices document into three sections addressing the 1) Pre-planning stage, 2) Event stage, and 3) Post-event stage. Mr. Room suggested that the Pre-planning section of the front document include a simple statement about the need to establish a recall plan and reference the attached sample plan following that statement. It was noted that Pre-planning included policies and procedures as well as training.

4. Discussion and Development of Suggestions for Possible Legislative and Regulatory Changes to Improve Drug Distribution in Hospitals

Ms. Herold stated that every fall the Board develops a legislative agenda to maintain current relevance with regard to pharmacy issues. Typically the board introduces a couple of bills each year. She invited meeting participants to offer suggestions for legislative changes. This discussion is summarized below. Ms. Herold stated that pharmacists may submit other ideas to her directly or come to the Board's October meeting.

Ms. Herold began the discussion and indicated she would recommend to the Board a change pertaining to satellites. Pharmacies would be required to attach a list of the satellites and their locations to their self-assessment checklist. Ms. Herold noted that unless an item is given enough importance by being included in a statute, it's easy to lose control. She asked the group whether there is a need for a clear legal definition of satellites given the complexities of the various hospital organisms throughout the state. A participant responded that yes, there is a need to define what a satellite or auxiliary pharmacy is.

Joshua Room, Deputy Attorney General, presented a document entitled *Possible Regulatory/Statutory Amendments to Address Real or Perceived Hospital Pharmacy Deficiencies in Authority/Responsibility to Address Drug Recalls and/or Other Matters of Distribution, Control and Recordkeeping*. This document explored the idea that language designating and describing a director of pharmacy services in Title 22 (Code of California Regulations) should mirror that for directors of nursing. Mr. Room noted that the first seven pages of the document are the most pertinent to pharmacists.

- Mr. Room noted that Title 22 is not within the section of the regulations that the Board of Pharmacy has any authority to promulgate, but it is the place to most easily make the change needed to elevate pharmacy directors to a status equivalent to that of nursing directors. This means that CDPH would need to be involved, however they have less autonomy for rulemaking than the Board tends to have. If the Board of Pharmacy pursued this independently, it would have to be done through Title 16 or through statute.

- In reference to the earlier discussion about the Best practices document and pharmacy directors' authority, Mr. Room asked whether such a change would be helpful to pharmacists. He noted that the thrust of such a change would be to require a hospital administrator to designate in writing a Director of Pharmaceutical Services and to provide that person with the authority and resources necessary to effectuate the regulatory requirements. Ms. Herold reminded audience members that this document is very preliminary and that the Board had not yet seen this document.

- One participant asked whether there could be a certification that would spell this out for the Administrator in an effort to make sure they agree with such a change in a Pharmacy Director's status. Ms. Herold asked whether there is an entity that certifies or accredits senior managers/administrators. A participant responded that there is not. Mr. Room noted that no statements exist regarding the qualifications of pharmacists that would be equivalent to the required qualifications for nursing directors.

- One participant commented that giving the pharmacy director authority doesn't necessarily mean resources will be made available. Another participant commented that from a small, rural hospital perspective, decisions about pharmacy resources need to be backed up by legislation.

- There was consensus from group that any support for the PIC's authority, particularly if legislated, would be helpful. One participant dissented saying that minimum requirements would be burdensome to fulfill administrative pharmacy positions, especially in small rural hospitals. Mr. Room responded that the requirements would be written so that they are not burdensome. It was noted that whether the PIC became the Director of Pharmaceutical Services had not been defined. A participant noted there are minimum staffing ratios for nursing and that something similar may be needed for pharmacists. Ms. Herold stated the Board would not be addressing this topic at this time.

- Under Section 70269, the phrase "a list of drugs" instead of the word "inventory" would be more accurate.

Audience members suggested the following additional legislative ideas:

- A participant stated that at a patient care level, the hospital needs to be able to make the decision to keep and perhaps decide to use a quarantined drug with patient consent if there is no alternative product available. Mr. Room responded there is no way to legislate this, but acknowledged there may be a way for the participant to write a proposal.

- A participant expressed concern that pharmacists are being pulled away from clinical duties to conduct floor inspections. Ms. Herold responded that this issue needs to be addressed with CDPH otherwise the Board would be usurping the authority of Title 22.

- A participant commented that for patient safety purposes, proper patient identification is important when picking up prescriptions. JCAHO requires identification for inpatient settings, but this element is missing for outpatient settings. Ms. Herold responded that the Board views this as a medication error and cites and fines the pharmacist. She noted the Board could consider adding more stringent guidelines such as asking for a recipient's birth date. One participant noted that in outpatient settings a complicating factor is that a person other than the patient often picks up the prescription. Mr. Room suggested that pharmacies establish their own procedures rather than seeking to regulate this issue.

5. Identification of Future Discussion Items of the Subcommittee to Evaluate Drug Distribution within Hospitals

Ms. Herold stated that the Subcommittee to Evaluate Drug Distribution within Hospitals has been an excellent forum for discussion and vehicle to address gaps in the recall system. However, Ms. Herold stated that the purpose and structure of the subcommittee may need to change over time depending what the Board deems necessary and optimal. She proposed that this subcommittee become part of the existing Licensing Committee that meets quarterly.

A participant noted that the Best Practices guidelines were not finished. Ms. Herold stated these would probably go to the Board at its October meeting or to the Licensing Committee meeting in December.

One participant asked about the status of compounding regulations inside hospitals versus outside hospitals. Ms. Herold acknowledged this was a topic the subcommittee could pursue. She stated there is currently a proposal under review by the Board and if approved, the regulation will go into effect nine months later.

A participant asked whether there is a committee to look at hospital practice. Ms. Herold responded that there is not, however it could be folded into the Licensing Committee. She encouraged participants to let the Board know what is specifically impeding hospitals' ability to provide quality care considering that the Board's concern is public safety.

Dr. Schell stated he was glad that an ad hoc committee was formed to deal with this topic and added that having a separate subcommittee as opposed to raising these issues in a standing committee, was successful. He invited participants to bring other issues to his attention especially if they are under the purview of the Board.

A participant asked about the process for adopting the possible regulatory or statutory changes related to pharmacy director authority described by Mr. Room. Ms. Herold responded that there are three possible outcomes: 1) the Board could write a letter to CDPH requesting they consider a rulemaking to modify Title 22 or the professional association could submit a similar request to CDPH, 2) the Board could initiate its own statutory modification, or 3) the Board could take no action.

A participant commented that these discussions have been very helpful. He expressed a concern that a more formal subcommittee with more boundaries could hamper the openness of discussion and the spirit of partnership. He encouraged the Board to continue with this type of a dialogue. There was consensus among meeting participants that the spirit of open discussion be maintained.

Ms. Herold mentioned participants were welcome to submit additional ideas for the subcommittee to consider. Dr. Schell indicated that this opportunity would always be available regardless of the specific committee form or structure.

6. Additional Public Comment

Ms. Fraser asked if there was further public comment. Ms. Gregg expressed appreciation for the open communication and educational nature of this subcommittee.

7. Closing, Evaluation, Adjournment

The meeting was adjourned at 3:00 pm.

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 facilities 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.
   - 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.

Nursing Tool
Medication Recall Checklist

Use this tool when inspecting your area for Recalled Medications. Complete checklist and return to the Pharmacy Department within 48 hours of receipt of Medication Recall Alert

Area being inspected: _____ **Date:** ____/____/____

Inspected by: _____ **Contact Number:** X_____

Inspect the following locations	Actions taken/Comments
☐ Med Room Area ☐ Drawers ☐ Cabinets ☐ Carts ☐ Other _____ ☐ Other _____	☐ No product found ☐ Products quarantined ☐ Returned products to pharmacy ☐ Other _____ _____ _____
☐ Nursing Station ☐ Drawers ☐ Cabinets ☐ Carts ☐ Other _____ ☐ Other _____	☐ No product found ☐ Products quarantined ☐ Returned products to pharmacy ☐ Other _____ _____ _____
☐ Other area/room *(specify)* _____ ☐ Drawers ☐ Cabinets ☐ Carts ☐ Other _____ ☐ Other _____	☐ No product found ☐ Products quarantined ☐ Returned products to pharmacy ☐ Other _____ _____ _____
☐ Med Kits, Crash Carts, Emergency Boxes etc.. *(Specify name and location kit/box found, N/A if no such item exists on the unit)* ☐ _____ ☐ _____ ☐ _____ ☐ _____	☐ N/A ☐ No product found ☐ Products quarantined ☐ Returned products to pharmacy ☐ Other _____ _____ _____

1. Pyxis Medstation machines will be inspected by Pharmacy personnel.
2. Focus your inspection on areas OUTSIDE of Pyxis Medstation.
3. Once recalled medication(s) are located, sequester it in a safe place and contact Pharmacy Department at _____ for proper return.
4. Return this completed form to the Pharmacy Department within 48 hours of receipt of Medication Recall Alert via direct drop-off or fax. Pharmacy Fax: _____.
5. For questions, contact Pharmacy Department at _____
6. Thank you for making Sharp Healthcare a safer place.

Sharp Hospital Logo HERE

Medication Recall Alert

To: Managers, Charge & Leads

FDA

Situation: FDA has posted a ***(State the type of recall)*** on ***(State recalled medication here and reason for recall)***. Details of the FDA recall can be found at *(Link to FDA website or* http://www.fda.gov/medwatch/index.html). Below is a list of recalled medications:

- *List item(s) stated in the recall here –*
  - Includes: *List specifics here if applicable or more room needed*

Background: Sharp _____ Department of Pharmacy has been inspecting all drug storage areas for ***(drug/product name here)*** and removing them to ensure they are no longer available for patient use. ** provide any other applicable background information **

Assessment: Recalled products are not acceptable in any unit at Sharp _____ including emergency kits, crash carts, procedural trays, nursing stations, and automated dispensing cabinets (Pyxis®).

Recommendations: Inspect your area for the recalled item(s) listed above. Look in drawers, cabinets, med kits, trays, and any other place medications are stored. Notify Pharmacy at _____ and return any recalled items to Pharmacy within 48 hours of this recall notice. Report any adverse drug events (ADE) associated with the use of ***(drug/product name here)*** through Sharp intranet eQVR system. Only use products provided by Pharmacy as instructed during this recall process. A joint effort among nurses, doctors, pharmacists, and all healthcare staff is required to ensure no recalled products are available for patient use.

For additional information, please contact the Pharmacy Department at _____. Thank you for your attention and your cooperation in this matter.

Distributor Perspectives on Recalls/Withdrawals

for the CA Board of Pharmacy Subcommittee to Evaluate Drug Distribution in Hospitals

Marjorie DePuy
Director, Industry Relations, HDMA
Larry Hunley
Distribution Center Manager
McKesson Corporation – West Region

September 17, 2009

HDMA
Healthcare Distribution Management Association

HDMA – Who We Represent

- Active membership includes 32 primary full-service healthcare distributors
  - National, regional, specialty
  - 164 distribution centers serving all 50 states
- HDMA's members offer value-added services that help ensure safe and timely delivery of healthcare products to 145,000 healthcare settings
- Associate membership includes 177 manufacturer members

Healthcare Distribution Management Association

HDMA Strategic Objectives

- Protect patient safety and access to medicines through the safe and efficient distribution of healthcare products and services
- Create and exchange industry knowledge and best practices to enhance the value of the healthcare supply chain
- Advocate for standards, public policies and business processes that produce safe, innovative and cost-effective healthcare solutions

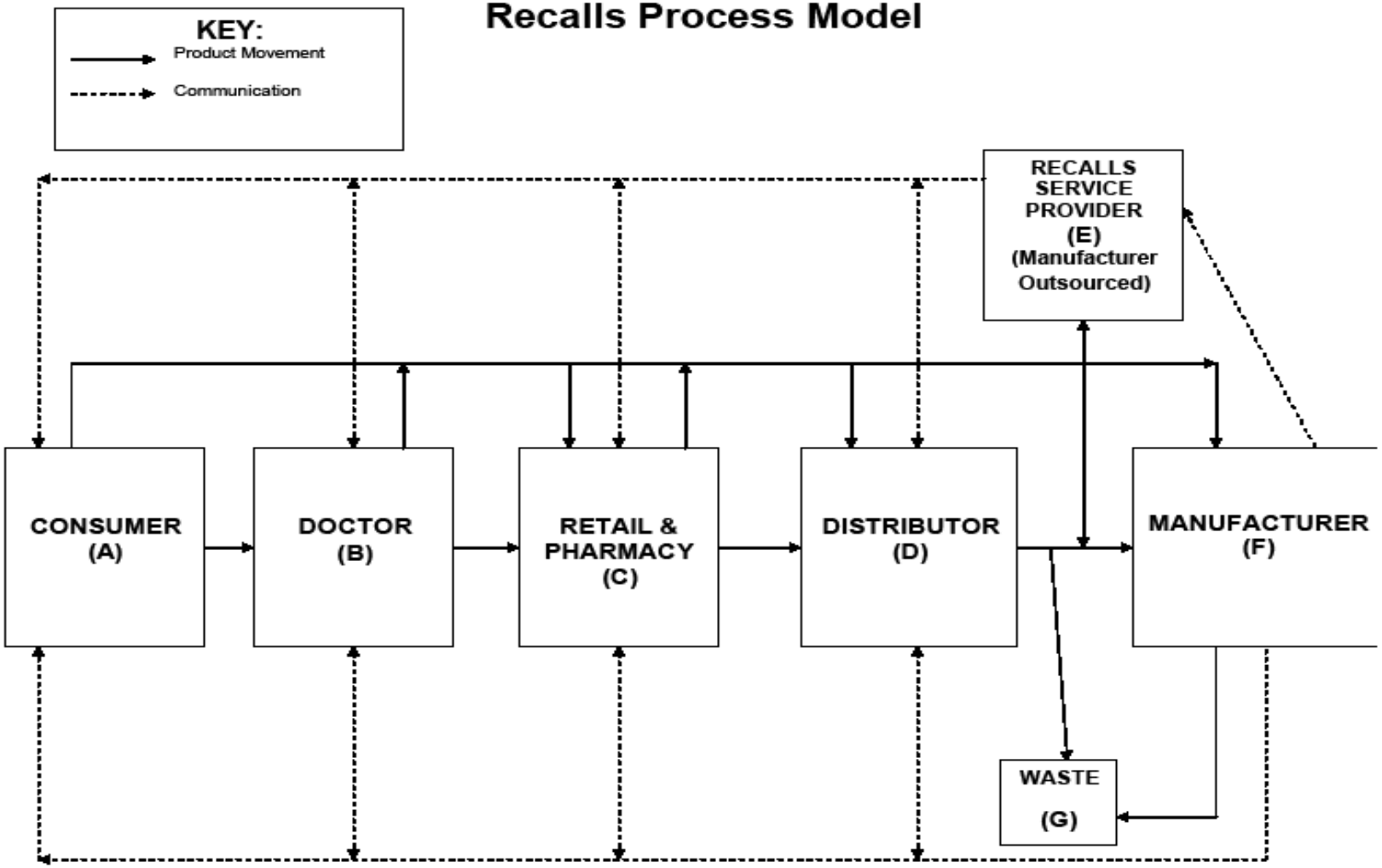
Healthcare Distribution Management Association

Recalls - Distribution Perspective

- Manufacturer initiates recall/market withdrawal.
- HDMA members have recall/withdrawal procedures in place.
- Distributors facilitate communications/product return as instructed.
- Shared goal: swift identification and quarantine of recalled product.
- FDA guidance and oversight.

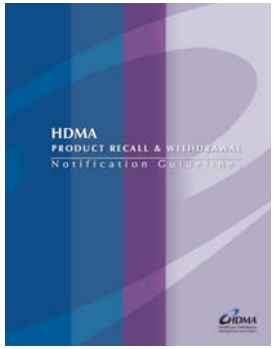
Healthcare Distribution Management Association

Recalls Process Model



HDMA Product Recall & Withdrawal Notification Guidelines - Contents

- General Recall Regulations and Responsibilities
- General Guidelines
- Instructions for Drug Recall Notice Form
- Drug Recall Notice (3 Sample Forms)
  - Wholesale/
  - Retail
  - Consumer



Healthcare Distribution Management Association

Drug Recall Notice (Sample Forms) Contents

- Product Information: Recalling Firm, NDC, Pack Size, Lot*, Expiration, Initial Ship Date*
- Product Information
- REASON
- LEVEL
- CLASS*
- ACTION* – By distributor, By retailer/ customer
  - Example: Stop dispensing and distributing these lots. Quarantine lots. Physical count. Business Reply Card. Packing Slip. Send Reply Card even if no product.
- Directions for return, including partials.
- CONTACT
- *Not always available on early notice.

Recalls - Company Perspective

- Individual companies determine the specific practices that are most effective.
- Companies focus on continual assessment and improvement to secure the supply chain
- McKesson has actively participated on HDMA Returns Task Force and will share company perspective.

Healthcare Distribution Management Association

McKESSON
Empowering Healthcare

Recall Processes

California State Board of Pharmacy

September 17, 2009

Larry Hunley, Distribution Center Manager

Agenda

McKESSON
Empowering Healthcare

- Pharmaceutical Recall Profile
- Process Overview
- Inventory controls
- Communication
- Product Quarantine Developments

Pharmaceutical Recall Profile

McKESSON
Empowering Healthcare

		Notification Level			
Year	**Type**	**Wholesaler**	**Retail/Hosp**	**Consumer**	**Total**
2007	Recall/Withdrawal	54	98	4	**152**
2008	Recall/Withdrawal	67	173	13	**240**
2009	Recall/Withdrawal	61	85	18	**146**
Total		**182**	**356**	**35**	**538**

- McKesson manages a significant number of recall events each year
- Same products can have multiple events
  - Added lots or change in notification level
- Recall events are increasing and in particular to the consumer/patient level
- Most pharmaceutical recalls/withdrawals are managed by manufacturer's recall provider such as Stericycle, Genco, etc.

Recall – Overall Processes

- Manufacturer communication process managed centrally with Product Management to ensure all recall elements are accurately captured
- Recalled items, lot #’s and expiration dates are loaded into SAP and McKesson warehouse management systems
- McKesson Warehouses immediately quarantine affected products and lots even if some recall elements are still pending
- Manufacturer determines who “pushes” notification to McKesson customers.
- Affected products are normally returned manufacturer’s recall provider including product removed from retail pharmacy and healthcare providers

Recalls – Inventory Controls

McKESSON
Empowering Healthcare

- Systematic identification of recalled product at point of receiving, put away, picking, shipping or returns processing to mitigate recalled items from being placed in saleable inventory
  - Affected products inspected visually at time of recall notification and immediately removed from saleable inventory
  - Any inventory movement within the warehouse prompts user to enter the lot # to identify products that must be removed from saleable inventory
- Real Time Reporting available
  - Open purchase orders, sales orders, shipping and customer returns
- Formal process to “expire” recall based on material (item, lot and expiration date).

Recall – Communication

- Manufacturer/Supplier
  - Obtain all data relevant data elements
  - Validate services required for McKesson notification
  - Pursuing additional lot and exp dates on all lot recalls
    - Some products and lots may be reintroduced into the supply chain

- McKesson Customer
  - Posted communication on Customer Portal
  - Additional recall notices sent via US Mail to pharmacy or health care provider when manufacturer requires McKesson notification
  - Disclosure of both recall level (depth) and class (Health risk) separately

Product Quarantine Developments

McKESSON
Empowering Healthcare

- FDA Actions
  - Recent controlled substances that were not FDA approved.
- Theft Alerts
  - Theft at manufacturer location or in transit to wholesalers

Drug Recall Best Practices

Health Services
LOS ANGELES COUNTY

Los Angeles County Department of Health Services

Los Angeles County DHS

Healthcare System Overview

LA County Department of Health Services (DHS)

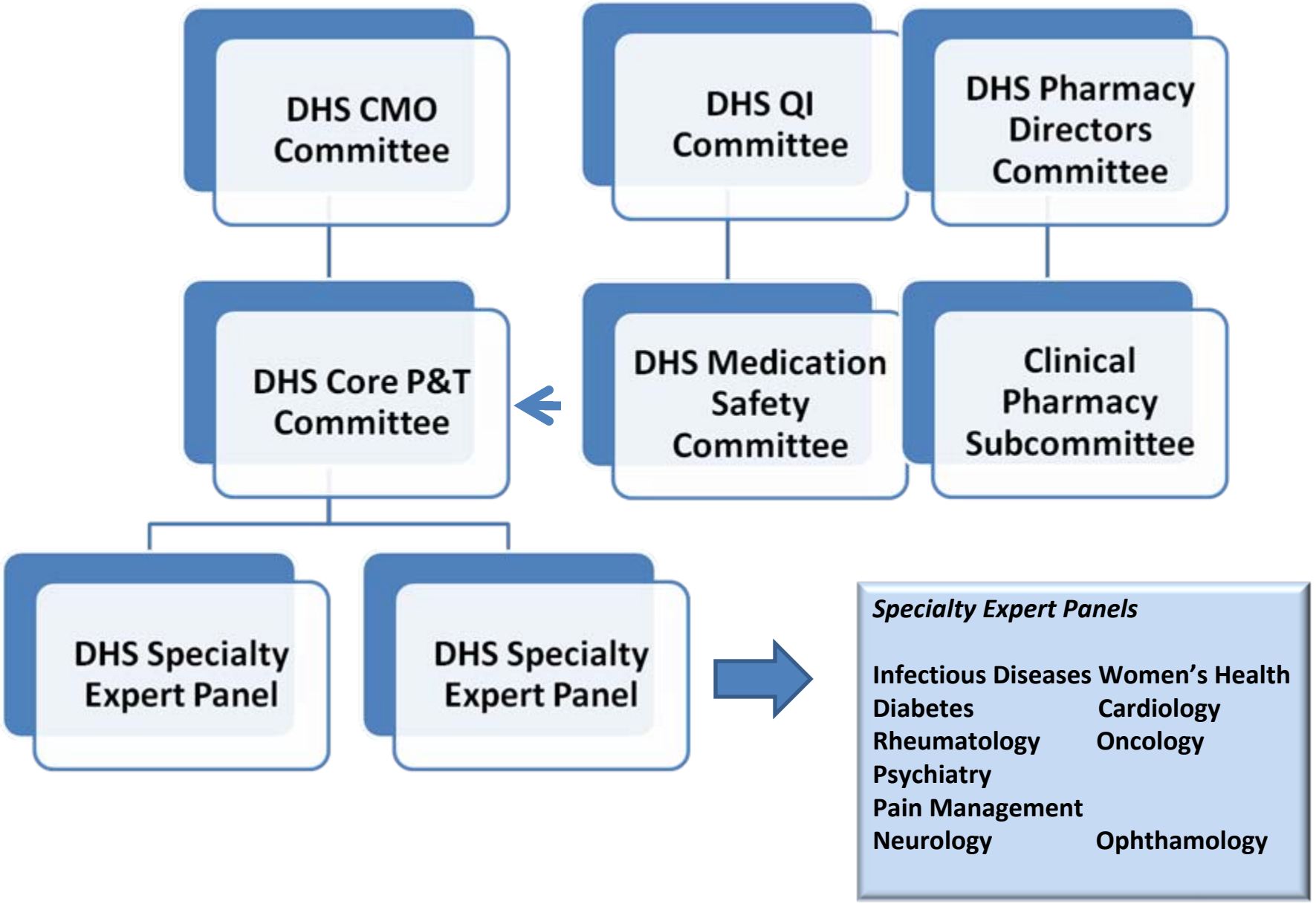
- Second largest public health care system in the nation
- Demographics:
  - 4,083 square miles with 88 incorporated cities and 2 islands
  - 39% of residents live below 200% of Federal Poverty Level, with over 2 million uninsured
- Ten million residents in service area
  - Inpatient care
  - Ambulatory care
  - Emergency services
  - Rehabilitation services
  - Managed care program
  - Juvenile Court Health
- 86,000+ hospital admissions
- 300,000+ ER visits
- 2.8 million annual ambulatory care visits

LA County Healthcare Network

- Four teaching hospitals
  - LAC+USC Medical Center
  - Harbor/UCLA Medical Center
  - Rancho Los Amigos National Rehabilitation Center
  - Olive View Medical Center
- 2 multi-service ambulatory care centers
- 6 comprehensive health centers
- 10 primary care health centers
- 100 private-partner primary care sites
- Emergency Medical Services agency
- 2 Medical School partners- UCLA and USC

Pharmaceutical Management

- *22 licensed pharmacies*
  - 4 Inpatient Pharmacies
  - 18 Outpatient Pharmacies
    - 4 million outpatient prescriptions dispensed annually
- *Centralized pharmaceutical purchasing*
  - $160 million per year
- *Centralized System Committees*
  - Pharmacy & Therapeutics Committee
  - Medication Safety Committee


DHS CMO Committee
DHS QI Committee
DHS Pharmacy Directors Committee
DHS Core P&T Committee
DHS Medication Safety Committee
Clinical Pharmacy Subcommittee
DHS Specialty Expert Panel
DHS Specialty Expert Panel
Specialty Expert Panels
Infectious Diseases
Women's Health
Diabetes
Cardiology
Rheumatology
Oncology
Psychiatry
Pain Management
Neurology
Ophthamology

Opportunities for Improved System Drug Recall Process

Health System- Wholesaler Collaboration Pilot Project

CardinalHealth

MESSAGE GRAM

FROM: CARDINAL HEALTH
PHARMACEUTICAL DISTRIBUTION
27680 AVENUE MENTRY
VALENCIA, CA 91355
FAX :1-661-294-8218

9/11/2009

*** URGENT PRODUCT RECALL ***

**** Retail Chains: Please follow your standard corporate policy for recall items. ****

Dear Valued Customer: Notice - Please sign and return this form to Cardinal Health.
According to our records you have purchased an item that has been recalled by the manufacturer. Please examine your stock to determine if you have the following products with the affected lots on hand. See below for product disposition instructions. If you have any questions please contact Cardinal Health Customer Service.

ITEM: 3732211 M.V.I. ADULT 10X10ML UNIT VL NDC#: 61703342281
MANUFACTURER: HOSPIRA WORLDWIDE INC
LOT NUMBERS: 9019A 9020A 9021A 9022A 9023A

REASON FOR RECALL: Unclassified retail level recall. Manufacturer recall because the top chamber may contain a small amount of solution from the bottom chamber. Return product to Cardinal Health.

PAGE 2 OF 2 01-819RCL

Signing this form provides Cardinal Health regulatory documentation that you received this recall notice.

- Please sign and return to Cardinal Health, indicating the amount of product you are returning, even if it is zero.
- If you are returning product to Cardinal Health, include a Return Authorization (using return code 60) in order to receive credit.
- Partials of recalled Controlled Substances must be returned directly to the manufacturer to receive credit.
- Partials of recalled Non-Controlled Substances may be returned to Cardinal Health. Partials of less than 25% of the original package quantity will not receive credit from Cardinal Health.

AMOUNT RETURNED: _____ Recall# 004747

Identified Concerns

- Wholesaler “lettergram” issued with delivery
  - Was it received?
  - Pharmacist reviewed the recall notice in a timely manner?
- Required research to determine *if* and *when* recalled drug was purchased
- Recall actions taken were maintained at local level; no system collaboration in place
- Lack of timely review by medical and nursing staff, due to paper based system

FDA Recall Definition

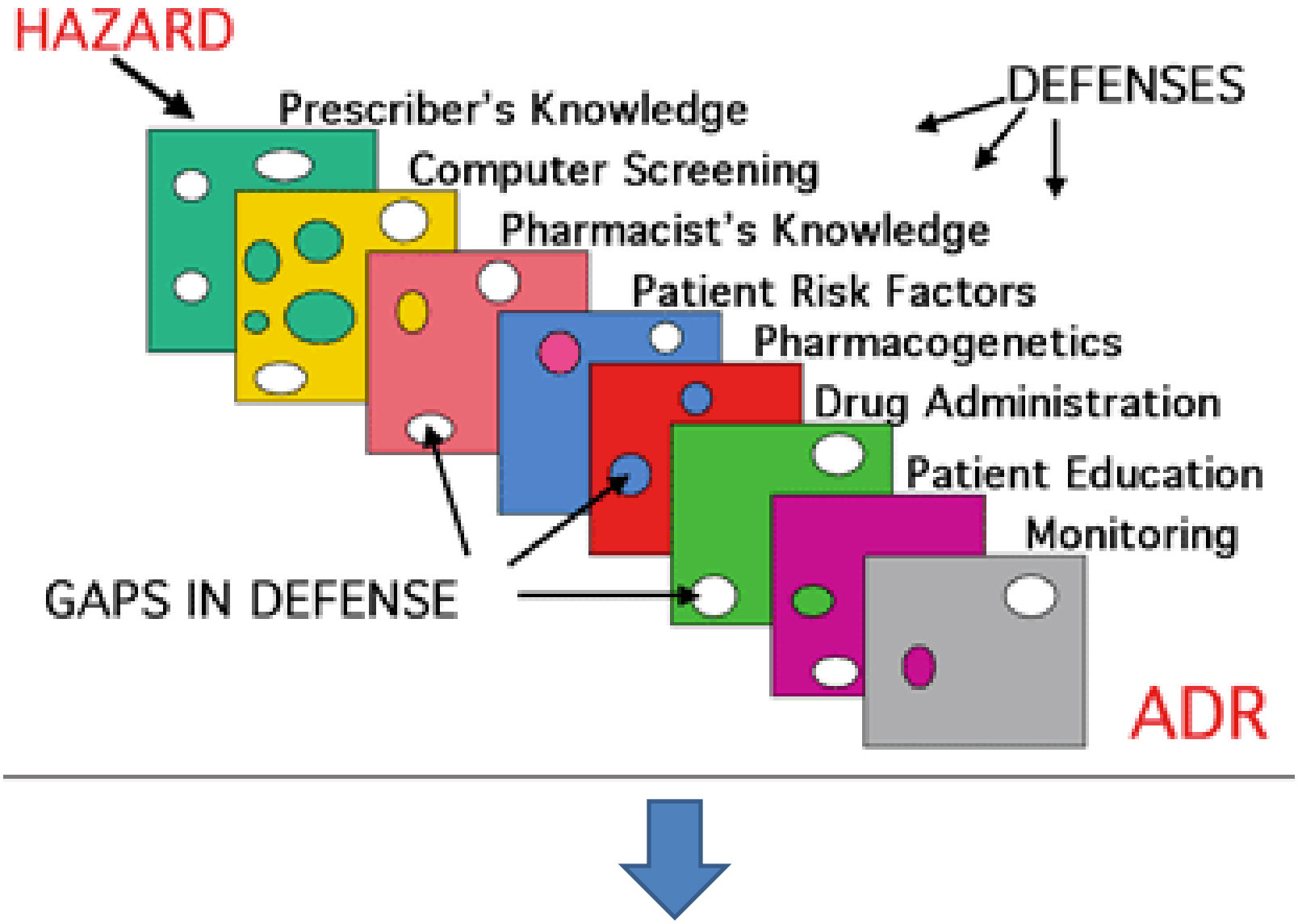
Class I recall: a situation in which there is a reasonable probability that the use of or exposure to a violative product will cause serious adverse health consequences or death.

Class II recall: 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 recall: a situation in which use of or exposure to a violative product is not likely to cause adverse health consequences.

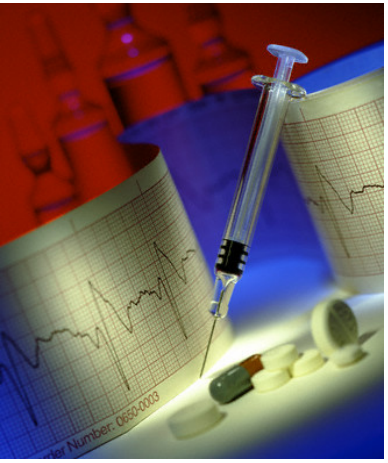
Market withdrawal: occurs when a product has a minor violation that would not be subject to FDA legal action. The firm removes the product from the market or corrects the violation. For example, a product removed from the market due to tampering, without evidence of manufacturing or distribution problems, would be a market withdrawal.

Medical device safety alert: issued in situations where a medical device may present an unreasonable risk of substantial harm. In some case, these situations also are considered recalls.



Drug Recall Process Change Needed to Maximize Patient Safety and Improve Regulatory Compliance

New System Policy Issued



Health Services
LOS ANGELES COUNTY

POLICIES AND PROCEDURES

SUBJECT: DHS DRUG RECALL PROCESS

POLICY NO: 329.004

PURPOSE:

To provide standardized system drug recall guidelines to be followed by all DHS institutions, with the purpose of maximizing patient safety and adherence to drug recalls and market withdrawals announced by the FDA or from a pharmaceutical manufacturer.

POLICY:

Recalls are actions taken by a pharmaceutical vendor to remove a specific product, medication, strength, or lot number from patient circulation. Recalls may be conducted on a manufacturer's own initiative, by FDA request, or by FDA order under statutory authority. The various types of FDA Drug Recalls are defined below[1]:

- **Class I recalls** are for dangerous or defective products that predictably could cause serious health problems or death. Examples of drugs that could fall into this category may include oversized tablets that may contain twice the active ingredient or a label mix-up on a life saving drug.
- **Class II recalls** are for products that might cause a temporary health problem, or pose only a slight threat of a serious nature. One example is a drug that is under-strength but that is not used to treat life-threatening situations.
- **Class III recalls** are for products that are unlikely to cause any adverse health reaction, but that violate FDA labeling or manufacturing regulations. Examples might be a packaging defect (plastic material delaminating) of a drug bottle or off color tablet due to use of an incorrect dye.
- **Market Withdrawals** - Occurs when a product may have a minor violation that would not be subject to FDA legal action. The manufacturer may voluntarily remove the product from the market until they correct the violation. For example, a specific lot number of a product

Amy Gutierrez - Advanced Recall Notification: Barr Labs - Amphetamine Salt Combination Tablets - 8/14/2009

From: "Iannone, Ed" <ed.iannone@cardinalhealth.com>
To: <agutierrez@dhs.lacounty.gov>, <APaules@dhs.lacounty.gov>, <bjoyo@dhs.lacounty.gov>, <cariate@dhs.lacounty.gov>, <hsefain@dhs.lacounty.gov>, <ksingh@lasd.org>, <nbalady@dhs.lacounty.gov>, <rkim@ladhs.org>, <RUkim@ladhs.org>, <sdsouza@dhs.lacounty.gov>, <smelnick@dhs.lacounty.gov>, <stlee@dhs.lacounty.gov>, <wkamikawa@dhs.lacounty.gov>
Date: 8/14/2009 1:58 PM
Subject: Advanced Recall Notification: Barr Labs - Amphetamine Salt Combination Tablets - 8/14/2009
CC: "Noel, Mike" <Mike.Noel@cardinalhealth.com>

This Advanced Recall Notification email compliments the current recall process and does not replace it. We still need the recall message gram's signed and returned to Cardinal from all affected facilities.

LAC purchases from Cardinal:
NO

Recall information:

CLASS I retail level recall. Manufacturer recall because affected lot may contain some tablets exceeding weight requirements. For return information and to obtain a DEA 222 form contact Cardinal Health.

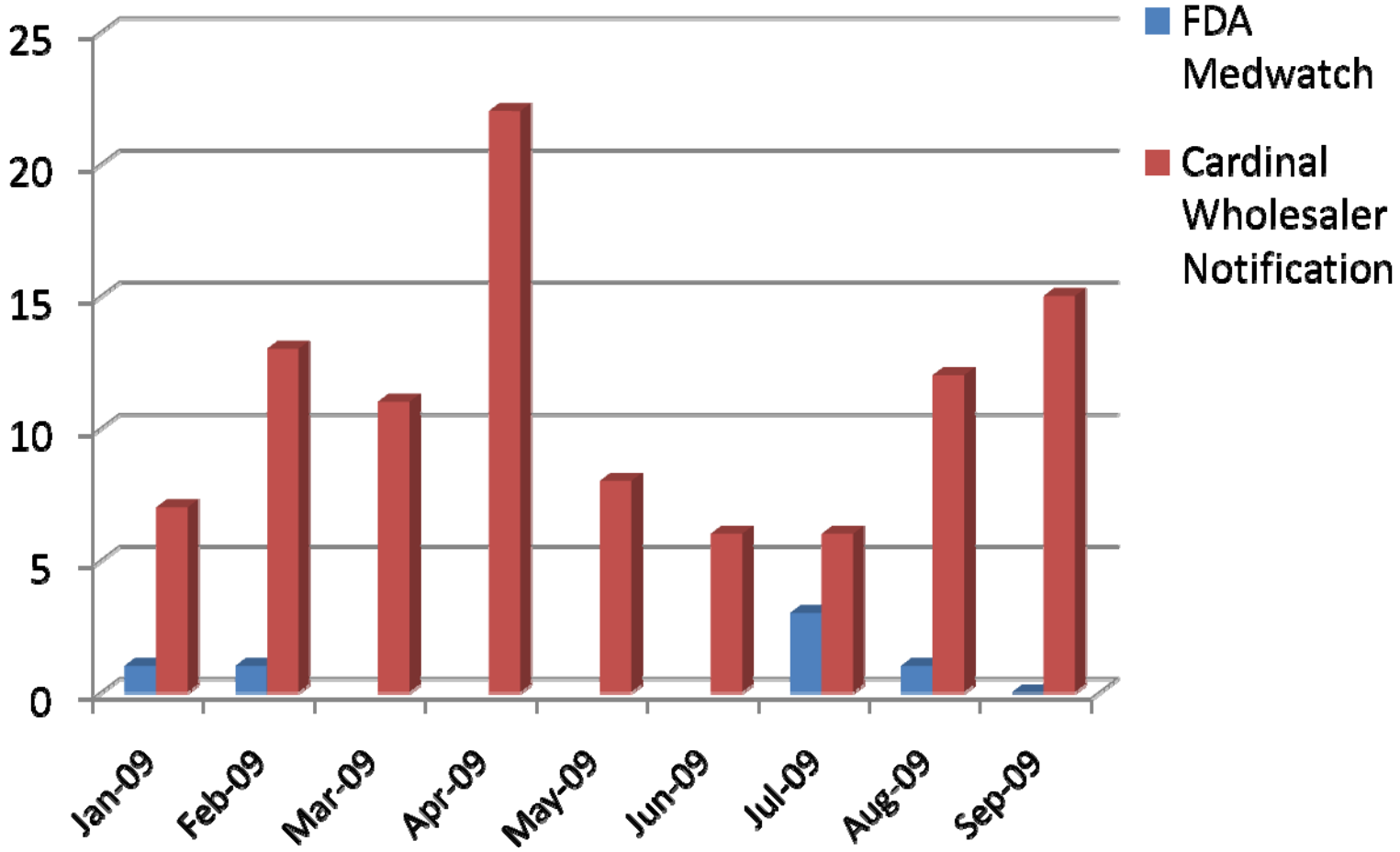
Time Frame:

6/11/2009 to current

DETAILS

CIN#: 3324340
NDC: 555097302
Product Description: AMPHET SALT CMB 20MG 100 C2
Lot Numbers: 311756

Drug Recall Notifications Received
Jan 1, 2009 to September 15, 2009



DHS Summary- Facility Actons
Drug Recall

Date of Recall:

Type of Recall:

Manufacturer Voluntary Recall

Drug Involved:

Recall Description:

DHS Facilities Impacted:

☐ All ☐ Inpatient Hospital only ☐ Ambulatory Care only

Facility Actions Taken:

Facility	Date	Actions	Follow-Up Needed?
Hospitals			
LAC+USC			
HUMC			
OVMC			
RLA			
Ambulatory Care Centers			
Roybal CHC			
Hudson CHC			
El Monte CHC			
Mid-Valley CHC			
San Fernando HC			
Humphrey CHC			
Long Beach CHC			
Wilmington HC			
MLK MACC			
High Desert MACC			
CHP			

Drug Recalls Examples : Jan to Sep 2009

- Unclassified retail level recall. Manufacturer recall because two patches were confirmed to be leaking. NOTE-NDC on patch is 0591-3214-54 (***fentanyl transdermal patch***)

- Unclassified retail level recall. Manufacturer recall due to a low level defect that may result in the patient not receiving the medication as they advance doses through the Diskus unit (***Advair Diskus***)

- Class I consumer level recall. Manufacturer recall due to potential for elevated endotoxin levels. Pharmacies should notify their customers. NOTE: NDC #s on individual vials are 0703-2856-01, 0703-2858-01, 0703-2859-01 (***propofol emulsion***)- **FDA MEDWATCH NOTICE ISSUED**

Drug Recalls Examples : Jan to Sep 2009

- Unclassified retail level recall. Manufacturer recall due to the presence of tablets that have high assay values out of specification (***furosemide)***

- Unclassified consumer level recall. Manufacturer recall due to some tablets might contain slightly higher levels of the active ingredient than specified. Pharmacies should notify their customers (***propafenone***)- **FDA MEDWATCH NOTICE ISSUED**

- Unclassified retail level recall. Manufacturer recall due to a mislabeled expiration date (***oxycodone oral solution***)

- Unclassified retail level recall. Manufacturer recall because the diluent ampule expiration of 10/08 is earlier than the carton expiration of 5/09 (vial expiration date)- (***Elitek injectable***)

Drug Recalls Examples : Jan to Sep 2009

- Unclassified retail level recall. Manufacturer recall because tablets may release the active ingredient at a slightly faster rate than required by the product's release rate specification at the 8-hour time point. (***Ultram ER tablets***)

- Unclassified retail level recall. Manufacturer recall because lots could have pouches which are not sealed properly and could potentially compromise external sterility of the syringes (***saline flush 0.9%)***

Date	Action
3/31/2009, 11:03AM	FDA email with recall notice – consumer level recall
3/31/2009, 5:08 PM	Cardinal Healthcare forwards recall notice + list of all DHS facilities which purchased recalled agent from 3/31/2006 to 3/31/2009
3/31/2009, 7:10PM	DHS Pharmacy forwards FDA recall notice with report of individual facility purchase history to all DHS facility pharmacy directors and medical directors, with notification to local facility healthcare staff
3/31/2009 8:10PM	Draft patient notification letter forwarded to County Counsel
4/1/09 6:38AM	FDA Medwatch distributes recall notice through alert system
4/1/09	DHS Pharmacy reviews potential options for purchase of oral digoxin from other manufacturers; places order for patient care use and to replace recalled product. AM- All medication removed from pharmacy and patient care areas
4/1/09, 12N	DHS Pharmacy commences data analysis of pharmacy system database for identification of patients dispensed recalled digoxin, by pharmacy and by NDC

4/1/09, 3PM	Conference call with chief medical officers, pharmacy directors, and county counsel regarding appropriate actions and clinical discussion concerning patient notification process. System cardiology expert panel contacted for clinical input.
4/2/09, AM	County Counsel and DHS Pharmacy complete patient notification letter, pending results of cardiology panel recommendations on optimal patient notification process + continuation of therapy
4/2/09; 1PM	DHS Core P&T Cardiology Expert panel meeting; recalled digoxin is agenda item. Cardiologists recommend: •simplify language in patient notification letter •attempt to phone patients •inform prescribing physicians of recall status •have patients discontinue recalled digoxin until such time that they are evaluated urgently within facility; process to be established for evaluation by each site
4/2/09 1:30PM	List of impacted patients forwarded by central pharmacy services to all sites with instructions on how to identify patient mailing information
4/2/09 6:30PM	Final approved “Patient Notification Letter” forwarded to impacted DHS facilities with instructions.
4/3/09	Patient Letters Issued with specific instructions

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Cardinal Health Recall Process

California Board of Pharmacy
September 17, 2009

Overview

- Current Process
- Trial Project
- Future Process

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Current Process

- Receive Vendor Recall Notice in Cardinal Health Corporate QRA
- Corporate QRA reviews notice for completeness
- Corporate QRA provides recall notice / instructions to DCs
- DCs create recall within DC inventory system
- Customer notices printed / sent to affected customers
- Current process meets regulatory requirements

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Trial Project

- 2 customers only - LA County / UCSF
- Email alert by local DC in addition to standard compliant printed notice
- Email sent to customer designated contacts
- Trial project assisting us in evaluation of potential future recall process

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Future Process

- FDA compliant email recall notification to customers
- Customer optional and customer managed email addresses
- Status - fact gathering and analysis phase
- Anticipated go-live summer 2010

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Questions