



California State Board of Pharmacy
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STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

**STATE BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
PUBLIC BOARD MEETING
MINUTES**

DATE: October 29 - 30, 2008

LOCATION: Radisson Hotel
5000 Sierra Point Parkway
Brisbane, CA 94005

**BOARD MEMBERS
PRESENT:**

Kenneth Schell, PharmD, President
D. Timothy Dazé, Esq., Public Member, Vice President
Stanley C. Weisser, RPh, Treasurer
Susan Ravnan, PharmD
Henry Hough, Public Member
Robert Gaul, RPh
Robert Swart, PharmD
Shirley Wheat, Public Member
James Burgard, Public Member
Andrea Zinder, Public Member
William Powers, Public Member

**STAFF
PRESENT:**

Virginia Herold, Executive Officer
Anne Sodergren, Assistant Executive Officer
Robert Ratcliff, Supervising Inspector
Judi Nurse, Supervising Inspector
Joan Coyne, Supervising Inspector
Janice Dang, Supervising Inspector
Joshua Room, Deputy Attorney General
Kristy Schieldge, DCA Senior Staff Counsel
Tina Thomas, Staff Analyst

President Schell called the meeting to order at 9:00 a.m.

President Schell recognized former board members, Rich Mazzoni, Ruth Conroy PharmD, Stan Goldenberg and Glenn Yokoyama PharmD. He recognized Lynn Rolston, Executive Officer from the California Pharmacists Association (CPhA). He also recognized Dawn Benton, CEO/EVP, and William Yee PharmD, Board chairman, of California Health-systems Pharmacists (CSHP).

I) Approval of the Full Board Minutes of the July 23 and 24, 2008

MOTION: To approve the minutes of the July 23 and 24, 2008 Board Meeting.

M/S: BP/JB

SUPPORT: 10

OPPOSE: 0

II) Enforcement Committee and Workgroup on E-Pedigree

A) Report on the Meeting of October 6, 2008

(1) Workgroup on E-Pedigree

(a) Overview of Provisions Enacted by SB 1307 (Ridley-Thomas, Chapter 713, Statutes Of 2008)

Executive Officer Herold stated that the legislative session ended September 30, 2008. Governor Schwarzanegger signed SB 1307(Ridley-Thomas) on September 30, 2008. Ms. Herold noted that a copy of the bill is provided within the board packet.

Ms. Herold explained that this law staggers implementation of e-pedigree requirements to:

- Fifty percent of a manufacturer's products by 2015
- The remaining 50 percent of the manufacturer's products by 2016
- Wholesalers and repackagers must accept and pass e-pedigrees by July 1, 2016, and pharmacies and pharmacy distribution centers must accept e-pedigrees by July 1, 2017

Ms. Herold provided the provided a summary of her presentation on SB 1307.

Ms. Herold stated that this legislation as signed was an agreed upon consensus date from everyone. She reviewed and emphasized the intent of SB 1307. She also reviewed exemptions from e-pedigree legislation.

Ms. Herold reviewed new provisions within legislation, which included:

- Expansion of the definition of manufacturing in pharmacy law for the purposes of e-pedigree, as well as provisions for contract manufacturing
- E-pedigree requirements for the smallest packaging unit made by the manufacturer
- Definition of third party logistics providers as defined in the law, and their exemption from pedigree requirements
- Definition of repackagers, as well as their requirements with relation to e-pedigrees
- Incorporates inference specifications and grandfathering provisions

Ms. Herold stated that there is preemption language that would repeal California's provisions if federal law regarding e-pedigrees is enacted, or if federal standards are enacted, that would take effect in California.

Senator Ridley-Thomas added a letter to the Senate Journal, reflecting the agreement of those who worked on amendments to California's e-pedigree law and that this would be the last extension. A copy of the letter was provided within the board packet.

(b) Progress on the Implementation of Electronic Pedigrees Pursuant to the California Business and Professions Code – Updates by GS1, Manufacturers, Wholesalers, Pharmacies and their Associations to Implement Electronic Pedigrees

Presentations to the Board:

Bob Celeste (GS1):

Mr. Celeste discussed the fundamentals of reliable product identification, location identification, and data of both.

Mr. Celeste discussed traceability in both directions of the supply chain. He noted the progress being done in hospitals, as well as how they are using standards for other purposes as well. He noted that traceability is equivalent to visibility when referring to a hospital setting. Mr. Celeste pointed out the benefit of extended information that can be acquired by good traceability standards, such as the condition of a product and its fit for use, which is based on maintenance history and certifications.

Mr. Celeste explained the information that is needed when utilizing traceability. He provided a breakdown as follows:

- “Who” - the global service relationship number used to identify a patient within a location at the time of a transaction
- “What” - the use of a Global Trade Item Number (GTIN) number, which can be used to look up information about a product as well being accessible through the Global Data Synchronization Network
- “Where” – the use of a Global Location Number (GLN), used to identify the places that items have been within the supply chain as well as within hospitals or pharmacies
- “When” - the use of a date stamp
- “Why” – Mr. Celeste reviewed the most significant events which have most recently occurred within the supply chain, including the elimination of custom account numbers by 2010 (to be replaced by GLN’s) and custom product numbers by 2012 (to be replaced by GTIN’s).

Mr. Celeste concluded by explaining how these standards will help the supply chain. He stated that by using standardized data and identifiers, industry will have a more reliable pedigree and disposition of those items within the supply chain. He added that future standards will assist the supply chain in “finding each other” to ask questions about authentication of a product, for example.

Joshua Room, Deputy Attorney General liaison for the board, pointed out that the standards will be most useful when there are more members of the supply chain utilizing them. He asked if Mr. Celeste had a sense of where everyone is within the industry on using the standards, and whether there are other motivators that need to be brought into play to make that happen.

Mr. Celeste stated that the GLN’s are separate from pedigree, but are a significant benefit to hospitals. He also noted the option to use GLN’s in place of DEA numbers, which are sometimes being used inappropriately for tracking. He added that there are benefits for using the identifiers beyond compliance, but they affect compliance in a large way.

Mr. Room stated the general hesitancy over patient privacy concerns by over-identifying the drug or the patient it is going to. He added that it seems the identifiers would assist in “masking” and addressing those concerns.

Mr. Celeste agreed. He reemphasized however that the GSIN is not a patient identifier, but rather an identification of the transaction with the patient.

(2) Enforcement Committee

(a) E-Prescribing Forum Set for November 20, 2008

Robert Swart stated that on November 20, 2008, the Board of Pharmacy will host an e-prescribing forum in conjunction with the Department of Consumer Affairs' Professionals Achieving Consumer Trust summit. He noted that other healing arts boards whose licensees prescribe drugs have been invited, as have public interest groups. He also indicated that the Dental Board and Medical Board have joined us as partners.

A number of patient and health care advocates have strongly pressed the need for increased use of e-prescribing for all medicine. A principal reason is that statistics indicate medication errors cost the health care system \$77 billion and cause 7,000 deaths annually. A number of these errors could be prevented by full implementation of e-prescribing.

By the mid-1990s, the board had sponsored legislation and promulgated regulations to ensure that e-prescribing was authorized in California law. Since then, various provisions have been added or amended to keep law supportive of allowing electronic prescriptions.

For the November 20 forum, the agenda contains a review of California's laws authorizing e-prescribing. There will be presentations by a software company that provides the software to perform e-prescribing. There will also be presentations by several large entities that are currently using e-prescribing to describe their experiences – what works and lessons learned.

Dr. Swart noted that the California Healthcare Foundation will be holding a forum in San Francisco on November 20th as well. Ms. Herold has been very involved with the group and a member of the board staff will be attending.

Dr. Swart explained that these two forums will provide opportunities for strong policy initiatives to move forward encouraging e-prescribing in California. Legislation may be one outcome of these efforts.

(b) Presentation by Bob Pack Regarding Controlled Substances Utilization Reports and Evaluation System (CURES) Moving to Provide Online, Near Real Time Reports to Practitioners in the Future

For a number of years, the board has fully supported the Controlled Substance Utilization Review and Evaluation System (CURES) to electronically track all Schedule II-IV medicine dispensed to patients. This data is submitted each week to the California Department of Justice by pharmacies and prescribers who dispense controlled substances, and contains information about the specific drug, strength and quantity dispensed by a pharmacy or practitioner, as well as the prescriber, the dispenser and the patient.

Underway for several years is a process whereby prescribers and dispensers can obtain from the Department of Justice copies of the dispensed drugs of a particular patient reported to CURES. This allows these practitioners to determine whether a patient is a "doctor shopper" for controlled drugs, and thereby prevent the prescribing and dispensing of controlled drugs to such patients. A copy of the required form, a "Patient Activity Report", can be downloaded from the board's Web site (under "publications," and "applications and forms"), and mailed or faxed to the Department of Justice.

Data is reported weekly by practitioners into the system, but by the time processing occurs and a PAR report is obtained, it can be weeks – usually not in time to prevent the prescribing or dispensing of controlled drugs, unless a patient returns to the practitioner or pharmacy for future controlled drugs.

Underway for several years is an effort spearheaded by public citizen Bob Pack working with several state agencies (including this board) to secure online, near real time reports for practitioners via a secured Internet system operated by the Department of Justice. Such a system would allow significantly faster access to CURES data. Mr. Pack was a founder of Netzero, so he has the technology background and contacts to help drive this initiative. A feasibility study report was developed for the Department of Justice for this system.

Mr. Pack provided background on his personal experience and loss of family members due to a woman driving while under the influence of a controlled prescription drug. He explained how this loss initiated the creation of a foundation and committee as an effort to implement “real time CURES” data. He indicated that Senator Torlaksen authored SB 734 (Chapter 487, Statutes of 2006), which allowed the project to move forward, given that private funding could be acquired. Mr. Pack noted that the groups involved in the project include the Department of Consumer Affairs, the Department of Justice and others. He also said that they are working with Relay Health, a division of McKesson, which provides technology implementation for tracking pharmaceuticals through the distribution chain. Mr. Pack described the specifics of how the “real time” CURES program works and how it will provide vital information to physicians and pharmacists to assist in reducing patient “doctor shopping”, etc. Mr. Pack explained that the foundation is seeking donations of private funding in the amount of \$1.5 million to fully implement while they are continuing to find ways to attempt to reduce the cost.

Board Discussion:

President Schell asked if the foundation is looking for the board to take action of any kind to support their activities. He also asked whether the intent was for the platform to be mandatory or voluntary for practitioners to utilize.

Mr. Pack responded that it would not be mandatory. He explained that the Attorney General’s Office held a press conference and announced the project formally. There will be a ramp-up phase to enroll doctors and pharmacists into the program. Mr. Pack explained that the more doctors use it, the better the system will be. They plan to encourage practitioners to use the platform, but there would not be any penalties if anyone chooses not to use it.

Ms. Herold explained that the board was the initial funder of the CURES program in order to get the project underway in the 1990’s. She explained that the goal was to provide on-line “real time” reports to practitioners and pharmacies in order to assist with identifying patients who are “doctor shopping”. She noted that, with the current CURES program, there is 3 - 6 weeks of lag time in getting the information to the user, which is better than prior capabilities.

Mr. Pack stated that the CURES database is the “gold mine”, but it is too difficult and time-consuming to obtain the information in its current state. He noted that, once the planned platform can be implemented, it will be feasible to conduct a second phase which would expedite “real-time” reporting as well.

Mr. Room noted that this project would also make the data collection process easier and more timely for e-prescribing in terms of how quickly the data is reported into the database for others to access.

Mr. Pack responded to President Schell's previous question on assistance from the board. He stated that anything the board can do would be helpful. He noted that he has been working with the California Medical Association foundation, whom are providing a letter of support in order to bring attention to the medical community.

Bill Powers thanked Mr. Pack for his persistence and diligence in seeing the project through. He asked if there are any efforts to tie the project into a rehabilitative treatment program for those who are "doctor shopping" and have drug seeking behavior. He also asked why it isn't a reasonable expenditure from the Medi-cal perspective, since many of those receiving the service are Medi-Cal recipients.

Mr. Pack responded that over the past two years, Medi-Cal has received tremendous media coverage on prescription fraud. He explained that Senator Torlaksen is very involved in the project, and agrees that Medi-Cal should support it financially, as it will save them millions of dollars. Mr. Pack indicated that a bill was passed, but no funds have been released for funding. He stated that he will continue to have discussions with Medi-Cal to seek assistance.

Tim Dazé asked if Mr. Pack has spoken with the Attorney General's Office about having a court sanction specifying that a portion of the fines placed on those who are convicted of drug offenses are placed into a fund for his project.

Mr. Pack responded that numerous ideas have been presented within their committee. He stated, however, that he has not spoken to them about that option, and will follow-up with that. He noted that this is a high profile project, and that there are many other states who would like to have a similar program. He reiterated that they have completed all phases of the project successfully, and are now only in need of funding.

Mr. Pack responded to Mr. Powers' previous question regarding treatment programs for those who are doctor shopping, and stated that the intent would be for practitioners to address the issue with the patient when discovered and counsel them accordingly.

Steve Gray (Kaiser Permanente) asked the board to consider making the project a newsletter article, identifying where and how associations can financially contribute. He also asked the audience to consider contacting foundations for funding. Dr. Gray pointed out the benefit to hospitals in that many people who have drug-seeking behavior are congesting emergency rooms in order to obtain prescriptions from those pharmacies where they are known to be chronically busy and rushed. He noted that the technical, political and legal issues have all been resolved, and it is now only a matter of getting funding in place. He asked those attending the meeting who are associated with pharmacy-related organizations to consider providing financial support. Dr. Gray noted that, since this is a non-profit charitable organization, many employers will match funds.

Mr. Pack explained that they are organized as a family foundation, therefore the state cannot take a grant of donation directly. He stated that they have arranged with the Attorney General's office that the foundation would be a "donation point" for the funds. The foundation would hold the funds and then contribute what is needed for the technology portion and donate the remaining funds to the State of California.

Ms. Herold explained that, because the Department of Justice regulates charitable trusts, the Board of Pharmacy is statutorily required to oversee the collection of funds from the foundation to any donation into the state, due to a potential conflict of interest. Ms. Herold noted that she spoke with Medi-Cal recently and they are very interested in further discussion.

(c) Comments Submitted to the Federal Drug Enforcement Administration on its Proposed Rule to Allow E-Prescribing of Controlled Substances

In late June 2008, the DEA announced proposed regulations to allow the e-prescribing of prescriptions for controlled substances. The proposed rule would allow pharmacies to receive and dispense controlled drugs pursuant to electronically transmitted prescriptions. Comments were solicited by the DEA, and due September 25, 2008.

An important piece needed to permit full scale adoption of e-prescribing is the ability to prescribe controlled substances via this manner. Federal requirements prohibit the use of e-prescribing; however, with the DEA reconsidering its position on e-prescribing of controlled substances, wider adoption and use of e-prescribing can be expected.

Whereas controlled substances account for 10-15 percent of prescription drugs dispensed, the inability for these drugs to be e-prescribed has been considered a deterrent to wide adoption of e-prescribing.

Dr. Swart stated that, during the July 2008 Board Meeting, the board discussed the DEA proposed regulations that would allow e-prescribing of prescriptions for controlled substances. He added that, at the conclusion of the board's discussion in July, the board voted to prepare comments to the DEA in support of the proposed rule to allow e-prescribing of controlled substances.

Dr. Swart stated that a letter was sent on behalf of the board in September which confirmed the board's encouragement that the DEA is moving forward to permit e-prescribing of controlled substances. He explained that the letter also detailed board concerns over some of the onerous requirements contained within the proposed regulations. Specifically the board's letter identifies possible obstacles to implementation that make far more stringent demands upon e-prescriptions than paper prescriptions, including e-record retention of five years and verifying the DEA permit of the practitioner every time before filling a controlled substances e-prescription. The letter encouraged the DEA to reconsider the necessity of some of the requirements. Dr. Swart noted that the letter is provided within the board packet

(d) Implementation of Drug Take-Back Programs from Patients by California Pharmacies (SB 966, Simitian, Chapter 542, Statutes Of 2007) and Presentation by the California Integrated Waste Management Board on Proposed Model Programs

Dr. Swart stated that, last year, SB 966 (Simitian, Chapter 542, Statutes of 2007) directed the California Integrated Waste Management Board (CIWMB) to develop the parameters for "model" drug take-back programs in pharmacies. He explained that these model programs are intended to provide consumers with the ability to dispose of unwanted prescription and over-the-counter drugs (but NOT controlled substances) without flushing them down the toilet or tossing them into the garbage. He noted that, under SB 966, these model programs must be in place by December 2008.

State and federal law regulates prescription medicine until it is dispensed to patients. It is not regulated again unless it is collected at consolidated points, at which point it becomes medical waste, and must be handled and destroyed in specific, mandated ways.

Dr. Swart stated that pharmacies have in some cases agreed to take back unwanted drugs from patients. However, this acquisition by pharmacies is not authorized in law.

Dr. Swart indicated that some communities periodically offer community take-back events, or special days at landfills where the public can take back drugs.

Dr. Swart stated that some drug manufacturers (and the state of Maine, where there is a pilot program underway) provide mailers that patients can use to send unwanted medicine to a predetermined location for destruction. He noted that this is the process preferred by the DEA for patients to dispose of controlled drugs.

Dr. Swart said that, currently, the CIWMB has compiled parameters of model programs, and plans on presenting this information to its board in November. He noted that a draft copy, which the CIWMB clearly emphasized as a draft, is contained within the board packet provided.

Since late winter, board staff have been attending meetings with a group of individuals from the California CIWMB, Toxics Program and Medical Waste Program, all divisions within various state agencies. Additionally Ms. Herold has made three presentations on California pharmacy law and pharmacy drug take-back programs in recent months to those who deal with water quality and waste management throughout California.

Dr. Swart indicated that the greatest problem for the board with drug take-back programs is the potential for these drugs to be diverted to the streets. There is a serious prescription drug abuse problem in the US, and the uncontrolled aggregation of prescription medicine is an attractive enticement. In some cases, drugs collected in collection bins could re-enter the prescription drug supply if pharmacies or wholesalers (or others) sell these items back into the supply chain.

Moreover, pharmacies are areas where health care is provided – it is difficult for this purpose to be combined with a recycling center, which is not necessarily an area of high sanitation.

Dr. Swart indicated that the appropriate destruction of unwanted prescription medicine is a national issue, and the National Association of Boards of Pharmacy (NABP) has a task force formed to develop policy for the NABP for discussion at its annual meeting in May. He noted that President Schell is on this task force.

During the Enforcement Committee Meeting of October 6, 2008, it was clear that some pharmacies are concerned with having to take back drugs from patients. Additionally, board staff have concerns with the openness of the model programs, that would greatly expand collection sites for prescription drugs without adequate controls.

Dr. Swart stated that, in January 2009, staff will have recommendations for additional statutory modifications to ensure protection of the public.

Dr. Swart introduced Jim Cropper from the Integrated Waste Management Board.

Ms. Herold stated that they have had several discussions with Mr. Cropper. She said that the most recent discussions involved participation of deputy directors and legal counsel from three agencies. She stated that they are attempting to make progress on the direction of the sharps take-back program. Ms. Herold indicated that the CIWMB was directed to develop model programs under SB 966. The Department of Public Health, the Department of Consumer Affairs and the Board of Pharmacy, are concerned that, without specific regulations or statutory provisions, they will be at a loss to enforce the provisions that are being put forth within these model programs. She noted that a memo was provided to the board which lays out the specific components the board requires when a regulation is to be enacted. Ms. Herold explained that, without a specific regulatory authority to which you can charge someone with a violation, there is great difficulty in enforcing provisions. The CIWMB envisions a completely different kind of model, and Ms. Herold stated concern because the Board of Pharmacy doesn't believe current pharmacy law will provide the board and its enforcement staff with the authority needed to do what the model entails.

Kristy Schieldge, board counsel, stated that the board understands the statutory obligation to adopt a model program. The board's recommendation was to adopt a program through emergency regulations that sets up a permit or registration process which enables licensees to participate. This would allow the licensees to be provided with the standards, opt-in or opt-out specifics, etc. She referred to the memo provided by the board and outlined specific criteria which would be helpful, including whom would be eligible to participate in the program. Ms. Schieldge also noted that there was a two-step process indicated within the memo. One phase involved recommendations to the CIWMB in terms of adoption of emergency regulations which would be enforceable by the Board of Pharmacy as well as the other government agencies. The second phase involved more specific recommendations by board staff related to "Best Management Practices" as requested by the CIWMB.

Ms. Herold stated that, as there are no current requirements for pharmacies or other entities to take back drugs, it was difficult to create provisions. She explained that the board provides enforcement of drugs until they are dispensed to a patient, and then oversee the drugs again only when they are aggregated for take-back to destroy. She discussed the periodic take-back events sponsored by various entities, and explained that the board wants safeguards put in place to ensure returned drugs do not enter general pharmacy stock which could result in the products ultimately being dispensed again to patients. The goal is to develop safe and effective ways to regulate drug take-back programs that don't result in additional problems to society.

Stan Weisser asked why the CIWMB didn't consider the pilot program in Maine, which involves mailers and is preferred by the Food and Drug Administration.

Mr. Cropper clarified that CIWMB is required to develop criteria and procedures for the collection of disposed pharmaceuticals. He explained that they surveyed many California programs, as well as the programs of other states and countries. He indicated that they did review the Maine program and feel that it is an excellent model. Mr. Cropper added that San Francisco is planning to implement a similar model in the near future. He stated that they do provide the mail-back program as one option that local governments, non-profit organizations and businesses can utilize. Mr. Cropper stated that CIWMB has had three stakeholder meetings, and that Ms. Herold has spoken on behalf of the Board of Pharmacy at two of those meetings. He also reviewed many other recent efforts made by the CIWMB, including upcoming meetings in November where Ms. Herold will be attending.

Andrea Zinder asked if controlled substances are currently controlled in terms of take-back.

Ms. Herold responded that they are prohibited unless an enforcement officer takes the drugs, and the peace officer is required to maintain custody of the drugs. She noted that a pharmacy or medical office would be in jeopardy of losing its DEA permit if they were to take back a controlled substance. She added the issue that many consumers don't know whether a drug is a controlled substance or not.

Ms. Zinder asked if any take-back program would exclude controlled substances.

Ms. Herold confirmed. In the case of a community event, CIWMB wants a pharmacist to attend the event in order to differentiate the controlled drugs and provide them to an enforcement officer in attendance as well.

Mr. Cropper responded that the CIWMB understands the substantial cost that would be involved in such a scenario and understands why it may be prohibitive. He noted that in San Mateo County, the police stations consider all drugs surrendered to them as controlled substances.

Mr. Room clarified that the board does not currently regulate drug take-back programs.

Mr. Weisser asked if CIWMB has contacted the numerous law enforcement agencies within California and determined if they are in support of the proposed programs.

Mr. Cropper responded that they have only talked to those operating the program in San Mateo County, but have not spoken to law enforcement. He explained that, in San Mateo County, the drugs are accumulated in their jail. Mr. Cropper noted that the Board of Supervisors has not stated any problems. He agreed that it would be beneficial for them to approach the law enforcement agencies for support.

Dr. Swart asked if a pharmacy could potentially lose their license if they were to take back a large amount of loose drugs where controlled substances were mixed in and expressed his personal concern as a pharmacist.

Mr. Room responded that it is a question for the Drug Enforcement Administration. He also pointed out that all of the restrictions discussed are primarily a matter of federal law, and that it is the DEA who has designated that such drugs would need to go to law enforcement. The DEA would thus be responsible for deciding if any action would be taken if a violation would occur.

Ms. Herold stated that, in relation to the model guidelines and comments being provided, her assumption is the pharmacists do not review what goes into the take-back bin or even have access to it. She stated that only a licensed waste hauler can access the contents of the bin. She noted that signage on the bins should indicate that patients are not to dispose of controlled substances, as she does not want to require pharmacists to review every drug that is placed in take-back containers.

Ms. Herold reviewed the comments provided to the CIWMB. She explained that there are three components of the take-back guidelines – ongoing collection sites, periodic collection events and mail-back programs. She explained that each section addresses specific components related to the type of collection. Ms. Herold noted that the DEA encourages the mailback program, but there are very specific issues to address, including the type of labeling necessary to avoid theft. She added that the document specifies who and what entities can accept the products. General guidelines are included for those entities who choose to participate in the take-back program, which indicate the following requirements:

- Must advise the CIWMB of an entity's intent to take back drugs
- The take-back program be free of charge
- Only over-the-counter, prescription and vitamins will be taken unless a peace officer is in attendance to collect controlled substances
- Periodic reports are conducted, indicating the drugs collected
- Only licensed waste haulers can pick up and relocate the collection bins
- If a theft occurs, it must be reported within 24 hours to the CIWMB, the Department of Public Health (Medical Waste division) and the Board of Pharmacy
- Written policies and procedures for the take-back program

Ms. Herold reviewed additional requirements proposed specifically for ongoing collection sites:

- When items are deposited into the collection bins, they are not to be handled by pharmacy staff or others
- Collection bins will have a 2-key system, with the waste hauler having possession of the second key required to open the bin

- Sharps are not to be included in the currently proposed take-back programs

Ms. Herold also noted some of the requirements specific to the mailback component of the program.

Mr. Room referenced discussion in the prior board meeting regarding the handling of drugs that are toxic to touch. He asked if this is being addressed.

Ms. Herold responded that no one within the pharmacy will be touching the product, and the container is removed by the waste hauler without anyone accessing the bin prior.

Mr. Cropper added that, in relation to community events, they have discussed the requirement of gloves and the need for a “medical monitoring program”.

Mr. Room suggested a separate guideline for drugs dangerous to pregnant woman, etc.

Ms. Herold reemphasized the requirements being proposed which mandate that there is no direct contact by pharmacy staff with the drugs being placed into the containers. She stated, however, that there may be an educational opportunity or requirement for the prescriber to ensure an appropriate method for those types of drugs to be collected in an alternate way and ensure they are not returned to pharmacies.

Mr. Cropper indicated that their program requirements for one-time community events be “government sponsored” only.

Ms. Herold responded that the board’s comments which were provided state that there are only five types of entities which would be allowed to conduct such one-time community collection events.

President Schell suggested that board members review the document and provide comment to him within the next five days in order to allow Ms. Herold time to provide those comments to the CIWMB.

Robert Graul asked Mr. Cropper if the intent is for the program to remain voluntary.

Mr. Cropper responded that it can be suggested for the future as to whether it will remain voluntary or be made mandatory. He added that they received the comments from the Board of Pharmacy yesterday and are attempting to incorporate the comments into their document. They will then place the document on their website, allowing the public, industry and the board the opportunity to comment at their upcoming committee and board meetings.

Dr. Gray stated that Kaiser is very interested in resolving the problem of viable take-back programs. He suggested that theft be reported to local police authorities.

Dr. Gray also suggested that specific criteria be provided in relation to the collection containers themselves (signage, storage, etc). Additionally, Dr. Gray suggested it be specified that the CIWMB’s program supersedes any local programs in place.

Lynn Rolston (CPhA) commended Jim Cropper in his efforts on the take-back program model, as it is a complex subject. She also acknowledged Ms. Herold for providing the detailed comments which support the needs of the pharmaceutical industry. She noted that it appears the author is looking to sponsor legislation in 2009, and that they will all need to remain vigilant as it is an important public health problem and an incredible logistical and tactical problem for everyone involved. Ms. Rolston ended by stating that CPhA will continue to support and assist the Board of Pharmacy.

Heidi Barsuglia (California Retailers Association) noted that their members continue to stress caution regarding the results of the take-back program in relation to reduction of pharmaceutical waste residue within the water supply. Studies have shown that the overwhelming majority of residue found within the water supply are not a result of the disposal of unwanted drugs, but rather it is the result of excretions from biological waste. California Retailers Association (CRA) understands, however, that the law is in place and will require the need for the model drug take-back programs. Ms. Barsuglia stated that there is a concern over the inability of pharmacies to absorb the cost of such programs, such as costs relating to securing the safety of the collection sites, destruction of the drugs, labor for sorting the drugs, the collection bins themselves, etc. Drug diversion and space availability within the pharmacies for the collection bins are also a concern by CRA and its members.

Bryce Docherty (CSHP) stated that they are very concerned about drugs being returned to pharmacies, specifically with relation to the health risks of exposure to pharmacy staff and patrons. CSHP developed a professional policy in the matter and, two weeks ago, the house of delegates voted to support the position that drug take-back programs should not be returned to a pharmacy. He added that CSHP believes that pharmacies should maintain a virtually semi-sterile environment, and that the idea of patients carrying gallon-size Ziploc bags of various expired medications, sharps, etc. through a hospital to locate the pharmacy's collection bin is troubling. Mr. Docherty noted, however, that the mailback program and the option to return drugs to a police station would be more viable options that CSHP would be comfortable with. Mr. Docherty stated that the purpose was to find a less cumbersome solution for patients to dispose of their unwanted drugs and avoid them being flushed down the toilet. There is concern now that, in an attempt to simplify the disposal process, it is being made very easy for the consumer but consequently creating a potential health hazard for pharmacies. He stated that CSHP will be attending the CIWMB meeting to provide oral and written testimony on their position and concerns.

Ms. Herold noted that the manner in which the board suggests patients dispose of their drugs is approved DEA and FDA policy as well.

MOTION: To empower the Executive Officer, in consultation with the board president, to submit comments of model drug take-back programs to the California Integrated Waste Management Board.

M/S: SW/HH

SUPPORT: 10 OPPOSE: 0

(e) Discussion Regarding the Role of Reverse Distributors in Picking Up Medical Waste and Returned Drugs

Dr. Swart stated that, during the October Enforcement Committee Meeting, the committee heard a presentation about how the disposal of drugs from pharmacies and hospitals occurs. He indicated that sometimes unwanted drugs are returned to manufacturers, or they are disposed of by medical waste haulers. There are specially licensed firms who are authorized to perform these services.

Dr. Swart explained that the board regulates reverse distributors, who are licensed as wholesalers. The board does not license medical waste haulers, who must be licensed by another state agency.

Presentations to the Board:

Kelvin Yamada (Department of Public Health):

Mr. Yamada explained the role of the Medical Waste division, providing regulation of waste after it is collected and aggregated and no longer has intrinsic value. He provided history on the Resource Conservation and Recovery Act of 1982, where distinction was made by the Federal Government between hazardous waste and non-hazardous solid waste. Mr. Yamada explained that they are the local enforcement agency in 25 counties and 2 cities in California, which is comprised of nine inspectors on staff. He noted that California made their regulations even more stringent, which resulted in the California Hazardous Waste Control Law. He explained that the Department of Public Health (DPH) presumes all pharmaceutical waste as hazardous waste unless the generator can prove otherwise. Mr. Yamada provided background on SB 966, and explained that pharmaceuticals are included within this bill, known as the Medical Waste Management Act, and regulated by DPH as bio-hazardous waste. He addressed the topic of household medical waste that, when returned by consumers and consolidated, are defined as regulated medical waste. He emphasized the current issue, which is that there are no exemptions in place for those who consolidate pharmaceuticals, and DPH is not involved until after those items are actually consolidated.

Mr. Yamada described the current process of collecting and hauling hospital pharmaceutical waste outside of California.

Mr. Yamada discussed the issue of household hazardous waste collection, and reviewed how those wastes are exempt from the definition of medical waste. He clarified that, once those home generated pharmaceutical wastes are consolidated, they then become hazardous medical waste. He provided an example of a criminal who accumulated large quantities of pharmaceutical waste which was being hauled for incineration by a non-registered waste hauler. The individual was ultimately arrested in Michigan. He is currently awaiting trial for 12 felony counts and could face up to 82 years of prison. Mr. Yamada emphasized the goal in avoiding this type of event in the future. He noted that DPH does not include any verbiage on waste containers that would indicate the waste as pharmaceutical product.

A member from the public asked why California doesn't build their own incinerator.

Mr. Yamada responded that there are serious issues with attempting to maintain an incinerator anywhere, including environmental groups who are against them. He noted that there was one in Oakland, but the environmental groups closed it down.

The member of the public asked if DPH pays a charge to ship their waste to Utah, Texas, etc. for incineration.

Mr. Yamada confirmed and stated that the cost has become very high. He noted that it is probably adding more pollution by trucking the items out of state versus the pollution caused in burning it. He added that they have asked for an alternative from the environmental groups as well, but have not been provided with anything viable so far.

Mr. Powers asked how this is being handled by other countries.

Mr. Yamada responded that there is a new "plasma heat" system which adds high heat to the waste, but are attempting to find out if it is working. He added that a lot of countries are incinerating their waste and their standards are lower than ours.

Mr. Powers commented that, regardless of how SB 966 came to pass, he feels strongly that it is an extremely important issue and is glad that it was brought forward.

Ms. Herold noted that it is a cross-disciplinary and national issue and many regulatory agencies are getting involved to address and resolve the issue.

President Schell recognized past board member, Stan Goldenberg.

President Schell recognized the chairman of the board of CSHP, William Yee.

(f) Discussion of Sharps Take-Back by Pharmacies

Dr. Swart explained that, since September 1, 2008, California law has prohibited the disposal of sharps in trash or recycling containers. He noted that information from the Integrated Waste Management Board's Web site was provided within the board packet, and that pharmacies are listed as one of the disposal locations. He added, however, that pharmacy law does not authorize pharmacies to take back sharps unless there is a county-adopted needle exchange program in place.

Regarding appropriate destruction, the Department of Public Health states that:

California Health and Safety Code, § 118286 (b)

On or after September 1, 2008, home-generated sharps waste shall be transported only in a sharps container, or other containers approved by the enforcement agency, and shall only be managed at any of the following:

- (1) A household hazardous waste facility pursuant to § 25218.13.
- (2) A "home-generated sharps consolidation point" as defined in subdivision (b) of § 117904.
- (3) A medical waste generator's facility pursuant to § 118147.
- (4) *A facility through the use of a medical waste mail-back container approved by the department pursuant to subdivision (b) of § 118245.*

The CDPH Medical Waste Management Program is recommending the use of sharps containers approved by the U.S. Food and Drug Administration (FDA).

In the interim, since California pharmacy law does not allow pharmacies to take back sharps containers, and beginning September 1, patients cannot dispose of sharps by tossing them into the trash, this does create problems for patients.

Additionally, the issue of how and where patients return sharps and who will pay for the expense of these returns continues. At the end of September, AB 501 was vetoed by the Governor. This bill, which the board supported, would have required manufacturers of prefilled injection devices (e.g., epipens) to provide information to patients about how to dispose of the items.

Dr. Swart provided his personal experience as a pharmacist in Washington, where patients would drop off used syringes at pharmacies after hours. This resulted in staff being stuck on two occasions by those sharps left on the pharmacy counter. He stressed the importance of ensuring strict guidelines on proper disposal of the syringes within a sharps container.

Board Discussion:

Mr. Powers asked how the board's support of the needle exchange program is affected by the proposed policy.

Ms. Herold stated that one of the program requirements of conducting a needle exchange program is to have a sharps take-back program in conjunction.

Public Comment:

Mr. Yamada explained that DPH registers sharps consolidation points, and that there are some pharmacies who have requested registration. He stated that they would like to adopt the policy language within their registration packet and include it as a statement to registration.

Dr. Swart wants to ensure that the sharps take-back program is clarified as being voluntary only.

Dr. Gray asked for clarification on whether pharmacies are currently allowed to accept sharps for take-back.

Ms. Schieldge responded that under current pharmacy law, there is no authority to take back sharps. She stated that there may be discipline brought for unprofessional conduct, but also wanted to recognize that there are no standards or regulations in pharmacy law currently that govern take-back.

Dr. Gray said his understanding is that if a pharmacy receives the permit, then they are under authority to take back the product.

Ms. Herold responded that the law does not specifically authorize pharmacies to run a sharps take-back program, even with a permit. She explained that they are seeking to deal with the legality of that, but in the interim there are some local ordinances which are requiring pharmacies to take back the drugs. Ms. Herold explained that the board is trying to provide some guidance to assist with the dilemma those pharmacies are in. She pointed out the issue where, in the counties that are currently requiring sharps take-back, the DPH has deliberately held back on providing permits until the Board of Pharmacy can address the issue.

Dr. Gray asked if the same policy applies to entire hospitals since their licenses are issued and enforced by the Board of Pharmacy.

Mr. Room responded that it is the pharmacies within the hospitals that are enforced by the board. They do not regulate the remainder of the hospital.

Mr. Powers stated that he finds the policy confusing and somewhat contradictory and will take a position to abstain because he is uncomfortable with it.

Ms. Zinder stated that the motion and policy seems to lack purpose and doesn't provide direction. She stated concern that by making the motion it may only cause more confusion.

President Schell provided clarification that the board's intent is to exercise its enforcement discretion. However, if there is action being taken due to a consumer complaint, for example, on inappropriate conduct relating to sharps take-back and safety, then the board would take disciplinary action to address the issue.

Ms. Zinder stated that she understands the intent, but is not sure it clearly states that within the written policy.

Ms. Herold explained that the policy was specifically developed in response to the September 1, 2008 date when the new law took affect. Additionally, there is a county which put forth the ordinance without knowledge of the board and expects to run a pilot program for two years.

Mr. Graul stated that, as a pharmacist and owner, he would be able to read the regulation and understand it. He added that the policy is indicating that, as long as what the pharmacy is doing is appropriate in relation to sharps take-back, then the board will not take disciplinary action against them for taking back sharps.

Mr. Weisser asked if legal counsel find the policy confusing. He also asked if the board reviews and approves all the policies that are developed, by way of action items.

Mr. Room responded that there is a general delegation that is in place to the Executive Officer and board staff for the purpose of enforcement actions, and that this is a fairly new phenomenon. In order to provide reassurance to some constituents who are licensees of the board, the board is not attempting to make an issue of the new law.

Mr. Weisser asked if a pharmacy decides to have a sharps take-back program, and the board decides that they are in violation of a non-related issue, how that would be addressed in light of the policy.

Mr. Room stated that the board will continue to exercise their enforcement responsibilities if necessary. He added that it will not provide complete defense if a pharmacy conducts inappropriately.

Ms. Schieldge added that administrative agencies are constrained by the statutes that they have jurisdiction over. She reminded them of the reason the board is addressing the issue, that currently the law says that the board can not allow pharmacies have sharps take-back programs, yet the pharmacies need to be able to follow the local ordinances which state that they are able to conduct drug take-back programs. The board does not anticipate actively pursuing cases unless one comes before the board.

Ms. Herold stated that part of the reason this issue is being placed before the board at this time is due to a request by another regulatory agency for guidance with respect to whether they can issue permits to the pharmacies, given the new law in effect as of September 1st.

President Schell noted that this is a temporary solution.

MOTION: For the board to adopt as an interim policy that:

California law does not authorize pharmacies to accept the return of sharps when appropriately contained in an approved sharps container. The board reserves its enforcement discretion about whether to intervene with any pharmacy that takes back sharps containers appropriately. However, until this matter is fully resolved, the board does not anticipate intervening in such practices. Nevertheless, this policy may change as a result of a complaint or public safety issue.

M/S: BG/TD

Support: 9 Oppose: 0 Abstain: 1

In addition to the policy, a legislative fix was recommended. A brief history was provided.

In July, recognizing that there was a potential problem for consumers since pharmacy law does not authorize pharmacies to take back sharps, and yet on September 1, the law would limit how patients could simply dispose of these items, board staff proposed an amendment to California Pharmacy Law to allow such a practice. However, the bill to authorize this was dropped at the end of August by Senator Simitian for other reasons. The amendment was simple, and would add:

A pharmacy may accept the return of needles and syringes from the public if contained in a sharps container as defined by Health and Safety Code § 117750.

MOTION: To recommend to the board to approve the following amendment:

A pharmacy may accept the return of needles and syringes from the public if contained in a sharps container as defined by Health and Safety Code §11750.

M/S: BP/SW

Support: 10 Oppose: 0

(g) Summary of Medication Errors Made by California Pharmacies 2007/08

At the July 2008 Board Meeting, the board held a forum on medication errors. Michael Cohen of the Institute for Safe Medication Practices, John Keats of California Patient Safety Action Coalition (CAPSAC), and Bob LeWinter of the California Department of Public Health provided presentations on activities underway to prevent pharmacies from making or repeating medication errors. Additionally, there was discussion of the findings of the 2006 SCR 49 Medication Errors Task Force report.

Also at the July Board Meeting, Ms. Herold provided a presentation of the medication errors cited and fined by the Board of Pharmacy during 2007-08. There were 402 medication errors reported to the board during this period, and 600 medication error cases closed during the period. Of these cases 94 percent were substantiated as errors.

During the discussion at the July Board Meeting and then later during the Communication and Public Education Committee Meeting (held in conjunction with the board meeting), Ms. Herold suggested including information in the board's newsletter or in a separate issue on some of the medication errors investigated by the board.

Dr. Swart noted that a list of drugs involved in the medication errors reported to the board was provided within the board packet. This list will be published in the next issue of *The Script*. He noted that the Communication and Public Education Report provides a more lengthy discussion of what will be published in the newsletter on medication errors.

(h) Discussion: Hospital Pharmacies' Control of Drugs within a Hospital and Proposal to Form a Subcommittee to Update Requirements for Hospital Pharmacies

Dr. Swart explained that, by early June, the board had completed its inspections of 533 hospital pharmacies in California and identified 94 hospitals where recalled drugs were still in patient care

areas. He indicated that the board has cited and fined the hospitals, pharmacists-in-charge and consultant pharmacists in those hospitals for failure to secure the hospitals' drug supplies by allowing recalled drugs to remain in the pharmacies, dispensing machines and in patient care areas. Several wholesalers and their designated representatives who shipped recalled drugs have received citations and fines as well.

Dr. Swart indicated that, currently the board's senior staff is holding office conferences with those who are contesting the fines. He added that there may be administrative hearings for the next level of appeal. As such, the board cannot discuss the specifics of the heparin recall with the board members at this time.

Dr. Swart stated that, at the October Committee Meeting, the committee floated the idea of forming a task force with hospital pharmacies and pharmacists, the hospital association and others to discuss how pharmacies, and the pharmacists-in-charge can better maintain control of drugs within a facility. He added that, during the meeting, the committee heard from UCLA on how it handles drug distribution within its multiple pharmacies, and also from Woodland Hospital on how it supplies drugs through the hospital from its one pharmacy.

It may also be time to look to revising California Pharmacy Law with respect to hospitals, which are very different than what they were when the laws were created. There has been no substantial review in the last 20 years, if not longer.

Board Discussion:

Mr. Powers asked what the role is of the committee.

Dr. Swart explained that there were two different approaches presented by the speakers from UCLA and Woodland Hospital at the last committee meeting in how they control their drug supply. He added that there has been significant concern voiced over holding pharmacists-in-charge (PIC) in a hospital setting responsible for losses of controlled substances where they may not have control within the structure of the hospital. The committee's role is to determine if a change needs to be made within pharmacy law to address the issue.

Ms. Herold stated that the board has not revisited how they regulate hospital pharmacies for at least 20 years. She added that the hospital pharmacy setting is quite complex, and the board needs to find a way for pharmacy law to accurately affect what they do. She noted one example of the satellite hospitals that are in existence, and that there are no provisions for operation of those types of settings. She mentioned the issue of recalls within hospital pharmacy settings as an additional issue to address.

Dr. Swart asked if President Schell would be assigning individuals to the subcommittee.

President Schell confirmed.

Mr. Burgard stated that the presentations at the last Enforcement committee meeting were very impressive to him. He said that he has had personal exposure to drug distribution and described the informal and inappropriate activity he has seen in some senior care hospitals. He concluded by saying that he is in favor of seeing the subcommittee move forward.

MOTION: To form a task force of two board members and work with other interested parties to improve drug distribution in hospitals.

M/S: JB/HH

Support: 10 Oppose: 0

(i) Minutes of the Meeting of October 6, 2008

Dr. Swart stated that the minutes of the Enforcement Committee and Workgroup on E-Pedigree meeting were contained within the board packet provided.

B) First Quarterly Report on Enforcement Committee Goals for 2008/09.

Dr. Swart stated that the strategic plan update for the Enforcement Committee for the first quarter of 2008/09 are contained within the board packet provided.

C) Enforcement Statistics 2008/09

Dr. Swart stated that the enforcement statistics from the first quarter of 2008/09 are contained within the board packet provided.

D) Public Comment

No public comment was provided.

III. Recognition of Pharmacists Licensed with the Board for 50 years

There were no pharmacists who have recently reached their 50-year anniversary of service as a pharmacist.

President Schell recognized former board member and president, Stan Goldenberg. President Schell said that he looked to Mr. Goldenberg as a guiding force as how the board perceived and played its role of public protection. He added that Mr. Goldenberg has been an esteemed colleague and friend and appreciates all the service Mr. Goldenberg provided for the board and the state of California. Mr. Goldenberg was presented with a clock by the Board of Pharmacy.

Mr. Goldenberg said that it has been his distinct honor to serve on the board for eight years, and as president for two years. He said that he has been privileged to meet and work with a talented group of individuals. He commended the board staff and Executive Officers. He gave personal thanks to Bill Powers, Clarence Hiura and John Jones. Mr. Goldenberg stated that as a board member and president, he appreciated the opportunity to create a living legacy. He thanked the board and administration for allowing him the opportunity to serve.

President Schell recognized former board member, Ruth Conroy. President Schell noted that he and Dr. Conroy joined the board at the same time. He stated that she is an individual whom he admires and respects as a professional pharmacist. He thanked her for her service to the state of California and to the board.

Ms. Conroy thanked everyone who served on the board, both professional and public members. She emphasized how the public members are very involved and put effort in to learning about something outside of their expertise. Ms. Conroy thanked Mr. Goldenberg for mentoring her. She added that it has been a distinct pleasure to serve on the Board of Pharmacy for five years.

President Schell recognized board member and former president, Bill Powers. President Schell gave special appreciation to Mr. Powers for his tremendous service to the board in promoting patient safety. He thanked him for his service to the state of California and the board. Mr. Powers has completed his two terms and will most likely be replaced prior to the next board meeting.

Mr. Powers thanked the board for the opportunity to serve the people of California. He stated that serving the public has been an important part of his life for the past eight years, and feels that the public does not understand the role of the agencies and its importance. Mr. Powers noted the substantial number of public members on the board, as some other boards are completely run by professional members. He said that he appreciated the opportunity to work with everyone on the board.

IV) Licensing Committee Report and Action

A) Report on the Meeting of September 29, 2008

1) Emergency and Disaster Response Planning

(a) California Dept. of Public Health: Request from San Diego County for Exemption to Distribute Prophylaxis Drugs to Emergency Response Staff Prior to a Declared Emergency

Susan Ravnán explained that in 2007, the board received a request from San Diego County to provide an unspecified number of up to 500,000 bottles of a 7-14 day dosing regiment of doxycycline or ciprofloxacin to first responders, that would be stored in their homes for their and their families' use, with the remainder being stored somewhere (unmentioned) else. She explained that the county was seeking an exemption from patient-specific labeling because it would be "difficult, if not impossible" to label these containers. She noted that this request was later withdrawn.

Dr. Ravnán further explained that, in September 2008, the board received a new request from San Diego County. This plan calls for Doxycycline 100mg #20 to be prescribed to approximately 100,000 First Responders and Critical Access Employees and their family members. Dr. Ravnán noted that each prescription will be written by the Public Health Officer (a licensed California prescriber) and transmitted to a pharmacy for dispensing.

Dr. Ravnán stated that San Diego County is seeking confirmation that this model satisfies the requirements in pharmacy law.

During the Licensing Committee meeting, several members of the committee expressed concern over this request including whether the Public Health Officer can write prescriptions without a good faith examination.

Based on the outcome of this discussion, the committee has requested that board staff send a letter to San Diego County detailing the committee's concerns and request that they come to a future committee meeting to respond to questions.

Board Discussion:

President Schell asked what the expected action of the board is at this time.

Anne Sodergren explained that the licensing committee will ask San Diego County to attend a meeting as there are some questions regarding whether their model is allowed within the parameters of pharmacy law. Additionally, board staff has spoken with the Medical Board and there

is concern in regards to a potential need for a “good faith examination” prior to dispensing of any drugs. Board staff will draft some of the concerns of the board as well as request that they attend a committee meeting to address those concerns and other questions.

Mr. Powers asked if Doxycycline is the only drug that they are asking to have dispensed and what the purpose of the drug is.

Dr. Ravnan confirmed and indicated that the drug is an antibiotic.

Mr. Powers asked what currently happens in the case of an emergency.

Dr. Ravnan responded that there may be emergency stock in a location such as a fire department. She noted that it varies by county.

Mr. Powers asked if a prescription is currently required from a physician for those emergency stock supplies.

Ms. Herold responded that a prescription would not be required under an emergency situation. She clarified that the county is asking for pre-distribution in advance of an emergency.

(b) New Name for Emergency System for the Advanced Registration of Volunteer Health Professionals (ESAR-VHPS)

Dr. Ravnan stated that in August board staff received notification that the ESAR-VHPS was renamed to Disaster Healthcare Volunteers of California.

Dr. Ravnan explained that this system, coordinated by the Emergency Medical Services (EMS) Authority, was created to allow for health care professionals to sign up to serve as a volunteer in response to a disaster. The EMS will continue to work diligently to increase the number of volunteers in this program.

2) Patient Privacy Issues Arising from Abandonment of Records – The Abandoned Records Project of the California Office of Privacy Protection

Dr. Ravnan stated that the committee was advised that the California Office of Information Security and Privacy Protection recently convened a meeting to discuss abandoned records. She explained that this can involve health information, financial information or other personal information. She further explained that such records contain personal information for which no responsible owner or custodian can be located, but does not include improperly disposed of records (such as records being placed in a dumpster.)

While the committee did not take any formal action on this issue, board staff will include an article in *The Script* about records retention requirements. Additionally staff will attend future meetings on this topic and will continue to provide the committee with updates as well as any recommendations to address gaps in pharmacy law.

Ms. Herold explained that pharmacy law has specificity in regards to the storage of records after a pharmacy discontinues business, including that those records must be stored within the premises of another licensed facility for a minimum of three years. She said that the Office of Privacy Protection is reviewing the issue of abandonment of records in general when an entity goes out of business and leaves the documents behind in an unsecured manner. The concern is over resulting stolen identity, etc. when no one is specifically held responsible for the proper disposal of those

documents. Ms. Herold stated that, in the case of a pharmacy, the requirements for record retention is clear. She added, however, the issue of electronic records stored on computers is an issue that does need to be addressed in the future, as well as records stored at an off-site location. Ms. Herold noted that there will be ongoing meetings, and at some point the board may want to address more enhanced specificity in the requirements as currently set.

Public Comment:

Dr. Gray indicated that there are pharmaceutical entities that contract with companies to store patient profiles, dispensing records, etc. within centralized database servers that may not even be located in California. He stated that, at times, those contractors will withhold those records from the pharmacy and others due to missed payments or otherwise. Dr. Gray's suggestion is to place regulation to disallow contractors from being able to withhold records in such a manner.

Ms. Herold requested that Dr. Gray provide his proposal in writing and submit it to the board.

Mr. Weisser clarified that there are still hard copies stored, with regard to patient confidentiality.

3) Update on the 2007 Compromise of the NAPLEX Examination

Dr. Ravnan stated that the committee was provided an update on the litigation against the Board of Regents of the University System of Georgia and two University of Georgia (UGA) College of Pharmacy professors. She explained that this litigation alleges that the University offered and the professors conducted a pharmacy examination review class in which the participants were provided with actual test questions from the North American Pharmacist Licensure Examination (NAPLEX) and the Multistate Pharmacy Jurisprudence Examination (MPJE).

Dr. Ravnan said that the National Association of Boards of Pharmacy (NABP) states that it continues to gather information related to this matter, which calls into question whether participants of the review course met the qualifications for licensure to practice pharmacy competently and safely. She said that the NABP also indicated that they believe that this course was also offered at other schools and colleges of pharmacy. The NABP is taking steps to identify relevant students and will communicate any NAPLEX score invalidations to the Board of Pharmacy, as well as the affected individuals.

Dr. Ravnan indicated that, should any California licensed pharmacist be identified, the board will be required to pursue disciplinary action against the pharmacist to remove them from practice. She added, however, that there have been none identified.

Dr. Ravnan stated that the board received a copy of the formal complaint filed by the NABP with the Accreditation Council for Pharmacy Education (ACPE) in regards to the accreditation status of the University of Georgia College of Pharmacy. This information states that during the ACPE Report of Proceedings for June 18-22, 2008, meeting of the ACPE Board of Directors, the University of Georgia College of Pharmacy was placed on probation (Spring 2009). NABP is requesting the immediate revocation of the University of Georgia's accreditation.

Discussion at the meeting included possible action the board would need to take if the ACPE revokes the accreditation of University of Georgia or if the board is notified of individuals involved in the compromise. Such action could include canceling the license of an intern or seeking revocation of a pharmacist license if necessary.

Board Discussion:

Mr. Hough stated that he recalls this as not the first time the two professors have been accused of this conduct.

Dr. Ravnan responded that she understands this was a repeat offense.

President Schell asked for clarification that an individual's license would be revoked if they had graduated from UGA and attended a class taught by one of the professors involved.

Ms. Herold responded that it would depend on the form in which it occurred and what type of notification the board received. She added that it would be a great challenge to address and would require working closely with departmental counsel and the Attorney General's office.

Ms. Sodergren stated that the additional issue is that if there are students who are currently attending the school, and the school lost its accreditation, then the condition under which a student was issued an intern license is no longer valid. In this scenario, legal counsel would need to be involved as well in order to determine a plan of action with regard to their intern license.

4) Fact Sheets on Application Procedures for Pharmacist Applicants

Dr. Ravnan stated that the committee was advised that approximately 50 percent of the pharmacist examination applications the board receives are deficient. She explained that, in an effort to improve applicant understanding of the requirements for licensure, board staff has developed fact sheets that will be placed on the board's Web site. She said that these fact sheets are specific to each of the three groups of applicants who qualify for the pharmacist examination: recent graduate, foreign graduate and licensed pharmacists from out of state. She stated that they are hoping the end result of these fact sheets will be a reduced number of deficient applications and fewer inquiries to board staff.

Dr. Ravnan indicated that, for the last several years, board staff has made site visits to California Schools of Pharmacy to provide presentations on the application process. She noted that these presentations reduce the number of deficient applications received from California graduates. Unfortunately, the board cannot complete this type of outreach to out of state schools; however, the board is hopeful that these fact sheets will have a similar affect.

Board Discussion:

Mr. Dazé asked if there is an area in particular that applicants are having challenges with.

Ms. Sodergren explained that there are various supporting documents that need to be provided along with the application (i.e. transcripts, etc.) and are often not received appropriately or are not sent to the board directly from the school as required.

Ms. Herold added that if the transcripts or other supporting documents are received in advance of the application, staff will hold them until the application is provided. The issue arises when documents do not arrive following the application. She added that the instructions provided with the application are very thorough (12 pages in length). Some applicants contact the board when they do not receive their license in a timely manner, even though they did not review the instructions completely before calling. Ms. Herold advised that the board is currently not taking status inquiry calls. She said that the fact sheets are an effort to provide information to them in a more succinct manner with regards to the proper requirements of applications based on their type of license. In

conjunction, the “You Track” form has been provided to allow applicants to track the status of their licenses more independently.

Public Comment:

Lorie Rice (UCSF School of Pharmacy) stated that this is not a unique problem just for applying for licensure. She stated there is a tremendous amount of applicants who apply for pharmacy school where applications are deficient as well. Ms. Rice stated that there is only so much that can be done to provide direction to an applicant, and that they are ultimately responsible for ensuring that their application and documents are completed appropriately. She added that she may be able to provide information on the number of students who did not complete the UCSF application process properly and thus went to another school of pharmacy because of it.

5) Licensing Unit Workload Adjustments Made to Accommodate Budget Restrictions

Dr. Ravnan explained that, effective August 1, 2008, the Governor signed Executive Order 09-08, which required the board to dismiss several non-permanent employees and to furlough one additional staff member. As a result, the board lost six key staff responsible for, among other duties, assisting with the processing of applications and other licensee maintenance processes such as change of pharmacist-in-charge applications, change of designated representative-in-charge forms, discontinuance of business forms, etc. Dr. Ravnan added that, during that time, staff has worked diligently to issue licenses in a timely manner while being short-staffed.

Ms. Herold stated that the board received notice two weeks ago that they can restore hiring of staff members. Those staff members’ main duty is to process applications and provide responses to applicant inquiries. Ms. Herold explained that the staff is inundated with calls from individuals wanting to check on the status of their applications, which thus significantly slows down the time staff has to process and issue licenses. She noted that they are currently in the process of rehiring a permanent intermittent and two retired annuitants. Ms. Herold commended the efforts of the licensing staff in this difficult time, noting that 169 licenses were issued within one week of releasing 369 results of the CPJE exams.

Mr. Hough commended the Board of Pharmacy staff for their hard work during the strenuous time of being substantially short-staffed.

6) The Coalition on Shortages of Allied Health Professionals – Formation of a Pharmacy Services Workgroup to Deal With Shortages of Pharmacists and Pharmacy Technicians

Dr. Ravnan stated that the California Hospital Association recently established a coalition to examine the shortages of allied health professionals. She explained that the mission of this coalition is to create and lead a statewide coordinated effort to develop and implement strategic solutions to the shortage of non-nursing allied health professionals. This coalition is comprised of workforce committees, an advisory council and four workgroups. Dr. Ravnan noted that board executive staff was invited to participate on the pharmacy services workgroup, and that the focus is on pharmacists and pharmacy technicians in the hospital setting.

Dr. Ravnan said that the first workgroup meeting was held on September 16, 2008. Participants included staff and members of the California Hospital Association, the California Society of Health-Systems Pharmacists, a representative from academia, representatives from various hospitals and health systems as well as board staff. Dr. Ravnan indicated that, during this first meeting, barriers to the profession for both pharmacists and pharmacy technicians were identified. Further discussion

resulted in the group concluding that there is not a shortage of pharmacy technicians; rather it is a shortage of *qualified* pharmacy technicians.

Some of the barriers identified for pharmacists included a limited number of student slots for individuals looking to enter the profession, the pharmacist examination and reciprocity, losing potential candidates to other healthcare professions (e.g., medical school), and untested new schools of pharmacy.

Workgroup meetings will continue quarterly over the next year. Based on the results of this workgroup, it is the hope that the coalition will develop and implement solutions to eliminate barriers, foster collaboration among CHA member hospitals and health systems, promote a long-term vision for the allied health workforce in California and develop links with workforce partners and stakeholders.

Ms. Sodergren indicated that the workforce group recently conducted a conference call meeting on October 22, 2008. The workgroup discussed the major barriers to increasing the supply of pharmacists. More specifically, the issues in the educational and training infrastructure for pharmacy which severely limit the number of pharmacists that can be educated and trained each year include limited number of pharmacy school "slots," a short supply of faculty to support the expansion of pharmacy schools, and an insufficient number of experiential training sites. The workgroup identified the lack of experiential training sites as highly critical, as there would not be enough sites to accommodate students even if there were sufficient faculty and school expansion. The workgroup concluded that all of these issues must be addressed in unison in order for the pharmacy education and training infrastructure to operate at optimum efficiency and thus increase supply.

Other issues discussed by the workgroup included state reciprocity and national licensing with state examination requirements for the scope of practice.

Ms. Herold added that this is just one of several groups that are being created to address the staffing challenges which will continue to arise for the next 10 – 30 years. She explained that one of the objectives of the Department of Consumer Affairs was to analyze whether the growth of the workforce is in line with the future demand in the healthcare industry. She noted, however, that the focus of this work group is on the hospital sector.

7) Update: Task Force to Evaluate Pharmacy Technician Qualifications

This year the California Society of Health-System Pharmacists (CSHP) sponsored legislation to increase the requirements for an individual to become licensed in California as a pharmacy technician. Dr. Ravnan advised that this bill was pulled due to concerns expressed by key pharmacy stakeholders, with the intent of pursuing legislation again in 2009.

CSHP is sponsoring stakeholder meetings to elicit recommendations and comments to refine the proposal for next year. The first stakeholder meeting was held on June 25, 2008. Board Member Stan Weisser was designated by President Schell to represent the board at these meetings.

Mr. Weisser indicated that the discussion at both the June 2008 Licensing Committee Meeting and the stakeholder meeting revealed that there is disagreement within industry about what and if there is a problem with the current existing pharmacy technician qualifications requirements as well as whether the draft legislative proposal correctly addresses the minimum qualifications. In addition, Mr. Weisser stated that there appears to be disagreement about whether continuing education is necessary for pharmacy technicians.

Mr. Weisser stated that CSHP is currently working jointly with CPhA to determine common interests. CSHP anticipates convening stakeholder meetings in the future to elicit stakeholder recommendations and comments to refine the proposal for next year.

On the national level, during the NABP annual meeting, a resolution was passed to establish a task force on standardized pharmacy technician education and training. This task force will assess and recommend revisions, if necessary, to language in *the Model State Pharmacy Act and Model Rules of National Association of Boards of Pharmacy*.

Public Comment:

Bryce Docherty (CSHP) thanked the board and staff for involvement, as well as CPhA, Kaiser, stakeholders, and retailers. He stated that there was a meeting with CPhA and board staff in early October to review their strategy for the remainder of this year, specifically to share with board staff some general concepts and ideas for the legislation going forward next year. He added that CSHP's board of directors approved the direction they are taking and no objections arose during that meeting. CPhA board of directors will be meeting in November, and envision having another larger stakeholder meeting prior to the end of this year, in hopes to hone in language to move forward with next year. Mr. Docherty noted that assemblyman member Bill Emerson would be the author of the legislation again. He added that they are looking at 1) standardization of pharmacy technician training 2) requirements for passing a "PTCB type" exam and 3) requirements for continuing education. Mr. Docherty explained that typically the legislative arena is the "last resort" for issues, however the reason for pursuing this issue through the legislative process is because CSHP wants to standardize and strengthen the current requirements, in light of the ongoing concern within industry of shortages of qualified pharmacy technicians. He gave examples of specific incidents resulting in harm or deaths because of errors by pharmacy technicians. He added that these incidents occurred in other states, but CSHP and its members do not want to wait until an incident occurs to take action. Mr. Docherty concluded by stating that they will continue to keep Mr. Weisser and the board updated on their progress and they will pursue legislation next year.

8) Veterinary Food Animal Drug Retailers – Qualification Processes for Designated Representatives

Dr. Ravnan stated that the committee discussed the board's veterinary food-animal drug retailers (vet retailers) licensing program. She explained that a designated representative of a vet retailer may distribute and label prescription drugs or drugs for extra-label use that are prescribed by a veterinarian for use on food-animals. She further explained that a vet retailer's premises must be supervised by a registered pharmacist or a specially qualified individual approved by the board who holds a current vet retailer designated representative license. A vet retailer may not operate unless the pharmacist or vet retailer designated representative is physically present on the licensed premises.

There are currently 23 vet retailers and 62 vet retailer designated representatives licensed in California.

Only a vet retailer designated representative or pharmacist may label the drugs that: (1) have been prescribed by a veterinarian, and (2) will be shipped to the veterinarian's client for use on food-animals. If the sole qualifying vet retailer designated representative or pharmacist leaves the employ of the vet retailer, the vet retailer must cease operations (and cannot perform labeling or shipping duties) until another pharmacist or vet retailer designated representative is employed and present. For this reason multiple designated representatives are needed.

Individuals employed by a manufacturer, vet retailer, or wholesaler may qualify to become vet retailer designated representatives on the basis of specific education, training, and experience in areas covering the essential knowledge necessary to oversee operations of a vet retailer and to read, label and dispense veterinary food-animal drugs.

The committee discussed the requirements for licensure for both a vet retailer license as well as the vet retailer designated representative. As the designated representative must have the ability to read prescriptions and prepare and label containers for food animals without the oversight of a pharmacist, specific training or education is required for licensure.

Dr. Ravnan advised that the University of California Davis in the past had a 40 hour training course that satisfied the requirements for licensure as a vet retailer designated representative; however, the board received information that this program is no longer offered. She noted that board staff is unaware of any other program in California that complies with the requirements in law.

Dr. Ravnan indicated that the committee heard testimony from Dr. Karle, representing the State Veterinary Association. Dr. Karle highlighted the current problems with this program. Dr. Karle stated that this is a consumer safety issue because vet retailers and designated representatives provide medication that ultimately ends up in our food supply. Similar to consumer medication errors, some of the problems encountered include: 1) selling the wrong prescription drug, 2) correct label but wrong drug, 3) selling the incorrect volume or quantity, 4) mislabeling or mishandling the product and 5) promoting incorrect drug use. Dr. Karle stated that many vet-retailer designated representatives are not acting responsibly and that the standards for licensing need to be raised, to include more training and continuing education.

Ms. Herold stated that the board is not sure of their direction at this time. She indicated that they are in discussion with Dr. Karle. She stated the concern that if they cannot adequately train individuals as vet-retailer designated representatives, then it may be time to seek the elimination of the program and move the responsibility back to the veterinarians. She noted that this is a special exemption that has been developed for food-animals, and that because the wholesalers are specialized and are allowed to label the product for end use application pursuant to a prescription without supervision of a licensed pharmacist, it is important to ensure that the safety of the food-supply is not jeopardized. Ms. Herold explained that, it becomes a concern when there is inadequate training available, as is currently the case. She added that, without any entity offering to provide the proper training, she recommends that the board consider whether to continue with the current regulatory program.

9) Proposal to Award Continuing Education for Competency Committee Members for Specified Duties

The committee discussed a request from the Competency Committee, which is a subcommittee of the board's Licensing Committee. Competency Committee members serve as the board's subject matter experts for the development of the California Practice Standards and Jurisprudence Examination for Pharmacists (CPJE). A committee member term is generally about eight years.

Annually, committee members attend approximately 3-4 two-day meetings to assist in examination development. Each two-day committee consists of approximately 2-4 hours of preparation time in addition to 16 hours of meeting time. Committee members also participate in 2-4 writing assignments based on the examination development need. Committee members spend approximately 50-80 hours preparing for and attending committee meetings on an annual basis in addition to multiple writing assignments and are compensated for time and travel.

Current pharmacy law requires pharmacists to earn 30 hours of approved continuing education (CE) every two years as a condition of license renewal. Currently, pharmacists can earn CE:

- Offered by approved providers (ACPE and the Pharmacy Foundation of California – 16 CCR §1732.05),
- Approved by Medical Board, Board of Podiatric Medicine, Board of Registered Nursing or Dental Board, if relevant to pharmacy practice (16 CCR §1732.2), or
- By petition of an individual pharmacist for a course that meets board standards for CE for pharmacists (16 CCR §1732.2).

Additionally, the board will award CE for:

- Attending one board meeting annually (6 hours of CE),
- Attending two committee meetings annually (2 hours of CE for each meeting, must be different committee meetings), and
- Completing the PSAM, which is administered by the National Association of Boards of Pharmacy (6 hours).

In June 2008, the Licensing Committee considered a request from the competency committee to earn 6 hours of CE annually for participation in this committee. The committee decided to request additional information on this topic and did not take action.

Dr. Ravnan stated that, based on further discussion with the committee during its annual retreat, the committee is revising and resubmitting its request. Specifically, she explained that one of the core functions of this committee is to complete an on-line review of all test questions prior to administration. She further explained that, as the test questions cover all aspects of pharmacy practice and law, this on-line review requires a significant amount of committee time to research items and confirm that a question and answer are valid. Given this, the committee requests that the board award up to six hours of CE annually for members that complete this on-line review. (Typically committee members are not compensated for their time to complete this function. If a committee member is seeking reimbursement for this time however, continuing education will not be awarded.)

MOTION: To award up to six hours of continuing education credit annually to complete on-line review of examination questions if the committee member is not seeking reimbursement for their time.

Support: 10 Oppose: 0

10) Competency Committee Report

(a) Update of the CA Practice Standards and Jurisprudence Examination for Pharmacists (CPJE)

Dr. Ravnan advised that the most recent quality assurance assessment ended October 1, 2008.

Ms. Herold indicated that the exam statistics for the last six months of the CPJE were contained within the board packet provided. She noted that exam statistics are released in April and October of each year.

(b) Report to the Legislature on the Impact Of Requiring Those Who Fail the Pharmacist Licensure Examinations Four Times to Take 16 Units of Remedial Education (B & PC § 4200.1)

Business and Professions Code § 4200.1 establishes a requirement in law that an applicant who fails either the California Practice Standards and Jurisprudence Examination for Pharmacists (CPJE) or the North American Pharmacist Licensure Examination (NAPLEX) four times, must complete 16 units of pharmacy education prior to being eligible to take either examination again.

In addition, this section also requires the board to collect specified data and submit a report to the legislature detailing the findings. The reporting elements include:

- The number of applicants taking the examination and the number who fail the examination for the fourth time,
- The number of applicants who, after failing the examination for the fourth time, complete a pharmacy studies program in California or in another state to satisfy this requirement,
- To the extent possible, the school from which the applicant graduated, the school's location and the pass/fail rates on the examination for each school.

The report includes data from January 1, 2004 through July 1, 2008.

Ms. Herold explained that for several years pharmacy law has required individuals to return to a school of pharmacy for 16 units of remedial education when they have failed the pharmacist licensure examination four times. Ms. Herold reviewed the statistics from the reporting period of January 2004 – July 2008, which reflected that 50% of the students who complete the remedial education after failing four times subsequently passed the exam. She concluded that the results provide some assurance that those individuals will more likely have some success in the pharmacy profession.

Dr. Swart asked if there has been any pushback from the schools of pharmacy in regards to admission into the schools because of space limitations.

Ms. Herold responded that admittance is very limited because actual patient care is a part of the curriculum. Because of this, some schools will not allow admittance of those who have failed the exam four times.

MOTION: To approve the report as drafted to be provided to the legislature, detailing the impact of requiring candidates for pharmacist licensure who fail the licensure four times to take remedial education before they can take the licensure exam.

M/S: SW/BP

Support: 10 Oppose: 0

In addition to approval of the report, the board also voted to repeal the sunset date in the B & PC Code 4200.1.

MOTION: For the board to empower staff to seek legislation to repeal the sunset date in the Business & Professions Code § 4200.1 with regard to the issue of allowing the applicants to take 16 units of remedial education after failing the pharmacist licensure examination four times.

M/S: BP/TD

Support: 10 Oppose: 0

11) Minutes of the Licensing Committee Meeting Held September 29, 2008

Dr. Ravnan stated that the minutes are contained within the board packet provided.

B) Discussion of Licensure of Ambulatory Surgical Clinics by the Department of Public Health Under Health and Safety Code §1204 That Are Owned by Physicians

Current law allows the board to issue a clinic license only to an entity also licensed by the Department of Public Health (DPH). Last September the court issued a decision changing the interpretation as to whom the DPH can issue a clinic license. This decision, the *Capen* decision, determined that DPH does not have jurisdiction over surgical clinics owned in part, or wholly by a physician. The ramifications of this decision is that DPH can no longer issue surgical clinic licenses to such entities, nor can such current licenses be renewed. The *Capen* decision determined that regulation of such clinics falls under the purview of the Medical Board. Without a license from DPH, the board is unable to issue a clinic license to allow such clinics to purchase drugs at wholesale as well as commingle medications. Without the board issued license each prescriber must maintain a separate drug supply or the drug supply must be wholly owned by the professional director or some single prescriber.

AB 1574 (Plescia) contained provisions that would have allowed the board to issue a clinic license to entities licensed by DPH, as well as to those accredited as specified or Medicare certified. The board had a support position on this legislation which was vetoed by the Governor.

Until a legislative fix is provided, the board cannot issue a clinic license unless the entity is also licensed by DPH. Board staff will withdraw pending applications that are ineligible for licensure because they are not licensed with DPH and will advise applicants in writing.

Public Comment:

Bryce Docherty, California Ambulatory Surgery Association (CASA), indicated that AB 1574 was vetoed by the Governor. The veto was based the *Capen* decision and the fact that regulatory jurisdiction of ambulatory surgery clinics (with any portion of physician ownership) lies with the Department of Public Health. Mr. Docherty advised that the Governor's Office is interested in pursuing their own legislation to develop the state specific licensure criteria for ambulatory surgery centers. He added that CASA welcomes that legislation and explained that, if the Governor's office is successful, it will most likely entail all ambulatory surgery centers (regardless of physician ownership) to be licensed with the state. Mr. Docherty concluded that, if such a bill by the Governor's office is not successful, then CASA will pursue legislation once again. He stressed appreciation for the board's support.

C) Licensing Statistics 2008/09

Dr. Ravnan stated that the statistics are contained within the board packet provided.

D) First Quarterly Report on Committee Goals for 2008/09

Dr. Ravnan stated that the goals are contained within the board packet provided.

E) Public Comment

No comments were provided.

V) Regulation Hearing

A) Action to Amend Title 16 CCR §1773 and Adopt §1773.5 Regarding Establishment of an Ethics Course as an Optional Enforcement Component for Discipline

Dr. Schell read the following:

This hearing is to consider to amend §1773 of Division 17 of Title 16 of the California Code of Regulations to include completion of an ethics course that meets requirements as specified in 16 CCR §1773.5 as outlined in the public notice.

At this time, the hearing will be opened to take oral testimony and/or documentary evidence by any person interested in these regulations for the record, which is now being made by tape recorder. All oral testimony and documentary evidence will be considered by the Board pursuant to the requirements of the Administrative Procedure Act before the Board formally adopts the proposed amendment to these regulations or recommends changes which may evolve as a result of this hearing.

If any interested person desires to provide oral testimony there is a sign-up sheet in the back of the room. It will be appreciated if the person commenting comes forward and give his or her name and address, and if he or she represents an organization, the name of such organization, so that we will have a clear record of all those who appear.

Please keep in mind the following when making comments:

- A. This is a public forum to receive comments on the proposed regulations. It is not intended to be a forum for debate or defense of the regulations.
- B. Written testimony may be summarized but should not be read. The board will give equal consideration to written and oral testimony.
- C. If you have a question about a proposed regulation, please re-phrase your question as a comment. For example, instead of asking what a particular subdivision means, you should state that the language is unclear, and explain why you find it to be unclear.

After all interested parties have been heard, the issue will stand submitted.

Dr. Schell opened the hearing for testimony.

Hearing Testimony:

Lynn Rolston (CPhA):

Ms. Rolston stated that CPhA is in support of comments submitted John Cronin. She explained that the comments talk about 1) identifying classes and violations which would trigger having the ethics course included in whatever was “meated out” by the board for those individuals, 2) identifying the goals of taking such courses at that time so that it is clear what they are supposed to learn from the courses and 3) identifying the sources of acceptable courses, as they think there a number of them

out there, and they need to be clarified. Ms. Rolston stated that, in an earlier board meeting, CPhA had asked that there be a task force at the next enforcement meeting to discuss citation and fines. The purpose of the task force would be to discuss which violations essentially triggered which fines, for example. This would allow for clarity as CPhA puts out communication to the licenses of the state, advising them of the change of the board policy with regard to additional citations and larger fines because of the change in law.

Ms. Rolston responded that they want more clarification, which she believes can be provided when going into that “next step” as discussed.

President Schell clarified whether CPhA neither supports nor opposes the regulation as it is proposed currently.

Ms. Rolston responded that as true.

She added that CPhA thinks that using an ethics course in the case of certain violations under certain circumstances is a fine idea and could provide a lot of merit, and that from that standpoint they support it. However, there is a lack of clarity in regards to when it would be applied, etc. which could be taken care of later. Ms. Rolston added that they wanted to make sure that they expressed their point of view.

Lorie Rice (UCSF School of Pharmacy):

Ms. Rice stated that the UCSF School of Pharmacy strongly encourages adoption of the regulation. She provided background, indicating that she served as the Executive Officer for the State Board of Pharmacy for seven years. She stated that the board did not have an ethics course at that time, and feels that it would have been quite helpful to have one. She commended board staff for issuing the large amount of licenses previously indicated while short staffed. Ms. Rice stated that she also served on the state Medical Board for six years, and chaired the ad hoc committee on ethics, resulting in the passing of a regulation in 2006 which created an ethics program for physicians. She explained that she was invited to the 2006 NABP District 7 and 9 annual meeting to discuss the creation of a comparable program for pharmacists and, subsequently, was invited to appear before the Board of Pharmacy in January 2007 to make a similar presentation. She added that she is ecstatic to see this in writing and supports the regulation as written. Ms. Rice indicated that she has a full copy of her NABP speech and will provide it to Ms. Herold. She said that what is important about the presentation is the point of differentiating between a pharmacist error and a willful ethics violation. She added that presently, the board’s disciplinary actions sufficiently respond to pharmacist errors, but do not deal with ethical violations. Those ethical violations can range from dishonesty, inappropriate exhibition of rage in a pharmacy, fraud, cheating on exams, etc. Ms. Rice stated that the creation of an ethics program will give the board the tools to understand a pharmacist’s insight into his/her conduct and assist in assessing whether an incident was aberrant or a “character defect”. She stated that the program’s evaluation will give the board more information in determining whether education and greater sensitivity will turn the pharmacist around or whether to expect a repeat of that same violation. The program itself will have the responsibility of telling the board whether the pharmacist is suitable for an ethics program, whether the individual is compliant with the program and, in fact, whether the individual will benefit from the program. She explained that, if the answer coming from the program in any of those criteria is “no”, then the licensee would be referred back to the board and alternative disciplinary action would be instituted. Ms. Rice stated that such programs are very appropriate for the board to have the authority and will definitely help the board to ensure greater public protection. She added that, since the creation of the Medical Board’s program, she has been advised that 106 physicians have been referred. The program has not been in existence for a sufficient period of time for a comprehensive evaluation, however they

are watching it very closely. Ms. Rice explained that the reason she requested to provide testimony second was because she did have some awareness of the comments which Ms. Rolston would be making, and wanted to respond to them. She stated that the idea of narrowing the board's flexibility down to determine which violations can result in referral to an ethics program is an insurmountable task. She explained that the task force of the Medical Board's program began to approach the concept of determining which specific violations would require an ethics program, and they found that it was impossible. She further explained that, with many violations, you need to look at the specific circumstances to decide if it is an ethics violation or not. Ms. Rice gave an example of Medi-Cal fraud. The board may look at the circumstances of such a violation and decide that the individual was simply not paying attention or that they said their "CPA told them it was ok," and thus an ethics program might be appropriate. On the other hand, if it was a repeated situation of Medi-Cal fraud, that person would have his license revoked rather than an ethics program. She stressed that flexibility is needed, and that if you narrow down the categories of what would be considered ethics violations, then it will take away the board's ability for appropriate discipline. Ms. Rice also referred to Ms. Rolston's comments on the number of ethics programs currently in existence. She stated that those programs in existence are more like "traffic school" type ethics program, and there is no evaluation about the appropriateness of the licensees' attendance, the success of the program, etc. She reiterated that the program being crafted by the board is quite perfect in and of itself. Ms. Rice concluded by stating her appreciation to the board in hearing her testimony and urged the board to pass the regulation as written.

Steve Gray (Kaiser Permanente):

Dr. Gray stated that, on behalf of Kaiser, he believes it is important to have the availability of ethics training. He stated that it has been helpful in many professions and has shown its worth over time. Dr. Gray had comments on the specifics of the regulation. He referenced §1773.5, which follows §1773, and noted that §1773 seems to apply to pharmacists only, where §1773.5 applies to pharmacists and intern pharmacists. He stated that the board might want to take a look at whether both sections should apply to pharmacists, intern pharmacists, and technicians as well. Dr. Gray stated that some of the problems they have with submissions of claims, undue influence, etc. are ethical issues among technicians, and so the board may want to make that change. He said that there is a larger issue relating to law which prohibits the owner-operator from interfering with the pharmacist-in-charge and the appropriate performance of their PIC duties. He stated that the board may want to consider whether this ethics course could apply to owner-operators as well. He noted that many PIC's take direction from the owner-operator, and the board may want to determine if the ethics course can be applied to them. He realizes however, that it may not be appropriate regulatory construction. Dr. Gray stated that, heretofore, the testimonies have indicated the ethics course would apply when someone has been found to be unethical in the context of fraud, for example. He said that there is a bigger issue where the pharmacists need training as far as professional clinical ethics when they have two options – one being regulatory and the other being their professional duty to care for the patient. He stated the concern over how to evaluate what the pharmacist should do. He added that the board has long recognized that, in certain situations, a pharmacist has to make those types of decisions. He also stated that the board has appropriately recognized that there are exceptions to regulations where the primary duty is to protect the patient or the public. Dr. Gray said that too many pharmacists come out of pharmacy school as "black and white thinkers", and pharmacists need to be reminded and taught to make a professional judgment and learn how to make those evaluations, when necessary, between two choices. He reiterated that such topic should be a part of the ethics training, and will provide some direction when it's not necessarily a fraud situation or "bad behavior", but rather guidance on how to make ethical decisions, as well as a way to move forward in protecting the public and the patients.

There were no further testimonies provided.

B) Discussion and Possible Action to Amend Title 16 CCR §1773 and Adopt §1773.5 Regarding Establishment of an Ethics Course as an Optional Enforcement Component for Discipline

Board Discussion:

Mr. Powers stated that he is not sure an ethics course would give a pharmacist the direction of how make a choice of two “bad” options. He said that if there is such an ethics course, he’d like to see it. He added that if he had to choose between the law and saving a life, there would be no question about his decision and hopes that would be the same decision by a licensee taking the course. He asked what the next step of the process is.

Ms. Herold provided clarification on the process for regulation. She stated that the first issue to vote on is whether or not to adopt the regulation.

Mr. Powers asked if the course would be in lieu of a fine.

Ms. Herold responded that the course is proposed as one of the optional settlement terms for formal discipline, and is not viewed as an alternative or component of cite and fines. She added that, as the board may refer someone into the Pharmacist Recovery Program, they may alternatively recommend taking an ethics course in conjunction with other disciplinary conditions and restrictions placed on them as a probationer.

Mr. Room reminded the board that, typically, when deciding what to do in any particular instance, there are several options available to the Executive Officer and the board. One of which is to take a formal administrative disciplinary action, which is typically in the form of an accusation. He explained that the ethics course would be an alternate term of probation which would result from a disciplinary action, and would not formally apply to a citation of fine, letter of admonition, etc. He stated that this would only be for the disciplinary cases typically. He added, however, that once a citation and fine is issued, there is still the ability to settle. Mr. Room reiterated that the only way this would be imposed involuntarily on a licensee would be as a term of probation resulting from an administrative decision.

Mr. Powers asked if this regulation would be in the jurisdiction of the board.

Ms. Herold responded that it would be at the time that she recommends a settlement. She noted that it may possibly also be used by an administrative law judge or a deputy attorney general representing the board in a disciplinary case.

Mr. Room added that it would ultimately be the decision of the board.

Mr. Dazé suggested looking at having an ethics portion added to the examination and licensure process. Consequently, if a licensee is required to take an ethics course, they would be required to retake the ethics portion of the licensure examination. Mr. Dazé added that it may be necessary to remind licensees of their ethical responsibilities to the public.

Mr. Weisser agreed with Mr. Dazé’s comments and felt that that approach would be far more effective.

Mr. Burgard stated that he is very much in favor of this. He stated that he is also in support of an ethics course within the examination portion of licensure. He noted that there is an ethics course within the professional engineers’ examination as well.

Dr. Swart supports the course. He added that this has to do with an individual's belief in what is right and wrong, and continued relapse will occur if not addressed.

Mr. Powers referenced the suggestion made by Dr. Gray regarding owner-operators taking the course, and stated that it may be effective due to economic pressures often placed on pharmacists by owner-operators. He also referenced the current economic state as an example.

President Schell stated that he appreciated reading the comments provided by Dr. Cronin and listening to the testimonies provided. He stated that he thinks the scope may be too narrow and agrees that there should be some clarification in a general scope in order to provide some guidance for pharmacists. He added that it truly does go back to their education in pharmacy school or further beyond. President Schell stated that, although he is in complete support of the ethics program being proposed, there were comments made today that he agrees with in terms of necessary clarity for all licensees. President Schell said that he is currently an ethics and integrity officer of an organization, and explained that they have programs that are provided to all employees on an annual basis. While he is not suggesting that for pharmacy licensees, it would be a wise choice for those who have conducted less than ethical behavior and something should be provided for them to assist in redirection.

Motion: To direct staff to take all steps necessary to complete the rulemaking process, including preparing modified text for an additional 15-day comment period, which includes the following amendments: change the word "medicine" to "pharmacy" at proposed § 1773.5(a)(5)(B). If after the 15-day public comment period, no adverse comments are received, authorize the Executive Officer to make any non-substantive changes to the proposed regulations before completing the rulemaking process, and adopt amendments to § 1773 as filed and adopt § 1773.5 of the proposed regulations with this modified text.

M/S: JB/BP

Support: 10 Oppose: 0

VI)Regulation Hearing

A) Action to Repeal 16 CCR §§1716.1 And 1716.2, Adopt §1735 – 1735.8 and Amend §§1751.-1751.8 Regarding Requirements for Pharmacy Compounding and Sterile Injectable Compounding

President Schell read the following:

This hearing is to consider adopting requirements for pharmacies that compound medications; proposed repeal to Repeal 16 CCR §1716.1 and 1716.2, and Amend §§1751-1751.8, and Adopt §§1735-1735.8 as outlined in the public notice.

At this time, the hearing will be opened to take oral testimony and/or documentary evidence by any person interested in these regulations for the record which is now being made by tape recorder. All oral testimony and documentary evidence will be considered by the Board pursuant to the requirements of the Administrative Procedure Act before the Board formally adopts the proposed amendment to these regulations or recommends changes which may evolve as a result of this hearing.

If any interested person desires to provide oral testimony there is a sign-up sheet in the back of the

room. It will be appreciated if the person commenting comes forward and give his or her name and address, and if he or she represents an organization, the name of such organization, so that we will have a clear record of all those who appear.

Please keep in mind the following when making comments:

- A. This is a public forum to receive comments on the proposed regulations. It is not intended to be a forum for debate or defense of the regulations.
- B. Written testimony may be summarized but should not be read. The board will give equal consideration to written and oral testimony.
- C. If you have a question about a proposed regulation, please re-phrase your question as a comment. For example, instead of asking what a particular subdivision means, you should state that the language is unclear, and explain why you find it to be unclear.

After all interested parties have been heard, the issue will stand submitted.

Hearing Testimony:

Maria Serpa and William Yee (CSHP):

Mr. Yee thanked the board for allowing them to make comment on the regulation. He stated that they are representing their 4,000 + members, many of whom have provided written comments to the board and CSHP.

Ms. Serpa stated that they have submitted letters to the board which were provided within the board packet. She stated that she is a pharmacist with Sutter Medical Center, but is representing CSHP. Ms. Serpa thanked the board for its efforts in putting together regulatory information and language on the issue of compounding. She stated that it is a large issue of patient safety and in dire need of regulations. She added that there is a need to document the process that is currently in place in relation to the compounding of medications. Ms. Serpa explained that compounding medications are typically topical products, such as a cream or ointment, or a liquid or elixir that a physician would ask a pharmacist to mix for each patient specifically. She stated that the documentation of how the products are mixed, the components included, pharmacy lot number, tracking of the product source, etc. are all a very important part of the regulation which CSHP supports. Ms. Serpa explained that CSHP's concern is when the regulation extends to the processing or compounding of sterile injectable products. She explained that they are referring today to sterile injectable products prepared in the hospital setting, which is very different than the traditional compounding of topical products conducted in a pharmacy setting. In the hospital setting, sterile injectable regulations are very distinct and specific. Ms. Serpa explained that current board of pharmacy regulations have separate sections that are regulated with specific required steps of preparation, documentation and patient safety. She noted that there are also federal regulations in the USP Pharmacopeia that have very specific training and documentation issues in terms of sterile injectable products. CSHP is concerned that including sterile injectable products within the compounding language being presented is an added layer and they are questioning the value. Ms. Serpa explained the process of filling a sterile injectable prescription which requires compounding in a hospital setting. She stated that the pharmacy receives the script for a patient that is written by a physician, and emphasized that they compound and dispense each dose, one at a time to be given to the nurse or patient directly throughout the day. She stated that the first dose is usually prepared right away, because it is a new medication order, and then delivered. Ms. Serpa further explained that, in the case of an emergency, they prepare a "stat" dosage which is delivered immediately. She explained that subsequent doses are prepared in an ID batch, and explained the timeframe for delivery of those ID

batches within her hospital. She stated that the labels for the ID batches are generated and tracked via a computer system, and that the system provides a list of who the patients are and their current medications. She stated that the system will also provide information on patients who may have been taking the medication within the last few days, for example, which is helpful in the case of a recall.

Ms. Serpa stressed that this system would require hospital pharmacists to go above and beyond what their current processes are for IV sterile preparation and compounding. She stated that it is asking them to conduct additional specific documentation of, for example, the lot number of each IV bag or vial, which requires additional time to document in some sort of spreadsheet or log. Ms. Serpa explained the added steps of documentation which would be necessary and how that could delay the first dose of medication which may be urgently needed for an emergency. She also explained the assignment of lot numbers, and that each dose, in a hospital pharmacy setting, would require generating a pharmacy-specific lot number. She reiterated that this is different than outpatient compounding of multiple dose/day prescriptions, where only one lot number is generated. She reiterated the concern over the system's value by explaining the creation and maintenance of the additional documents that would be required. She pointed out that the documented information required is in addition to all of the information they currently are able to maintain within their computer system as required by current regulation. Ms. Serpa gave specifics on the volume of documentation (700 line items per day), including the generation of a lot number for each dose, which would be required in her facility, as well as the time lost in creation of the documentation, thus delaying the dispensing of medication to patients. She noted that the documentation would most likely be handwritten as their current computer system does not allow for the tracking of each individual lot number (dose). She detailed that it would require approximately 28 pages of documentation per day, which would ultimately be stored for the purposes of inspection. She stated that she would still refer to her computer in the case of a recall, because the information she needs for those instances is already there.

Dr. Yee provided a different perspective, explaining that he has worked in a 300-bed community hospital which provides pharmacy services 24 hours a day. He stated that there are 25 pharmacists on staff and they do respond to emergency "code blue" pharmacy requests as needed. Yee stated that, in addition to having a centrally kept lot number system within the pharmacy, a separate documented lot system for each emergency dose of drugs dispensed by a physician would be required as well. He stated that CSHP requests consideration for some amendment of the language to exclude immediate use of "stat" medication from the regulations as set forth. He referred to subsection (b) of §1735.3 and reviewed the language they have proposed in writing to the board.

Mr. Room clarified whether, based on the prior written submissions as well as their testimony provided today, CSHP's objections are to the specific provisions within (6) and (8) of subdivision (a), which are the manufacturer's name and lot numbers and the pharmacy-specific reference, and asked if their objections go beyond those two provisions.

Ms. Serpa confirmed, stating that she understands that the current regulations for sterile injectable products include all of those provisions.

Jenny Partridge (California Pharmacists Association Academy of Compounding Pharmacists):

Partridge thanked the board for their efforts over the last two years on this regulation. She stated that CPAAC is in support of the regulation and are very excited about it. Partridge noted one item in question relating to the language within §1751.2 (b), which states "...the name and concentrations of ingredients contained within a sterile product." She explained that, logistically, that would be very

difficult with all of the preservatives and individual ingredients that are contained. She noted that in §1735.4, both (a) and (c), it specifically states "...principal active ingredients...". She stated that they wanted to make sure that was the same intent of §1751.2 (b) as well.

Allan Schaad (Catholic Healthcare West – Woodland Healthcare):

Mr. Schaad stated that CHW has 32 hospitals throughout California. He stated their concern on the "overreaching shadow of the umbrella that this casts", and doesn't believe they will be able to incorporate it into their workflow. Mr. Schaad stated that they foresee tremendous burden with the recordkeeping requirements, as mentioned by Ms. Serpa prior. He said that there is a lot of ambiguity with what is to be required. He indicated that the need to enforce the regulation throughout the hospital would be somewhat difficult, and that they would have to be able to explain to staff why the procedures are required for patient safety. He referenced letters provided by others and feels that their items of concern should be taken into consideration. Mr. Schaad stated that the directors of their hospitals agree that the burden of the regulation requirements would be too great, and the value would be too small. He added that the specifics are overwhelming.

Mr. Room referenced a letter provided by CHW, which appears to be in line with Ms. Serpa's and Yee's comments, but are objecting specifically to provisions (b) and (d) of §1751.2. He asked if his objections are broader than what was stated within the letter.

Mr. Schaad stated the objections are much broader, and indicated that he and his colleagues felt that CSHP did not expand their objection to the regulations enough in terms of emphasizing the burden it would place.

Heidi Barsuglia (CRA):

Ms. Barsuglia stated that their members thank the board for addressing the concerns as outlined in their comments in response to the proposed regulations earlier this year. She stated, however, that their members cannot support the compounding regulations as they are currently written, because some of the requirements would hinder pharmacies from engaging in non-sterile basic compounding. Ms. Barsuglia provided a partial definition of non-sterile basic compounding. She stated that, since only non-sterile products that are already commercially available are being used for those formulations that require only basic pharmacy skill sets, CRA members question the need for pharmacies engaging exclusively in that type of compounding to meet the same requirements as for the more complex types of compounding. CRA members still question the need for a pharmacy engaging in only non-sterile basic compounding to have to complete a self-assessment and questions the need for pharmacies to have to comply with requirements for: 1) compounding policy and procedures manuals, 2) documentation of the facilities and equipment necessary for compounding, 3) documentation of pharmacy staff training, 4) ongoing competency evaluation and 5) a written quality assurance plan if the pharmacy in fact only engages in that type of compounding on a non-routine basis. Ms. Barsuglia concluded by stating that CRA does not support the regulations going forward with the language as written.

Jenny Partridge (representing herself):

Partridge explained that she is an independent consultant who focuses primarily on compounding pharmacies and pharmacists. She indicated that she works with over a half-dozen pharmacies and assists them with policies and procedures, training, quality assurance, and marketing. She stated that she has been using the draft self-assessment, and finds them to be very helpful. She added

that the training required for utilizing the form, as well as the quality assurance is not difficult. Partridge indicated that software is available from various manufacturers which will provide for pre-assigned lot numbers, manufacturer information, expiration date, etc., so that the information is all readily available for printing out of reports. She concluded by stating she works with compounding information and systems daily, and that the assessment and regulations are working well.

B) Discussion and Possible Action to Repeal 16 CCR §§1716.1 And 1716.2, Adopt §§ 1735 – 1735.8 and Amend §§ 1751.- 1751.8 Regarding Requirements for Pharmacy Compounding and Sterile Injectable Compounding

President Schell decided to have discussion surrounding the testimony that has been heard, followed by determining whether the board will want to 1) adopt the regulation as noticed, 2) create a subcommittee of the board or 3) proceed with a 15-day notice.

Ms. Schieldge added clarification that the option of a subcommittee would involve a two-person committee which would work directly with staff to review and analyze the comments presented, both orally and in writing, and make recommendations to the board as to whether to amend the language, repeal the language, etc. She also clarified the option of proceeding with a 15-day notice, which would entail making amendments based on the comments received and send it out for another comment period. She reiterated the three options of action which can be taken by the board at this point.

Mr. Powers stated that every time the board has tried to issue regulations, something new comes up. He reminded the board that this issue has been on the table for four years, and came initially because of serious patient harm which required the need for regulation of compounding sterile injectables.

Mr. Weisser shared his concern, stating that when hospital pharmacies share concerns about how expeditiously important medications can be given to the patients when needed in times of emergency, it is necessary to be allowed an opportunity for more time to review their comments.

Mr. Powers responded that, somewhere along the line, the board needs to say enough is enough. He added that, if we don't do it correctly the first time, then we'll do it again another time, but need to take action soon.

Mr. Dazé stated his concern in regards to comments made regarding the recordkeeping requirements. He indicated that everything can be done electronically, and that the regulation doesn't say it has to be on paper. He added that, based on the information indicating that there is computer software available to provide the data needed, then the concern over the volume of documentation has been addressed. Mr. Dazé referred to the issue raised by CRA of regulating non-sterile and sterile compounding pharmacies under the same umbrella. He indicated that, being a public member, he is not that familiar with how things work and he is concerned if the board is trying to regulate entities under the licensing requirement whether they are not intended because of lack of clarity under the regulation.

Mr. Room gave historical background on the sterile compounding law, indicating that it was a direct result of the 2001 Doc's pharmacy incident referenced by Mr. Powers. He indicated that is when the board first started issuing separate sterile injectable permits to the pharmacies' in order for them to prepare sterile injectable compounding, as well as having their own separate regulations. Mr. Room stated that, other than the statutory authority to pharmacists to generally do compounding, there has been no law in California regulating non-sterile compounding. He added that this was an attempt to revisit the issue of sterile compounding to see if any updates were needed, as well as to

generate some minimum standards to non-sterile injectable compounding. He provided additional background on the history of regulations. Mr. Room explained that these are two distinct portions of the regulatory statute which will apply to non-sterile compounding and sterile compounding. He added, however, that the board has said that sterile injectable compounding is presumed to be more dangerous. Because of this, any specifics added to the non-sterilized compounding, due to increased knowledge by the board over this process, would also apply to sterile injectable compounding.

Dr. Ravnan stated her concerns in regards to the pharmacy-specific lot numbers. She indicated that she has worked in the hospital pharmacy setting, and is familiar with sterile compounding. She said that adding the pharmacy-specific lot number does not add any patient safety issues. Dr. Ravnan added that, in the case of a recall, the pharmacy should have proper policies and procedures in place to recall those medications, which most of them do. If it's a matter of a product being recalled several months from patients being released from the hospital, Dr. Ravnan said that that would be a separate issue where the lot number would not be beneficial. She also noted that, making the sterile products is not solely limited to the pharmacists, and that nursing stations are also involved. Because of this, she is hesitant to place the responsibility on the pharmacy in terms of documentation, and added that there could be a shift to having compounding done completely within the nursing stations and thus the board would then no longer have control.

Ms. Herold asked if pharmacy-specific lot numbers would assist a hospital in identifying if a medication error occurred, since the lot number would not match what was ordered for the product.

Dr. Ravnan responded by referencing Ms. Serpa's comments, in that the hospital already has the information within their computers for a short period time and immediate action can be taken. She explained, however, that in the case of an example where the recall was noticed several months later, then the data would not be beneficial.

Ms. Herold gave an example of a hospital making a certain batch of IV's where various drugs are mixed for each specific patient, and asked if the lot numbers would then be helpful in identifying whether an error occurred when a patient had an unusual reaction.

Mr. Weisser clarified that the NDC number would be used rather than the lot number for identification in those cases.

Ms. Herold asked if it is the pharmacist or pharmacy technician who conducts the compounding in a hospital.

President Schell noted his background within hospital pharmacy settings, and responded that either the technician or pharmacist could conduct the compounding. He noted, however, that the pharmacist always conducts the final review which involves comparing the order with the prescription as written. He added that in "code blue" situations, it is exclusively the pharmacist who provides the product; pharmacist – pharmacist, or pharmacist – technician only, but never technician – technician. He further explained that for immediate use product, it would almost exclusively be a pharmacist involved except in situations where there were complex products (i.e., a patient with clotting issues). In those situations a technician may provide the compounding of the product, the pharmacist would check it, and then the product would be either hand delivered or dispensed via courier to the place where the patient is being treated.

Ms. Herold asked for clarification that in a routine "batch process", which is what is being requested for exemption, it would normally be the technician.

President Schell responded that in a team batch process, the technician may be one who would be associated with providing the batch process, but the pharmacist always checks the product and the compounds which go into the making that product. He noted that he is speaking from his own personal experience, where they would document all of the items within their batches, including lot numbers and serial numbers. President Schell added that, in his experience, there was a compounding log, which the technician would fill out and the pharmacist would review. He indicated that each product would also be checked by the pharmacist against the compounding log and the products would then be physically checked and subsequently frozen or dispensed.

Mr. Weisser asked it that would be for multiple doses.

President Schell confirmed.

Mr. Graul stated that it appears that the bulk of the comments provided today, with the exception of CRA's oral comments, are directed at the sterile compounding portions. He added that a subcommittee could expeditiously address those items and direct them back to the board for full approval in a fairly quick manner and be able to move forward with the 15-day comment period.

Dr. Swart asked if it is common for the immediate use to be defined as something needed within 24 hours. He stated concern over considering every order needed within a 24-hour period, rather than actual emergency orders, such as "code blue" or stat orders for a patient undergoing surgery.

President Schell responded with an example of what he would consider as appropriate for exemption, and added that the exemption would apply to single, rather than multiple use orders within that 24-hour period. President Schell indicated that it would be important to indicate the specific allowance of one-time usage (within 24 hours) within the language.

Dr. Swart recommended that the subcommittee assess the community pharmacy settings where they are mixing topical creams together, and not hold them to the same standard as the compounding of sterile injectable, in terms of self-assessment.

MOTION: To create a subcommittee of the board, not to consist of more than two board members who will work with board staff to review all comments received, make a determination on the comments and make recommendations to the board at the next scheduled board meeting.

M/S: SW/TD

Support: 10 Oppose: 0

VII) Public Comment for Items Not on the Agenda – Agenda Items for Future Meetings

Steve Suen addressed the license renewal process and stated frustration over being unable to renew licenses electronically. He added that, during the course of this year, he has seen his co-workers travel to Sacramento to renew their license because they neglected to check the box on the renewal form indicating that they have completed 30 units of CE. Mr. Suen requested that funding be pursued to allow the board to update the Web site to allow license renewal on-line and allow for a more efficient process.

The board meeting was recessed at 4:02 p.m.

The board reconvened at 8:05 a.m. on October 30, 2008

VIII) Closed Session

The board went into closed session pursuant to Government Code §11126(c)(1) to discuss and evaluate the administration of the pharmacist licensure examination.

The board went into closed session pursuant to Government Code §11126(c)(3) to deliberate on disciplinary matters.

IX) Legislation and Regulation Committee Report and Action

A) Regulation Report and Action

1) Board Approved Regulations – Undergoing Administrative Review

(a) Amend Title 16 CCR §1760 – Disciplinary Guidelines

At the April 2008 Board Meeting, the board voted to adopt a regulation change to amend Title 16 CCR §1760 – Disciplinary Guidelines. During discussion at this Board Meeting, counsel recommended that the board add several responses to comments submitted during the written comment period.

Staff has since received these comments from our counsel and the compiled rulemaking was submitted to the department on September 12, 2008

Mr. Graul stated that the board believes this has been forwarded to Office of Administrative Law for final review.

2) Board Approved Regulations – Awaiting Notice

(a) Title 16 CCR §1785 – Self-Assessment of a Veterinary Food-Animal Retailer

The adoption of §1785 of the California Code of Regulations would establish a self-assessment form for veterinary food-animal drug retailers and require the designated representative-in-charge to complete this form to ensure compliance with pharmacy law. This form would also aid these licensees in complying with legal requirements of their operations and therefore increase public safety as a result of this compliance.

The draft form was reviewed and approved at the September 2007 Enforcement Committee Meeting. During the October 2007 Board Meeting, the board voted to approve the regulation for the 45-day comment period.

The Licensing Committee is completing a program review of the Veterinary Food-Animal Drug Retailer program. Board staff will be recommending to the Legislation and Regulation Committee that this rulemaking be placed on hold until the conclusion of program review to ensure any recommendations made and implemented are incorporated into this rulemaking.

Mr. Graul stated that a copy of the draft language is contained within the board packet provided.

(b) Title 16 CCR §1780 – Update the USP Standards Reference Material

Mr. Graul explained that CCR §1780 sets minimum standards for drug wholesalers. He further explained that §1780(b) references the 1990 edition of the United States Pharmacopeia Standards

(USP Standards) for temperature and humidity standards. He noted that the USP Standards is updated and published annually. Consequently, this section requires an amendment to amend § 1780(b) to reflect the 2005 version of the publication and to hold wholesalers accountable to the latest standards.

At the April 2007 Legislation and Regulation Committee Meeting, the committee was advised to review the updates made in the USP Standards Reference Material referenced in the proposed language to ensure that the board was fully aware of and in support of the USP changes. Given this, board staff did not include this proposed regulation change, but rather sought input from the pharmacy industry to highlight potential problems with referencing the 2005 edition of the USP Standards Reference Material.

At the July 2008 Legislation and Regulation Committee Meeting, staff requested guidance from the board on pursuing this regulation change, as no additional information was submitted. The committee was advised that comments are forthcoming detailing the possible consequences of incorporating the 2005 version of the USP Standards Reference Materials. Upon receipt, the committee will review the concerns and make a recommendation to the board as warranted.

Also, during the July 2008 Board Meeting, the board heard testimony about the complexity of review of the four volumes of USP Standards Reference Materials. It was suggested that the board contact wholesalers to determine what requirements are in place and how they satisfy USP requirements currently. Unfortunately because of staff shortages, board staff has been unable to complete this review and survey.

Mr. Graul stated the issue is whether referencing the 2005 USP standards is a unreasonable burden. He noted that standards do need to be updated at some point in time.

Public Comment:

Dr. Gray stated that at the July 2008 meeting, he demonstrated the complexity in terms of USP development of standards. He agrees that there needs to be review and upgrading in regulation of the standards, however it would require more careful study as it has significant changes in available technology in what those standards would require. He added that, although it might be appropriate to go forward with the change, once the wholesale industry is aware of the amended standards, they will address the challenge due to the high cost for some associated with the new temperature control requirements. He noted concern for pharmacies and hospitals as well with relation to their current mode of storage and how it may be affected by the temperature ranges specified. Dr. Gray also noted the additional cost of purchasing the reference book (volume sets) in order to review and understand the standards, as they are highly complex.

Mr. Powers asked when the last time was that the standards were changed.

Mr. Graul responded that they are currently using the 1990 edition. President Schell noted that the standards have been changed since then and are changed fairly frequently.

Mr. Powers questioned why this change is more significant.

Mr. Graul clarified that they are only referring to §1780(b) which is specific to wholesalers, and not pharmacists and hospitals.

Dr. Gray responded that the USP standards are referenced several places within the regulations, and not just in §1780(b).

Dr. Swart asked if there is an issue with the board referencing outdated standards.

Ms. Schieldge responded that it is up to the board, but there is no liability to referring to outdated standards. She stated that the staff can address the issue in terms of their own policy and what standards they choose to reference and implement.

Dr. Gray stated that at the committee meeting, it was determined that this would affect out-of-state wholesalers, and thus there would be staff investigation to determine what other states are doing.

Supervising Inspector, Robert Ratcliff referenced B & P Code § 4342 and reviewed language which indicates that it is already required in statute.

Mr. Dazé commented that it appears we are already bringing the CCR up to standards for wholesalers.

There was additional discussion regarding the best approach to address the standards issue, either with the creation of a subcommittee or allow to staff to take action.

Mr. Burgard stated that he is in support of a subcommittee. He discussed other feasible options relating to the specifics of the requirement in temperature control and HVAC units which would be less costly.

Mr. Powers asked how the process has been handled in the past when the UPS standards required updating.

Ms. Herold responded that they have not done this in the past because of the way the statute already reads. She stated that they assumed it was a fairly clear amendment, however Dr. Gray has brought forward the potential for greater consequences for the wholesalers in relation to the temperature control requirement. She noted that the board agreed to conduct a survey, which has not yet been done.

MOTION: To create a subcommittee to address the issue of updating the USP standards reference material within Title 16 CC §1780.

M/S: BP/RS

Support: 9 Oppose: 0

(c) Title 16 CCR §1751.8 – Accreditation Agencies for Pharmacies that Compound Injectable Sterile Drug Products

Business and Professions Code §4127.1 requires a separate license to compound injectable sterile drug products. Section 4127.1(d) provides exemptions to the licensing requirement for pharmacies that have current accreditation from the Joint Commission on Accreditation of Healthcare Organizations, or other private accreditation agencies approved by the board. Since the inception of this statute, the board has approved two such agencies.

This proposed regulation would specify the criteria the board uses to evaluate these agencies.

(d) Title 16 CCR §§1721 And 1723.1 – Dishonest Conduct During a Pharmacist's Licensure Examination/Confidentiality

At the October 2007 Board Meeting, the board voted to approve proposed amendments to 16 CCR §§1721 and 1723.1 that would strengthen the penalty an applicant would incur for dishonest conduct during an examination as well as further clarify the penalty an applicant would incur for conveying or exposing any part of the licensing examination.

This recommendation was generated from the board's competency committee, which is responsible for the development of the CPJE examination. According to the board's current exam psychometrician, the cost to generate a new test item is \$2000/item. Compromised test items pose not only a financial loss to the board, but also inhibit the board's ability to test for minimum competency, and if an otherwise incompetent applicant passes the exam because the exam has been compromised, such a breach is a public safety issue.

3) Proposed Regulation Language for Board Discussion and Possible Action

(a) Amend Title 16 CCR §1715 – Self-Assessment Forms for Community and Inpatient Pharmacies

This section establishes requirements for the pharmacist-in-charge (PIC) of a licensed pharmacy to complete a self-assessment form to ensure compliance with pharmacy law. This self-assessment form is to assist pharmacies in increasing their compliance with legal requirements and therefore increase public safety as a result of this compliance. Additionally, this form makes the pharmacy inspection process more meaningful and provides relevant information to pharmacies and their PIC.

Board staff is working on updates to the Self-Assessment forms to incorporate changes made in pharmacy law since its last revision in 2007. As these forms are incorporated by reference in § 1715, the board must pursue a regulation change to require use of the new form.

Mr. Graul stated that the committee is recommending the board to direct staff to pursue a section 100 change to incorporate the revised self-assessment forms. He stated that the information is contained within the board packet. He noted that, because it is only an update without substantial change, it is a section 100 change.

(b) Amend Title 16 CCR §1784 – Self-Assessment Form for Wholesalers

This section establishes the requirement for the designated representative-in-charge of a licensed wholesaler to complete a self-assessment form to ensure compliance with pharmacy law. This self-assessment form is to assist wholesalers in increasing their compliance with legal requirements and therefore increase public safety as a result of this compliance. Additionally, this form makes the pharmacy inspection process more meaningful and provides relevant information to wholesalers and their Designated Representative-in-Charge.

Board staff is working on updates to the Self-Assessment forms to incorporate changes made in pharmacy law since its last revision in 2007. As these forms are incorporated by reference in §1715, the board must pursue a regulation change to require use of the new form.

MOTION: To approve the proposed regulation changes in the self-assessment forms for (1) community and inpatient pharmacies and (2) for wholesalers.

Support: 9 Oppose: 0

Dr. Gray asked for the effect of the vote.

Ms. Herold explained that it must be filed with the Office of Administrative Law and approved. She indicated that the goal is for the forms to be in final form by July 1, 2009.

Dr. Gray asked if there will be any further opportunity to comment on the content.

Ms. Sodergren and Ms. Schieldge provided clarification on the term "Section 100".

B) Legislative Report

1) Discussion and Action on Enacted Legislation

(a) Board-Sponsored Legislation for 2008 – SB 1307 (Ridley-Thomas)

As chaptered, this legislation includes additional provisions to improve implementation issues involving serialization and electronic pedigrees. Specifically, it indicates that the serialization number must be contained in the electronic pedigree, delays the implementation date and staggers the implementation dates for e-pedigree compliance, allows for the grandfathering in of existing drug stock in the supply chain, and allows the board to establish criteria for inference requirements by regulation. In addition, this proposal specifies that, should the federal government enact an electronic pedigree requirement, California requirements will be repealed to conform with the federal requirements.

Mr. Graul stated that the board will continue to hold implementation meetings to meet with industry, although perhaps less frequently.

(b) Chaptered Bills Impacting the Board's Jurisdiction or Practice of Pharmacy

Mr. Graul indicated that the following bills were provided within the board and were signed by the Governor.

- AB 1394 (Krekorian) Counterfeit: Trademarks

This bill modifies the system of penalties and fines related to criminal counterfeit trademark infringement.

Board Position: Support
Status: Chaptered

- SB 963 (Ridley-Thomas) Regulatory Boards: Sunset Review

This bill was significantly amended prior to its final passage and enrollment. As enacted this bill extends the sunset dates for several boards with the Department of Consumer Affairs whose sunset date would have occurred in 2009.

Board Position: None
Status: Chaptered

- SB 1441 (Ridley-Thomas) Healing Arts Practitioners: Substance Abuse

This bill would create the Substance Abuse Coordination Committee within the Department of Consumer Affairs to develop uniform and specific standards that each healing arts board must use in dealing with substance-abusing licensees.

Board Position: None
Status: Chaptered

- SB 377 (Aanestad) Highway Signs: Pharmacies and Attractions

This bill requires the Department of Transportation to adopt rules and regulations governing the placement and standards for roadway signs indicating the proximity of 24-hour pharmacy services.

Status: Chaptered

(c) Vetoed Bills Impacting the Board's Jurisdiction or Practice of Pharmacy

Mr. Graul indicated that the board had a formal position which was vetoed by the Governor. A copy of the bill and the veto message was provided within the board packet.

- SB 1779 (Committee on Business, Professions and Economic Development) Professions and Vocations:

This bill contained omnibus provisions for the board as well as several other boards within DCA. The board's provisions included four types of changes. First, provisions sought would have allowed for the use of mobile pharmacies in the event of a declared natural disaster if certain criteria are met or on a temporary basis when a pharmacy is destroyed or damaged. Second the board sought changes to several sections of the Business and Professions Code to clarify the reporting requirements to document a change in the pharmacist-in-charge (PIC). The PIC is responsible for the overall operations in a pharmacy. There were also similar changes for the designated representative-in-charge (DRC) of a wholesaler or veterinary food-animal drug retailer. This proposal would have defined the term "pharmacist-in-charge" currently referenced throughout pharmacy law as well as place into statute the approval process currently used by the board when evaluating a pharmacy application for approval of a proposed PIC or DRC. Also included in this proposal were several corrections to references to §4052, which was recodified in 2006. Lastly, this bill contained several general omnibus provisions to clarify and make technical changes.

Status: Vetoed

d) Bills That Failed Passage by the Legislature

The board took positions or watched the following bills that failed passage by the legislature:

- AB 1436 (Hernandez) Nurse Practitioners

This bill would revise the educational requirements for qualification or certification as a nurse practitioner and would require a nurse practitioner to be certified by a nationally recognized body approved by the Board of Registered Nursing. The bill would also expand the scope of practice to allow a nurse practitioner to perform comprehensive health care services as specified and is authorized to admit and discharge patients from health facilities, change a treatment regimen and initiate an emergency procedure in collaboration with healing arts practitioners.

- AB 1587 (De La Torre) Personal Information: Pharmacy

This bill would exclude from the definition of marketing a written communication or written message provided to a pharmacy patient by a pharmacist or pharmacy personnel that meets specified conditions.

- AB 1947 (Emmerson) Pharmacy Technicians

This bill would increase the minimum requirements for licensure as a pharmacy technician to include both certification by the Pharmacy Technician Certification Board as well as either completion of a technician training program or a specified associate's degree. In addition, would require pharmacy technicians to complete 20 hours of continuing education each renewal cycle.

- AB 2756 (Duvall) Pharmacists: furnishing drugs during an emergency

This bill would specify that for purposes of furnishing dangerous drugs and devices during an emergency, a pharmacist is not required to await a declaration of emergency as long the declaration is reasonably anticipated due to the severity of the emergency or natural disaster.

- SB 1270 (Cedillo) Pharmacy: dangerous drug and devices pedigree

This bill would create an Electronic Pedigree Taskforce to provide the board with updates regarding industry readiness on the implementation of the pedigree requirements as well as submit an annual report to the board and specified legislative committees.

C) Legislation And Regulation Committee Report

- 1) Action on Legislative Proposals Recommended for Sponsorship by the Legislation and Regulation Committee During the Committee Meeting of October 29, 2008

Omnibus provisions previously approved by the board – SB 1779 (Senate Business and Professions Committee)

As the Governor vetoed the board's omnibus bill, board staff recommends inclusion of all of the following provisions again.

Mr. Graul reviewed the omnibus provisions which have been recommended by the committee to the board with the proposed language.

Use of Mobile Pharmacies:

Section 4062 Furnishing Dangerous Drugs During an Emergency

This section allows for the use of a mobile pharmacy in the event of a declared natural disaster if certain criteria are met.

Section 4110 License Required, Temporary Permit Upon Transfer of Ownership

This section allows for the use of a mobile pharmacy on a temporary basis when a pharmacy is destroyed or damaged.

Pharmacist-in-Charge and Designated Representative in Charge

Amend §§4022.5, 4101, 4113, 4160, 4196, 4305, 4329, 4330 and Add §4036.5

The Board of Pharmacy is proposing changes to several sections of the Business and Professions Code to clarify the reporting requirements to document a change in the Pharmacist-In-Charge (PIC). The PIC is responsible for the overall operations in a pharmacy. There are also similar changes for the Designated Representative-in-Charge (DRC) of a wholesaler or veterinary food-animal drug retailer. This proposal would also define the term “pharmacist-in-charge” currently referenced throughout pharmacy law as well as place into statute the approval process currently used by the board when evaluating a pharmacy application for approval of a proposed PIC or DRC.

Corrections to Sections Referencing Prior Business and Professions Code §4052

Omnibus changes based on recodification of Business and Professions Code §4052

In 2006 Business and Professions Code §4052 was recodified into four sections. The below B&PC and H&SC sections reference old §4052 and require update.

- Section 733 – Dispensing Prescription Drugs and Devices
- Section 4027 – Skilled Nursing Facility – Intermediate Care Facility – Other Health Care Facilities
- Section 4040 – Prescription; Content Requirements
- Section 4051 – Conduct Limited to Pharmacist; Conduct Authorized by Pharmacist
- Section 4060 – Controlled Substance – Prescription Required, Exceptions
- Section 4076 – Prescription Container – Requirements for Labeling
- Section 4111 – Restrictions on Prescriber Ownership
- Section 4174 – Dispensing by Pharmacist Upon Order of Nurse Practitioner
- H&SC 11150 – Persons Authorized to Write or Issue a Prescription

General Omnibus Provisions

Amend §4059.5 - Who May Order Dangerous Drugs or Devices, Exceptions

A technical change to this section clarifies that a designated representative must sign for and receive delivery of drugs by a wholesaler. This is important for accountability of drug purchases and receipt in wholesale operations.

Section 4081 - Records of Dangerous Drugs and Devices Kept Open for Inspection; Maintenance of Records, Current Inventory

This section corrects a drafting error that occurred in Senate Bill 1307 (Chapter 857, statutes of 2004). The term “exemptee-in-charge” was incorrectly updated to “representative-in-charge” and requires correction to the appropriate term “designated representative-in-charge.”

Amend §4126.5 – Furnishing Dangerous Drugs by Pharmacy

This section clarifies specifically who in the supply chain may receive dangerous drugs furnished by a pharmacy.

Amend §4161 – Nonresident Wholesaler: When License Required: Application

This section clarifies that any person that sells, brokers or distributes dangerous drugs or devices within California must be licensed.

Amend §4231 – Requirements for Renewal of Pharmacist License: Clock Hours; Exemption for New Licensee

This section addresses the need to authorize the board to automatically inactivate a pharmacist license when a pharmacist who certifies completion of the required CE as part of a renewal fails to provide proof either as part of an audit or investigation. This authority already exists when a pharmacist fails to certify completion of continuing education as part of the renewal application.

Amend §4362 – Entry Into Program; Discipline Exceptions

This section specifies the administrative co-pay participants pay as part of their participation in the PRP. The board subsidizes the administrative cost, however requires the participant to also pay a portion of the administrative costs of the program. The current administrative co-pay, \$75.00, is set by contract only. The board has not sought a change in this co-pay in over 10 years, and has continually absorbed the additional monthly administrative fee, currently about \$230/month per participant.

This section allows the board the ability to waive a participant's co-pay for demonstrated financial hardship.

Amend H&SC §11165 – Controlled Substance Utilization Review and Evaluation System: Establishment; Operation; Funding; Reporting to Legislature

This section requires amendment to mandate that a clinic that dispenses schedule III and schedule IV controlled substances must report weekly to CURES, similar to the requirements for pharmacies and prescribers who dispense controlled drugs as specified.

Mr. Graul noted that there are no subsequent changes to the above omnibus provisions, as they were included in last year's omnibus bill which was vetoed by the Governor.

MOTION: To accept the committee's recommendation from the October 29th Legislation and Regulation Committee meeting, to move forward the omnibus provisions citing the changes made in §4062.

Support: 9 Oppose: 0

Add §4013 – Subscriber Alert

This section needs to be added to require all board licensed facilities to join the board's e-mail notification list.

Board Discussion:

Mr. Dazé asked why the board doesn't have all licensees required to join the notification list, rather than only pharmacies.

Ms. Herold responded that it was decided to only require facilities to join, but there is consideration to include PIC's as well within the requirement. She noted that there are approximately 107,000 licensees currently.

Dr. Swart pointed out the issue of firewalls and filters within organizations which would cause challenges in licensees receiving the e-mails.

Ms. Herold stated that a critical aspect of the process is the requirement of the licensees to maintain current e-mail addresses with the board, as this would be a large workload for board staff members to take on. She stated that it is to the board's discretion if they would choose to have all licensees join for notification.

Mr. Powers asked if requiring all licensees to join would cause more workload for board staff.

Ms. Herold responded that it would not as it would be the responsibility of the licensees to update the board of e-mail address changes.

Dr. Swart reiterated concern over the large amount of “bounce backs” that could occur when involving such a large database of e-mail addresses. There was additional discussion regarding the technical challenges with regard to e-mail and other system related issues.

Ms. Herold noted that, although she is in strong support of the requirement, it would require that each licensee has internet access in order to utilize the Web site link provided within the alerts.

No action was taken at this time as the item was not agendized.

Amend §4112 – Nonresident Pharmacy: Registration; Provision of Information to Board; Maintaining Records; Patient Consultation

Mr. Graul explained that this section requires amendment to explicitly state that a person cannot act as a nonresident pharmacy unless he or she has obtained a license from the state.

MOTION: To amend §4112 – Nonresident pharmacy: registration; provision of information to board; maintaining records; patient consultation

Support: 9 Oppose: 0

Amend §4401 – Pharmacists: Biennial Renewal

Mr. Graul explained that this section needs amendment to require pharmacists to notify the board of any misdemeanor or felony convictions, or whether any disciplinary action has been taken, as specified subsequent to the licensee’s last renewal.

MOTION: To pursue amendment to §4401 – Pharmacists: Biennial renewal as part of the board’s omnibus provisions in 2009.

Support: 9 Oppose: 0

Amend §4403 – Reissuance Without Payment of Fees Prohibited

Mr. Graul explained that this section needs amendment to require pharmacy technicians and designated representatives to notify the board of any misdemeanor or felony convictions, or whether any disciplinary action has been taken, as specified subsequent to the licensee’s last renewal.

MOTION: To pursue amendment to §4403 – Reissuance without payment of fees prohibited as part of the board’s omnibus provisions in 2009.

Support: 9 Oppose: 0

Other Legislative Proposals for Board Sponsorship:

Immunizations by Pharmacists Pursuant to Published Recommendations of the Advisory Committee on Immunization Practices

At the April 2007 Board Meeting, the board voted to pursue a statutory change to allow a pharmacist to initiate and administer immunizations pursuant to the published recommendations of the Advisory Committee on Immunization Practices.

Beginning in November 2007, board staff worked with stakeholders to address questions as well as to elicit support for this proposal. However, in April 2008, after consideration it was decided not to move the proposal this year. It is being brought before the board for consideration and possible sponsorship in 2009.

Ms. Sodergren provided background on the bill. She stated that board staff feels the bill strengthens consumer protection with respect to the administration of immunizations, as it would specifically require training and continuing education and expands the conditions under which a pharmacist can initiate and administer immunization. Ms. Sodergren added that, although there was broad support for the bill last year, they were unable to pursue the legislative proposal in 2008. Therefore it is being brought forward to the board again to pursue in 2009.

Public Comment:

Dr. Gray stated that he is speaking in strong support of the concept. He added, however, that they will not have Kaiser pharmacists conducting immunizations as they have other departments providing the service currently. Dr. Gray stated that, by adding pharmacists as an option for administering immunizations, it will dramatically increase the portion of the population that is immunized. He questioned the language in the subsection. Clarification was provided by board staff.

MOTION: To approve the proposed language to be pursued by the board as recommended by the Legislation and Regulation committee.

Support: 9 Oppose: 0

Request from the California Pharmacy Foundation for Clarification of Business and Professions Code §4076

Mr. Graul stated that, at the July 2008 Board Meeting, the board heard a request from Dr. Steve Dr. Gray, representing the California Pharmacy Foundation. The Foundation is requesting that the board sponsor legislation that will clarify a pharmacist's authorization within Business and Professions Code § 4076(a)(10) and allow a pharmacist to place the "purpose" of the medication on the label that is affixed to every prescription container dispensed to a patient. One of the Foundation's primary focuses is on the reduction of medication errors and they believe that clarifying when and how a pharmacist is authorized to place the additional information within the prescription label will improve patient outcomes.

It was recommended that this matter be referred to the Legislation and Regulation Committee for discussion and to recommend if it is feasible to pursue this proposal in 2009 with its anticipated legislative calendar.

Mr. Graul noted a minor change within the language of subsection (a)(10), which relates to the addition of the purpose being placed on the label *if requested by the patient*.

Dr. Ravnan stated that she is in support of having the purpose of a prescription placed on the label. She stated her concern over the ramifications if the patient provides the incorrect purpose which is placed on the label.

Mr. Graul stated that, during committee discussion, it was stated that if a patient provides the pharmacist with the incorrect purpose for their prescription, then a consultation is necessary in order to educate the patient.

Dr. Ravnan responded that would be clear when it is an obvious error by the patient. However, in other cases there are prescriptions that are used for multiple conditions.

Mr. Dazé stated that, from a litigation viewpoint, it could be egregious to place a purpose on a prescription when it is incorrect.

President Schell stated that there will be some degree of professional judgment which is incumbent on the role of the pharmacist to consult with a physician at times when they question the information being provided by the patient.

Dr. Swart shared his concerns over what will be placed on the label relating to what the patient indicates.

Ms. Schieldge provided two options. The first would be to keep the current language which requires that the indication be placed on the prescription itself. The second would be to require the need for the pharmacist to verify the purpose with the prescriber.

Mr. Graul stated that the second option would be a large barrier.

Ms. Herold commented that the single greatest need by the patient, as reflected in the survey results, is to provide the purpose on the label. She stressed that, regardless of how the information is verified, the patient needs to be allowed to have the information on the label, and that it may result in avoiding medication errors. She added that it may initially require some problems for the pharmacists in needing to contact the prescriber, but pointed out that this should be part of their duty anyways when there is a question or concern.

Mr. Graul stated that, in the absence of this, the current practice at some pharmacies is to place a "post it" note or some other non-permanent option on the bottle when requested. He added that, when there is a question on the purpose, it should be common practice for the pharmacist to contact the prescriber for verification. He also said that in most cases the purpose will be very clear in relation to the drug being prescribed.

Mr. Weisser pointed out that there is no language within the proposal that states the pharmacist will indicate on the record if the patient requests the purpose be placed on the label.

Ms. Herold confirmed that that is currently not part of the proposal.

Dr. Swart questioned whether that would be deviating from the prescription.

Ms. Herold stated the issue is that the directions of use are a separate component and are handled in a separate subdivision of the section. Ms. Herold stated that, in her opinion, placing the purpose on the label is separate, and not blended with the directions for use.

There was discussion regarding the feasibility of placing the purpose within the prescription itself.

Dr. Gray stated that there are a lot of things within pharmacy law that are not mandated to be documented by regulation or statute, however appropriate organization policies typically address them. He pointed out that, by making this change it will become part of the Pharmacy Practice Act which thus provides liability insurance coverage to the pharmacists in making that professional judgment. Dr. Gray also noted that the continuous calls from pharmacists to verify the purpose of a drug will likely result in prescribers providing it initially to avoid the disruption.

Ms. Schieldge asked if Dr. Gray objects to the placement of language requiring the physician to verify the prescriber to confirm the purpose.

Dr. Gray confirmed his objection. He stated that skilled pharmacists should be knowledgeable of the purpose of the drugs prescribed, and placing an affirmative obligation which would be a barrier to both ends of the process.

Ms. Herold stated that, in the 1950's, it was illegal to be able to place even the name of the drug. She emphasized that it's time to go to the next step and provide more knowledge and assistance to the patient.

Dr. Swart stated that it needs to be addressed at the physician level, requiring them to provide the purpose of the drug rather than to rely on the patient to provide the information.

MOTION : To modify the proposed amendment of B & PC Code §4076(a)(10).

Support: 8 Oppose: 1

2) Update on the Committee's Strategic Plan for 2008/09

Mr. Graul stated that the strategic plan is contained within the board packet provided.

3) First Quarterly Report on Committee Goals for 2007/08

Mr. Graul stated that the strategic plan is contained within the board packet provided.

D) Public comment

No public comment was provided.

X) Communication and Public Education Committee

A) Report of the Meeting of October 2, 2008

Ms. Wheat stated that they have had two meetings since the prior board meeting.

1) Summary of the Ongoing Discussion of Medication Errors and How to Prevent Them

Ms. Wheat explained that, at the July 2008 Board Meeting, the board held a forum on medication errors. Michael Cohen of the Institute for Safe Medication Practices, John Keats of California

Patient Safety Action Coalition (CAPSAC), and Bob LeWinter of the California Department of Public Health provided presentations on activities underway to prevent pharmacies from making or repeating medication errors. Additionally, the meeting included discussion of the findings of the 2006 SCR 49 Medication Errors Task Force report. Ms. Wheat stated that Ms. Herold also provided a presentation of the medication errors cited and fined by the Board of Pharmacy during 2007-08. There were 402 medication errors reported to the board during this period, and 600 medication error cases closed during the period. Of these cases 94 percent were substantiated as errors

Ms. Herold indicated that at the July board meeting, there was interest in sharing the profiles of the medication errors which were presented. She stated that the board staff will convert some of the statistics and include case studies to be placed within the January issue of the *Script* newsletter. She added that the Institute of Safe Medication Practices will provide information, including a more comprehensive list of drugs which are mistakenly confused due to similar names, for staff to incorporate into the article.

Ms. Wheat noted other efforts discussed during the committee meeting on October 2, 2008 to educate the public on taking measures to protect themselves and avoid medication errors. She added that the board discussed the possible distribution of the TALL man letters used to distinguish drug names, which are a beneficial tool in avoiding medication errors as well.

2) Discussion of Comments Submitted In Response to Proposed Rule Changes to 45 CFR Part 88, Ensuring That the Department Of Health and Human Services Funds Do Not Support Coercive or Discriminatory Policies or Practices In Violation of Federal Law

Ms. Wheat stated that, since the last board meeting, staff was advised about a notice for comments on a proposed rule of the federal Department of Health and Human Services for providers to exercise moral or religious convictions that may prevent them from performing certain health care functions. She indicated that the proposed rule deals principally with prohibiting certain entities from requiring any person "to perform or assist in the performance of any part of a health service program or research activity funded by the Department [of Health and Human Services] if such service or activity would be contrary to his religious beliefs or moral convictions." Comments on the proposed regulation were due by September 25, 2008.

Ms. Wheat advised that, since California has a law that ensures a provider's right to exercise conscience convictions provided patient care could still be provided, the board submitted comments to this effect.

Mr. Weisser referenced the recent change to allow pharmacists the ability to administer immunizations. He asked about a situation where a pharmacist is apprehensive towards administering such immunizations due to potential side effects, and whether such a situation would fall within this arena.

President Schell reiterated that the regulation is related to moral, ethical and religious dilemmas. He stated that he is unsure whether they can refuse to administer a prescription for an immunization. He added that a pharmacist should work with the employer to resolve the situation and accommodate the patient, and that there should never be a refusal of service to the patient because of individual beliefs.

Ms. Herold stated that not every pharmacist will be administering immunizations as specific training and continuing education is required. The assumption then is that a pharmacist who is uncomfortable with administering immunizations would then not be placed in such a situation as they would not seek the training. She noted specific vaccines that are not part of the CDC guidelines.

3) Discussion Regarding Action to Implement SB 472, Patient-Centered Medication Container Labels

(a) Reports Of Patient Surveys Undertaken

The first special public forum was held at a community center in Fremont on April 12, 2008. Approximately 40 people attended, though most attendees were from the pharmaceutical industry. As only three attendees at the initial forum were “public” participants, it became apparent that the board would need to find alternative venues to increase participation from consumers.

In May 2008, board staff developed a prescription label survey for distribution at public outreach events. The survey is available in English and Spanish. It is designed to elicit information from the public about prescription labels using the following questions:

1. What information on the label is most important to you?
2. Do you understand the directions on the prescription label?
3. What would you change on the prescription label?
4. What would make the prescription label easier to read?
5. Other suggestions?

Since late May, board staff have been using the survey to interview attendees at public events. Consumers have been invited to complete surveys on-site during the events, or mail them to the board using the self-addressed envelopes provided. This method of soliciting information has proved less intimidating to consumers than individually speaking at public hearings. Board staff attending the community events has also reported positive feedback when discussing this initiative with the public.

AARP has invited consumers to “Put in Your Two Cents on Prescription Labeling” in the AARP September 2008 newsletter

The board has also provided consumers with one-page fact sheets entitled, “Do you understand the directions on your Rx medicine label?” The fact sheet provides background information related to SB 472, and printed samples of faux prescription labels as a visual aid.

Ms. Wheat indicated that a total of 175 consumers completed surveys as of the Communication and Public Education Committee Meeting on October 2. Not every consumer provided an answer to each question, while others provided multiple answers to individual questions. Many consumers gave the same response (i.e., larger font) to more than one question.

Ms. Wheat stated that trends have been identified in the answers provided thus far. She explained that many responses suggest that the purpose of the drug should be printed on the prescription label, and that a larger or bolder type font should be used.

Ms. Wheat indicated that, during the committee meeting of October 2, the committee strongly supported the suggestion by the pharmacy associations who attended the Communication and Public Education Meeting to aid the board in distributing the survey by having their pharmacists distribute the surveys.

Ms. Wheat concluded by providing the timeline envisioned for the process of implementing SB 472 as:

2008: Conduct Public Hearings Statewide – Six Meetings Were Envisioned
2009: Develop Regulations And Adopt The Requirements By The End Of The Year
2010: Pharmacies Implement Requirements To Be Ready For 1/1/11

Implementation

2011: Requirements Become Effective And Labels On Prescription Medicine Are Compliant

Board Discussion:

Mr. Powers stated that he is on the board of the California Alliance for Retired Americans. He stated that they had a convention 10 days prior, where the topic of patient-centered labeling was discussed and surveys were circulated. Additionally, surveys were distributed at a recent meeting of the Older Women's League. Mr. Powers indicated that all 50 additional survey responses were collected as a result.

Ms. Wheat noted that a total of 100 additional surveys have been collected since the prior committee meeting, and were not included within the board packet.

(b) Discussion of Presentations and Agenda Planned for November 20, 2008 Forum

Ms. Wheat stated that the board will capitalize on the department-sponsored Professionals Achieving Consumer Trust Summit scheduled for November 2008 as an ideal opportunity to engage other professions in the development of a patient-centered prescription label.

Ms. Wheat advised that the board has secured a presentation by Mike Wolf, PhD, of Northwestern University who is a national expert in designing patient-centered labels. She explained that Dr. Wolf and his colleague, Stacy Bailey, will attend the board's forum and will provide a summation of their research in designing labels that provide optimal health information to patients. She noted that there will also be a presentation by Michael Villaire of the Institute for Healthcare Advancement.

President Schell asked if there were any potential barriers identified in moving forward with the labeling changes.

Ms. Wheat responded that they have not discussed that as of yet, and that their current focus, per legislation mandate, is to get as many survey responses as possible in order to have a substantial collection.

Ms. Herold stated that the California Pharmacy Foundation has provided the board with a contact at a radio station. The radio station will be distributing the consumer survey questions over the radio. She added that the Latino Caucus has English and Spanish versions of the survey for distribution, and Grey Panthers will be contacted as well. Ms. Herold noted Mr. Powers' significant efforts to share information to the senior community. She emphasized that the data collected thus far continues to parallel the data drawn by national studies.

Ms. Wheat stated that the staff has contacted the sponsor of the bill recently, to ensure that they have an opportunity to be involved moving forward.

4) Update and Discussion Regarding Consumer Fact Sheet Series With California Schools of Pharmacy Interns

Several years ago, the board approved a proposal by the committee to integrate pharmacy students into public outreach activities. The intent was to offer students the opportunity to work with the board on meaningful projects promoting consumer education, while the board would benefit from the production of the materials. Initially the project was initiated with UCSF.

At the October 2007 Board Meeting, the board accepted the committee's recommendation to invigorate this program by offering other schools of pharmacy the opportunity to have their students develop one-page fact sheets on various topics, and then have the developed fact sheets reviewed by an expert. Representatives from other California pharmacy schools were very interested in this project for their students.

At that time, the board directed staff to proceed with the committee's recommendation for development of a template for future fact sheets, and work with the schools of pharmacy to initiate this intern project.

Ms. Herold stated that she met with several of the pharmacy school deans and representatives. From that meeting, she discovered that the dean is not necessarily the main point of contact for movement of the project. Ms. Herold stated that she spoke with Sam Shimomura and he has offered to identify the appropriate contact within each school of pharmacy in California. She stated that she will then use the contact list to identify the persons who oversee the interns within their campus. She noted that there are three schools in particular who are very interested in the project, and that all schools indicated interest during a survey last year.

Ms. Wheat indicated that the intent of the program is to get the schools involved. She noted that there was discussion at the prior meeting to implement a timeline for the schools to submit their fact sheets to allow for recognition of the school and students at a future board meeting.

Board Discussion:

Mr. Hough commented that the committee felt this project was critical for the students, as it would be an integral part of their training and allow them an opportunity to enhance their professional competency by interacting with the public.

5) Development of New Consumer Informational Brochures

Ms. Wheat stated that the board staff has finalized the following fact sheets:

- Traveling Medicine Chest
- Pill Splitting – Not for every person, and not for every pill
- Vaccinations and Travel Outside the U.S.

She indicated that updates are underway to the drug discount program brochure and development of a new brochure on measuring devices for children's medicines.

6) Request of Pharmacists Planning Services Incorporated to Develop a Brochure on Patient Adherence

Ms. Wheat stated that the board received a letter from Fred Meyer, requesting that the board develop a brochure on patient adherence and compliance as part of its intern fact sheet series.

Ms. Wheat explained that discussion during the committee meeting concluded that the fact sheets developed in the future will be a function of how many interns become involved in the project. Some of those in attendance at the meeting had questions about the data and specific need for the brochure being requested by Mr. Meyer.

7) Update on the Script

The next issue of *The Script* is scheduled for publication in January 2009 and will focus primarily on new laws and regulations enacted in 2009. Unfortunately, as a result of the Governor's Executive Order, for several months the board lost its newsletter editor, retired annuitant Hope Tamraz. Ms. Tamraz has agreed to volunteer to perform this work in the event her position is not restored; which fortunately, in mid-October was authorized -- provided the board conduct a recruitment.

Mr. Weisser commended staff member, Hope Tamraz, in volunteering to continue the development of *The Script* newsletter.

Ms. Wheat asked if the next issue is still scheduled to be run in January.

Ms. Herold confirmed. She noted that Hope continues to volunteer in order to keep *The Script* running. She added that another board had attempted to recruit Ms. Tamraz, but that she will be able to return to the Board of Pharmacy via the recruitment process shortly.

8) Update on the Public Outreach Activities

Ms. Wheat indicated that the list of activities which have been conducted and planned for the future are contained within the board packet provided.

B) Minutes of the Meeting of the Communication and Public Education Committee of July 24 and October 2, 2008

Ms. Wheat indicated that the minutes of the last two committee meetings are contained within the board packet provided.

C) First Quarterly Update on Committee Goals for 2008/09

Ms. Wheat stated that the goals are contained within the board packet provided.

D) Public Comment

No public comment was provided.

XI) Organization Development Committee Report And Action

A) Report of the Meeting of October 20, 2008

1) Proposed Changes to Board Meeting Dates and Locations for 2009

President Schell explained that the board has received requests from several organizations regarding events, which would require modification of some board meeting dates. The proposed changes were provided within the board packet. The only change is to move the April 22 – 23 board meeting to April 29 – 30, 2009 to accommodate the CPhA Legislative Day.

President Schell stated that no vote is needed to approve these changes, but any conflicts with schedules of board members should be resolved. He noted that these dates will be added to the board's Web site following this meeting.

2) Status Update on Fee Audit Underway

President Schell stated that there is a fee audit currently underway. He explained that the board will need to seek a statutory increase in fees to take effect in July 2010. He indicated that staff will continue to monitor the fund condition and provide a report to the board at each meeting. However, the board will need to sponsor legislation to increase fees next year.

As part of the background for the fee increase, the board initiated an audit of its fees to ensure the fees are set at the appropriate levels with respect to the expenses of providing services. This process, which involves a cost allocation of all duties performed by board staff, is scheduled to be completed by the end of 2008.

President Schell explained that the fee balance is diminishing. As this was anticipated, the board is preparing to pursue a fee increase next year. He stated that it is necessary to take action in 2009 to ensure all is in place to be able to implement the fee increase in a timely fashion. He added that the auditor's report will be completed and released to the board before the January Board Meeting.

3) Budget Update and Report

(a) Budget for 2007/08

Ms. Herold reviewed the 2007/08 final budget figures. She noted the \$200,000 gap is the smallest gap between revenue and expenditures that the board has had in a while.

Ms. Herold explained that the new fiscal year started July 1, 2008, without a state budget being in place until mid-September. The budget contained a \$1 million loan from the board's fund to the state's general fund. This loan will be repaid in the future, in advance of any need for the board to increase fees because of a deficit in the board's fund.

Ms. Herold explained that, if there is a point where the fund condition warrants a repayment, those funds will be restored into their budget, as long as it is feasible for the state to do so. Ms. Herold reviewed the projected revenue and expenditures for 2008/09 as well.

Ms. Herold further explained that the board underwent budget cutbacks that included loss of temporary staff and contracted services. However, the Governor's office has recently allowed the board to restore these positions, although they have been directed to conserve as much as possible without harming their public protection mandate. Ms. Herold added that the Governor has called a special session to address the significant budget deficit this year. She explained the board's "special fund" exemption, but that they will likely receive budget restraints which will include hiring freezes, staff furloughs, travel restrictions, etc.

(b) Fund Condition Report

Ms. Herold explained that pharmacy law requires one year of fund reserve for expenditures. She indicated that last year the board fund ended with 13.4 months in reserve, however, budget projections for 2008/09 will place fund reserve at 9 months in reserve, followed by 5.8 months for 2009/10 and 2.3 months for 2010/11. These figures reflect the definite need for a fee increase.

(c) Reimbursement to Board Members

Ms. Herold stated that the report of all reimbursement is contained within the board packet provided. She explained that the board members are paid \$100/day for attendance of board meetings, and that all other expenses related to the meetings are reimbursed via self-reported claim reports.

(d) Ethics Course For Board Members Due

Ms. Herold stated that, by the end of the year, most board members will need to take the two-hour ethics course required by California law. This course must be taken every two years and most members are due to repeat it before the end of the year. This course is available online, and those board members who need to complete it before the end of the year have been advised by the Department of Consumer Affairs. Ms. Herold indicated that she will follow up with notices in early November.

4) I-Licensing Progress

President Schell explained that the I-Licensing project will offer online application and renewal of licenses (a much needed relief from mail-in renewals). He explained that a feasibility study report was approved by the Department of Finance several years ago, and the board is in the first tier of new agencies that may be able to offer this service in the future. Nevertheless, the board is still a long way from implementing this system for its licensees.

The board spent \$50,000 in 2006/07 on programming specifications needed for its programs. In the next three years, the board will spend \$342,000 as its share of costs to implement this system department-wide.

Recently, the department changed the name of the program from I-Licensing to BreEZe. A new logo has also been designed. Meanwhile delays in securing vendors and hiring new staff overseeing the project at the Department of Consumer Affairs have delayed the project. The board is about two years away from implementing I-Licensing according to current estimates and timelines. President Schell concluded by stating that the department hopes to award the contract for the system by August 13, 2009.

5) Recognition Program of Pharmacists Who Have Been Licensed for 50 Years

President Schell stated that, since July 2005, the board has acknowledged 750 pharmacists with 50 or more years of licensure as pharmacists in California. He advised that fifty-eight pharmacists reached this milestone between April and July 2008. Each was sent a certificate and invited to a future board meeting for public recognition. President Schell indicated that there have been no additional pharmacists reaching this milestone since July.

B) Personnel Update

In mid-October, the board was advised that it could fill all vacant positions and rehire staff lost due to the budget restrictions imposed over the summer in the absence of a state budget. As mentioned above, the caveat was to not make expenditures that are unnecessary.

Ms. Herold indicated that, in light of a potential hiring freeze, the board is moving quickly to recruit and fill the open positions within the board. She reviewed the specific positions which are currently open. She noted that, per SB 1441, a manager is required to oversee the Pharmacist Recovery Program whom has expertise in substance abuse. The management position is viewed as a part-

time position and they are actively recruiting. Ms. Herold noted that staff member, Debbie Anderson, has been promoted to the Licensing Unit Manager position, and the board is recruiting to fill her prior position as Licensing Analyst.

Ms. Herold recognized Anne Sodergren and Judi Nurse for having recently graduated from the Department of Consumer Affairs Management Academy Training. She explained that the course is a six-day intensive session in developing future leaders. She noted that another of the staff's supervising inspectors will be attending the next Academy training session, scheduled for December 2008.

C) Professionals Achieving Consumer Trust Summit – Joint Board Meeting in November 2008 with other Departmental Boards and Bureaus

President Schell stated that, during the week of November 17, 2008, the Department of Consumer Affairs will host a Professionals Achieving Consumer Trust Summit for all boards, bureaus and the public to showcase the department's regulatory agencies and consumer protection functions. He explained that the week-long meeting will take place at the Westin near LAX. On November 20, 2008, the board will hold two public meetings.

President Schell indicated that the board will host an e-prescribing meeting with the Medical Board and Dental Board. He noted that other DCA healing arts regulatory boards have been specifically invited to attend. President Schell noted that he feels the forum will be helpful in providing a better understanding to other boards regarding e-prescribing and how it will affect them.

Additionally, the board will host a public session on the SB 472, Patient-Centered Labeling project. President Schell explained that this forum will aid the Board of Pharmacy as it collects information from patients and other stakeholders to improve prescription container labels as required by legislation signed by Governor Schwarzenegger last year (SB 472, Corbett, Chapter 470).

President Schell stated that there may be an additional board meeting during the week of the summit to discuss the subject of compounding, as it is critical to the stakeholders.

D) First Quarterly Report on the Committee's Goals for 2008/09.

President Schell stated that the goals are contained within the board packet provided.

E) Public Comment

There were no comments provided.

Mr. Powers commended the board staff for all their hard work. He thanked Ms. Herold and the staff for their support to the board.

The meeting was adjourned at 11:08 a.m.



Standards Development and Adoption Update

California Board of Pharmacy

October 29, 2008





Contents

- Building Patient Safety
- Significant Events
- Pedigree future (DPMS, EPCIS, Discovery)





Who is GS1?

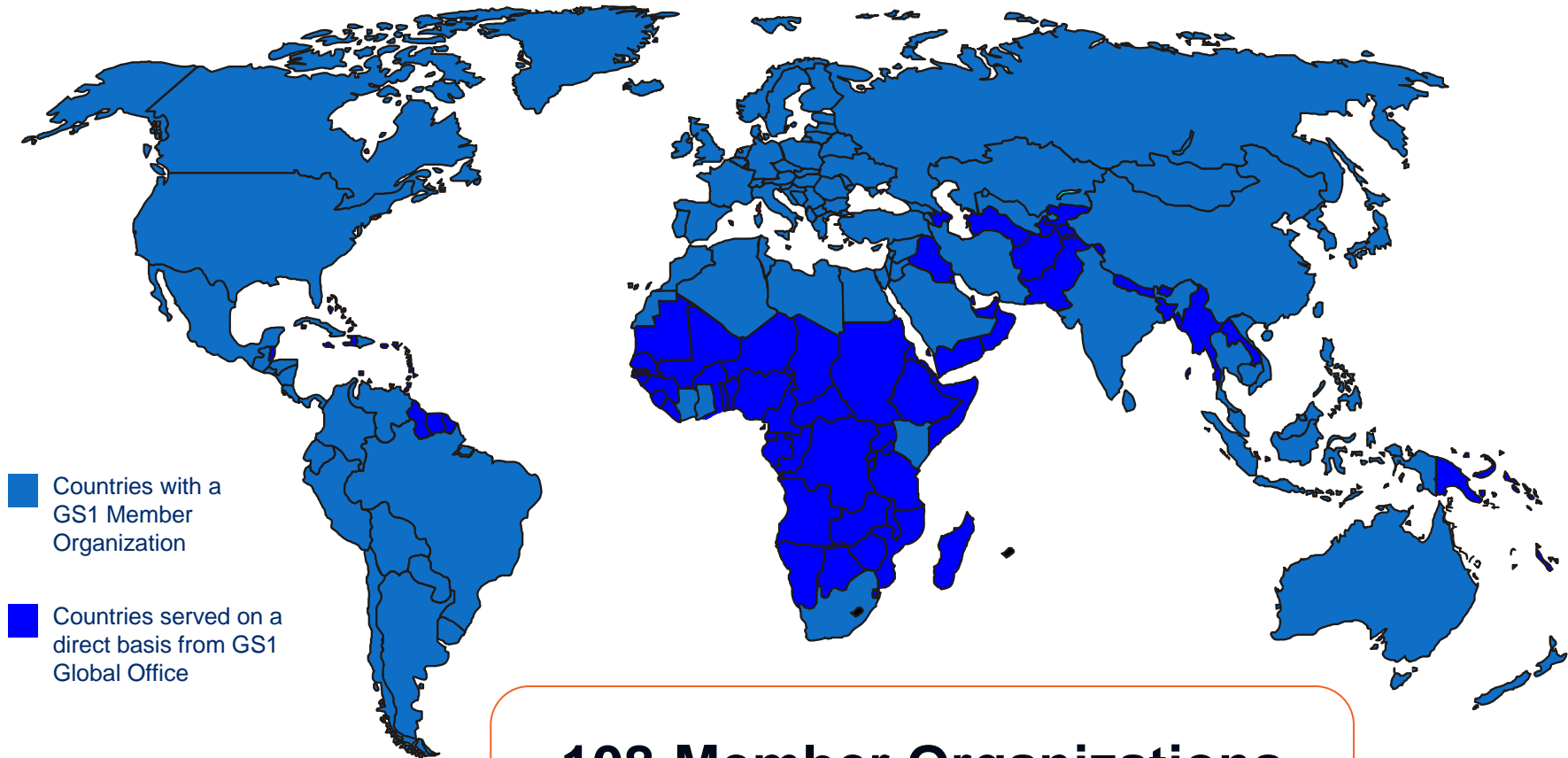
GS1 is a not-for-profit organization dedicated to the design and implementation of **global standards** to improve the efficiency and visibility of **supply chains** globally and across sectors

- **108** member organizations
- **35** years of experience
- **Neutral** platform for all supply chain stakeholders
- Over a **million** companies doing business across **150** countries
- Over **6 billion** transactions a day

GS1 is the most widely used supply chain standards system in the world



GS1 Around the World



108 Member Organizations
150 Countries Served



Why Global Standards?



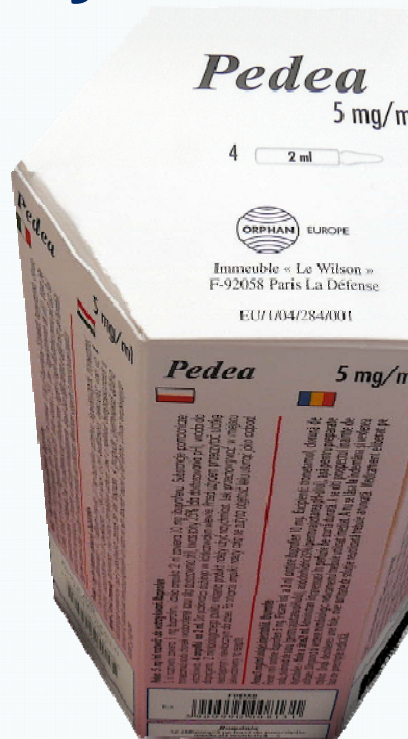
The package has:

- 6 machine readable codes (5 bar codes, 1 data matrix).
- 17 flags (UK, Ireland, Malta, Netherlands, Belgium, Germany, Austria, France, Spain, Portugal, Greece, Cyprus, Norway, Sweden, Denmark, Iceland, Finland) (not Italy)
- 12 different language texts (English, French and German are used in more than one country).





Why Global Standards?



The package has:

- 6 machine readable codes (5 bar codes, 1 data matrix).
- 17 flags (UK, Ireland, Malta, Netherlands, Belgium, Germany, Austria, France, Cyprus, Norway, Sweden (not Italy))
- 12 different language texts (English, French and German are used in more than one country).

Imagine what this could do to supply chain processes



GS1 Healthcare US - Relation to GS1 Healthcare



GS1 Healthcare Role:

- Global focused
- Standards development per roadmap
- Ensuring global standards harmonization
- Communication on global standards and activities



GS1 Healthcare US Role:

- U.S. focused
- A primary customer contact for US based companies / divisions and regulators
- **Drive adoption / implementation**
- Non-voting comment to global standards development





The Global Language of Business

OVERALL BENEFIT:
Eliminate Disruptions and Reinvest In Growing The Business

BarCodes and eCom™

- GS1 System identification numbers
- Bar code standards
- Electronic commerce transaction standards using EDI and XML
- Training and education
- Implementation support



- U.S. Member Organization of EPCglobal Inc™
- Promotes implementation and adoption of EPCglobal Standards and EPC/RFID technology
- Training and education
- Implementation support



- Independent Data Pool
- Data Synchronization Services
- Participant and supporter of Global Data Synchronization Network
- Training and education
- Implementation support

RØSETTANET

- Consortium of high-tech and other industries
- Business Process Standards
- Enablement services
- Implementation support



GS1 US

- Founded in August, 1970
- 250 Employees (9 in Healthcare)
- Over 200,000 customers (16,000 in Healthcare)
- GS1 Healthcare US launched 1/1/08
- UNSPSC Administrator (2003)





GS1 Healthcare US

165 Workgroup Participants

Associations

Advamed

AHA - American Hospital Association

AHRMM - Assoc. for Healthcare Resource & Materials Mgmt.

ASHP - American Society of Health System Pharmacists

CHeS - Coalition for Healthcare eStandards

CHSCR - Center for Healthcare Supply Chain Research

GHVRHIO - Greater Hudson Valley Regional Health Information Organization

GPhA - Generic Pharmaceutical Association

HDMA - Healthcare Distribution Management Assoc.

HIDA - Health Industry Distributors Association

MITA - Medical Imaging & Technology Alliance

NACDS - National Association of Chain Drug Stores

NCPD - National Coalition of Pharmaceutical Distributors

NCPDP - National Council for Prescription Drug Programs

SMI - Strategic Marketplace Initiative

Government Agencies

Dept. of Veteran Affairs

DoD - Department of Defense

FDA - US Food and Drug Administration

US Army

GPOs

Amerinet

Consorta

Healthtrust

Medassets

Novation

Premier

Distributors

AmerisourceBergen Corporation

Cardinal Health Inc.

McKesson US Pharmaceutical

Owens & Minor

US Oncology

Hospitals

Ascension Health

BJC Healthcare

Carolina Healthcare System

Geisinger Health System

Intermountain Healthcare

Mayo Clinic

Ministry Health Care Inc.

Norton Healthcare

Novant Health

Ridgeview Medical Center

Sentara Healthcare

Sisters of Mercy (ROI)

SSM Healthcare

University Healthcare System Augusta (UHCS)

University of Kentucky Medical Center

Wellspan Health

Yale New Haven Health

Retailers

CVS Caremark

Target

Walgreens

Wal-Mart



GS1 Healthcare US

165 Workgroup Participants (Continued)

Manufacturers

3M

Abbott Labs

Alcon Labs

Amgen

Amphastar Pharmaceuticals

Apotex

Baxter

Becton Dickinson

Bristol-Myers Squibb

Covidien

Genzyme Corporation

GlaxoSmithKline

Honeywell Imaging and Mobility

Hospira

Johnson & Johnson

Kimberly Clark

Kinetic Concepts

Kyowa Pharmaceutical, Inc.

Medimmune Inc.

Medline

Medtronic

Merck

P&G

Pfizer

Purdue Pharma

Sage Products

Talecris Biotherapeutics

Teva Pharmaceuticals USA

Upsher-Smith Laboratories, Inc.

AAkar Technology Inc.

Solution Providers

Accenture

Acsis Inc.

Aegate Ltd

Authentix Ltd

Axway

Booz Allen Hamilton

Capgemini

Datagility

DataPros for Healthcare

Deloitte Consulting, LLP

Domino Amjet

Edge Dynamics

Elge Inc.

GHX

Globe Ranger

IBM

Infosys

Inmar/MedTurn

Lawson Software

Loftware, Inc.

Maxiom Consulting Group, Inc.

Ontuet

Product Identification & Processing Systems

RfXcel Corporation

SAP Labs, LLC

Sensitech

Sterling Commerce

Supplyscape

Systech

Terso Solutions

Unisys North America

VCG & Associates



GS1 Healthcare US Leadership Team

- AHRMM – Deborah L. Sprindzunas
- Amerinet – Mary Beth Lang
- Becton Dickenson – Dennis Black
- Johnson & Johnson – Michael Rose
- Mayo – Joe Dudas
- McKesson – Ron Bone
- Novation – Dennis Byer
- SMI – Dennis Orthman
- Univ. Kentucky Medical Center – Jean Sargent
- Walgreens – Steve Addante

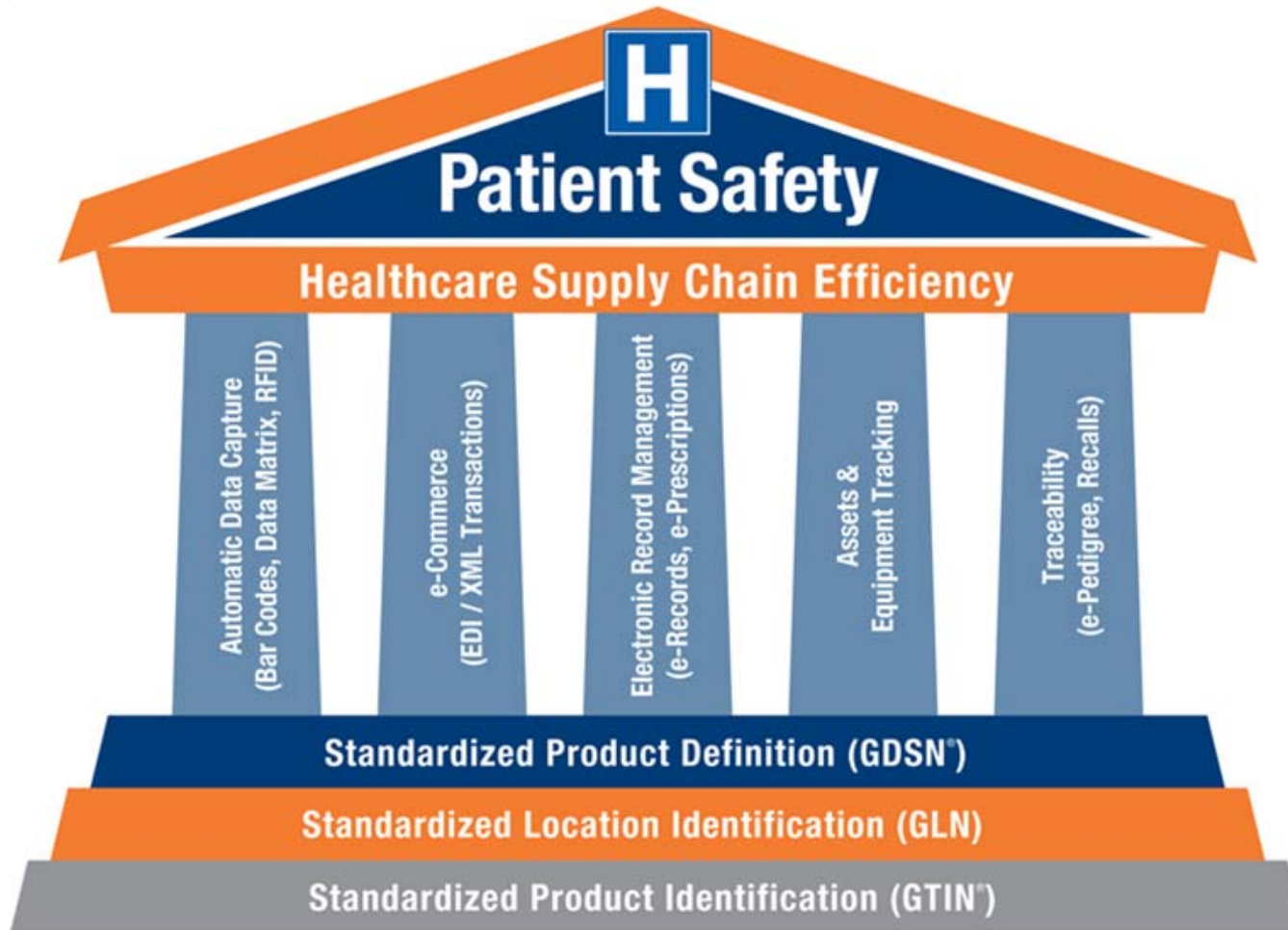


Building Patient Safety





Building Patient Safety

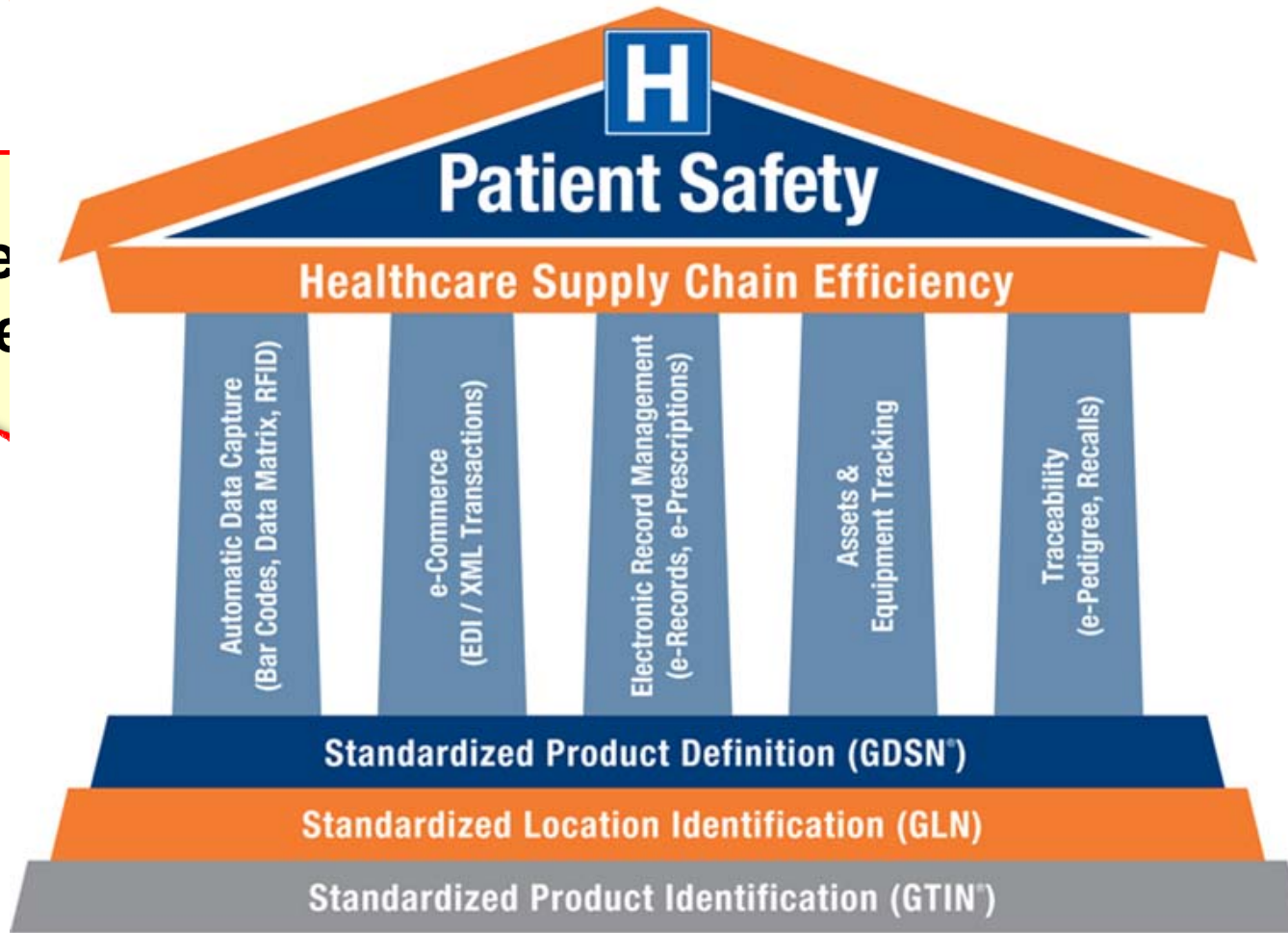


Standardization  Interoperability



Building Patient Safety

The
Fundame



Trace Built
a Strong
ation of the
amentals

Standardization → Interoperability



What is Traceability?



Traceability  Visibility



Moving from
Guessing
To
Knowing



What is Traceability?

- Where has the item been?
- Where is it now?
- Where is it going?

Supply chain
Chemicals (OSHA)
Instruments (Crutchfield –Jacobs)

Extended Traceability Data

- What condition is it in?
- Is it fit for use?

Temperature History
Maintenance History
Certifications
Sterilization





Traceability / Visibility

What do you need to know

Who

- Supported by GSRN (Global Service Relationship Number)

What

- Supported by the GTIN (Global Trade Item Number) and Serial Number

Where

- Supported by the GLN (Global Location Number)

When

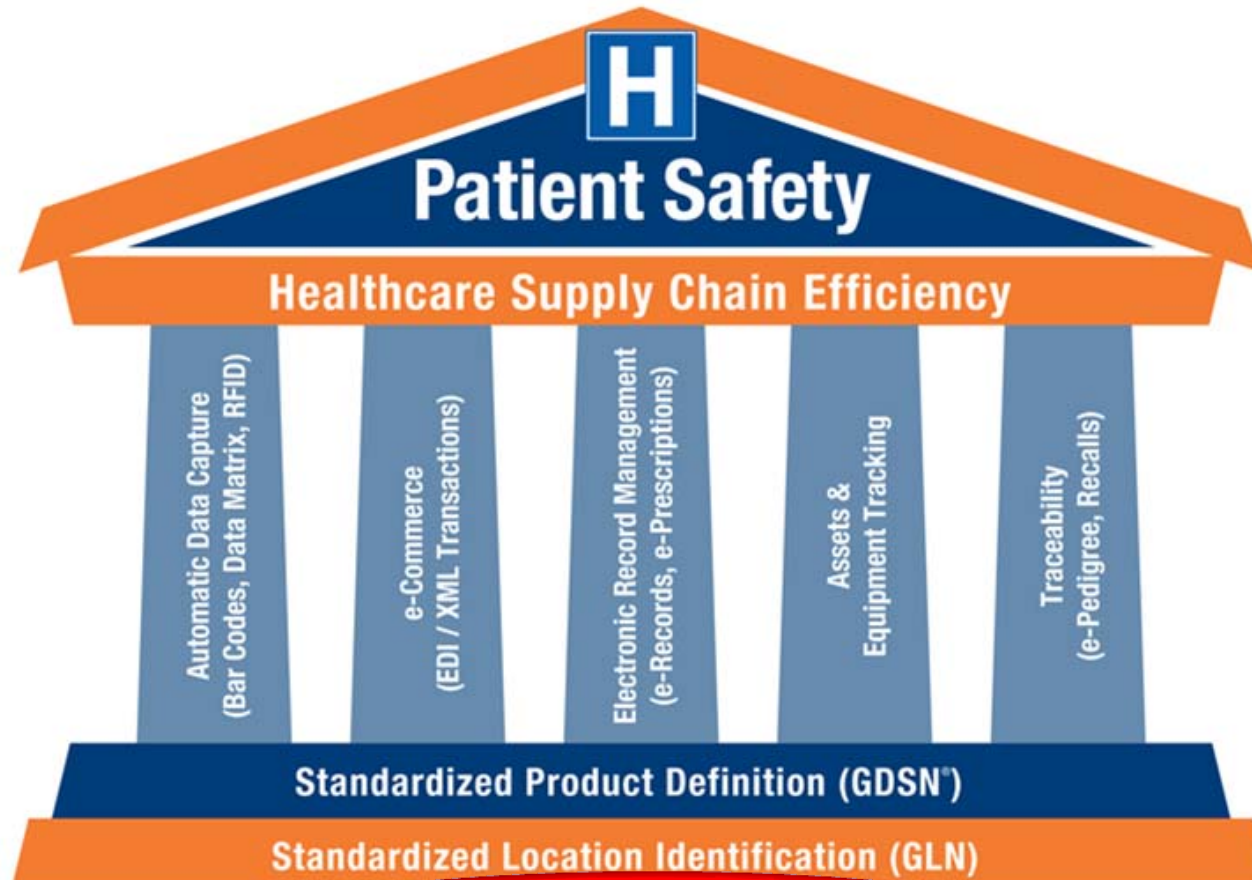
- Supported by time/date stamps

Why

- Supported by Event types (ship, receive, etc.)



Building Patient Safety





Same Product – Different Numbers*

■ Industry Distributor Numbers for 3M Product # 8630:

Nearly every hospital has a different Product ID for 3M 8630! Makes ordering, recalls, and proper identification to the patient difficult.

- Allegiance - M8630**
- Owens & Minor- 4509008630**
- BBMC-Colonial- 045098630**
- BBMC-Durr - 081048**
- Kreisers - MINN8630**
- Midwest - TM-8630**
- Pacific - 3/M8630**

UnitedUMS - 001880

* Source: Department of Defense Data Synchronization Study





Same Number Different Products *

Makes Sourcing of needed products difficult and increases errors in ordering and distribution to the patient.

■ Part Number: 10313

refers to:

Medtronic's - "NEEDLE CARDIOPLEGIA ADULT 16GA 5/8IN TIP 10IN"

Hantover's - "CARTRIDGE REPLACEMENT STUNNER YELLOW F/CALVES/HEAVY HOGS"

Chattanooga Group's - "ACCESSORY TRACTION **REPLACEMENT STRAP** XL FOR HALTER THORACIC RESTRAINT"

HF Scientific's - "TEST KIT WATER FREE CHLORINE DPD 25ML SAMPLE PHOTOMETRIC 1000/PK"

■ Part Number: 1050 refers to:

3M Company's - "DRAPE INCISE 35 3/8X 17 5/8IN"

Tyco's - "PAD TELFA 3 X 4IN STER"

* Source: Premier Inc. Product Item Master

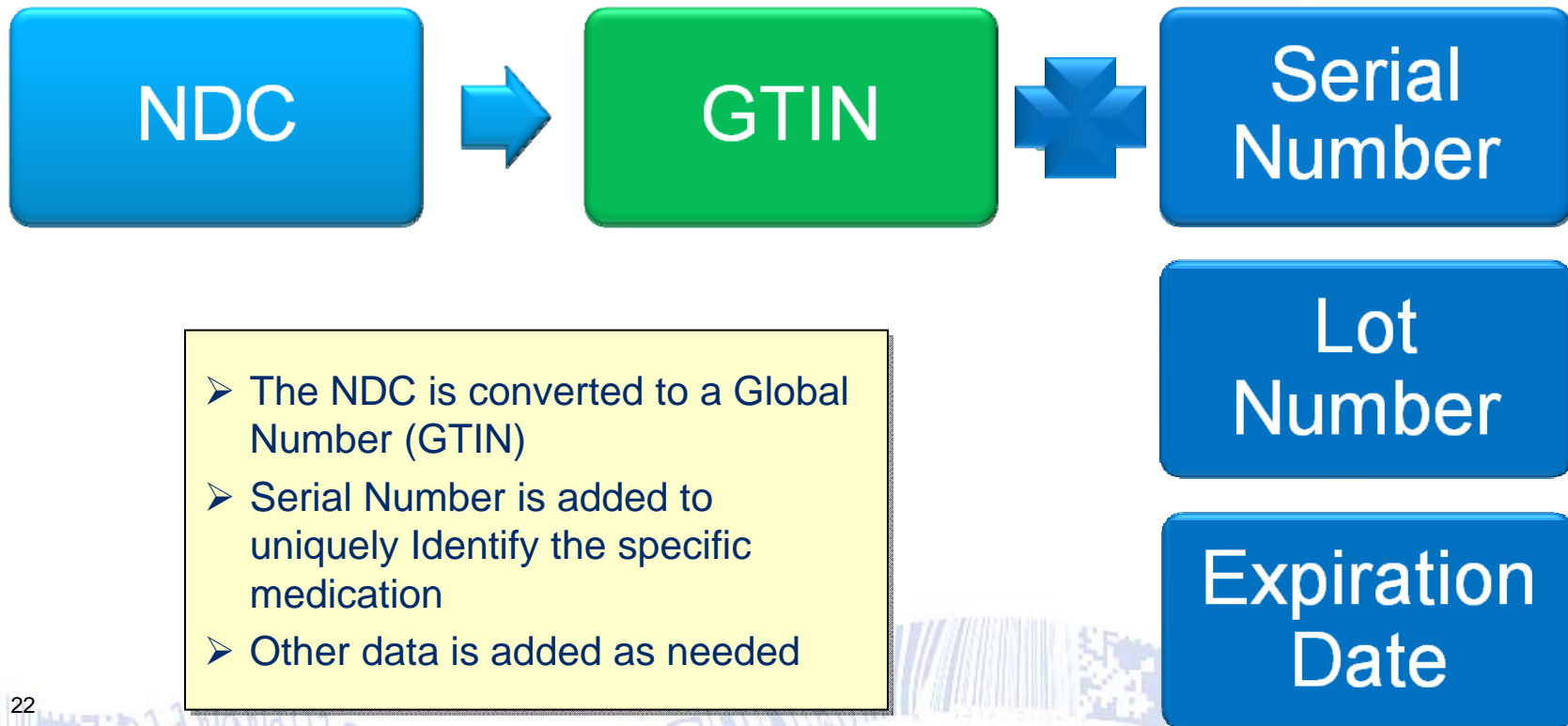


Traceability / Visibility

What do you need to know

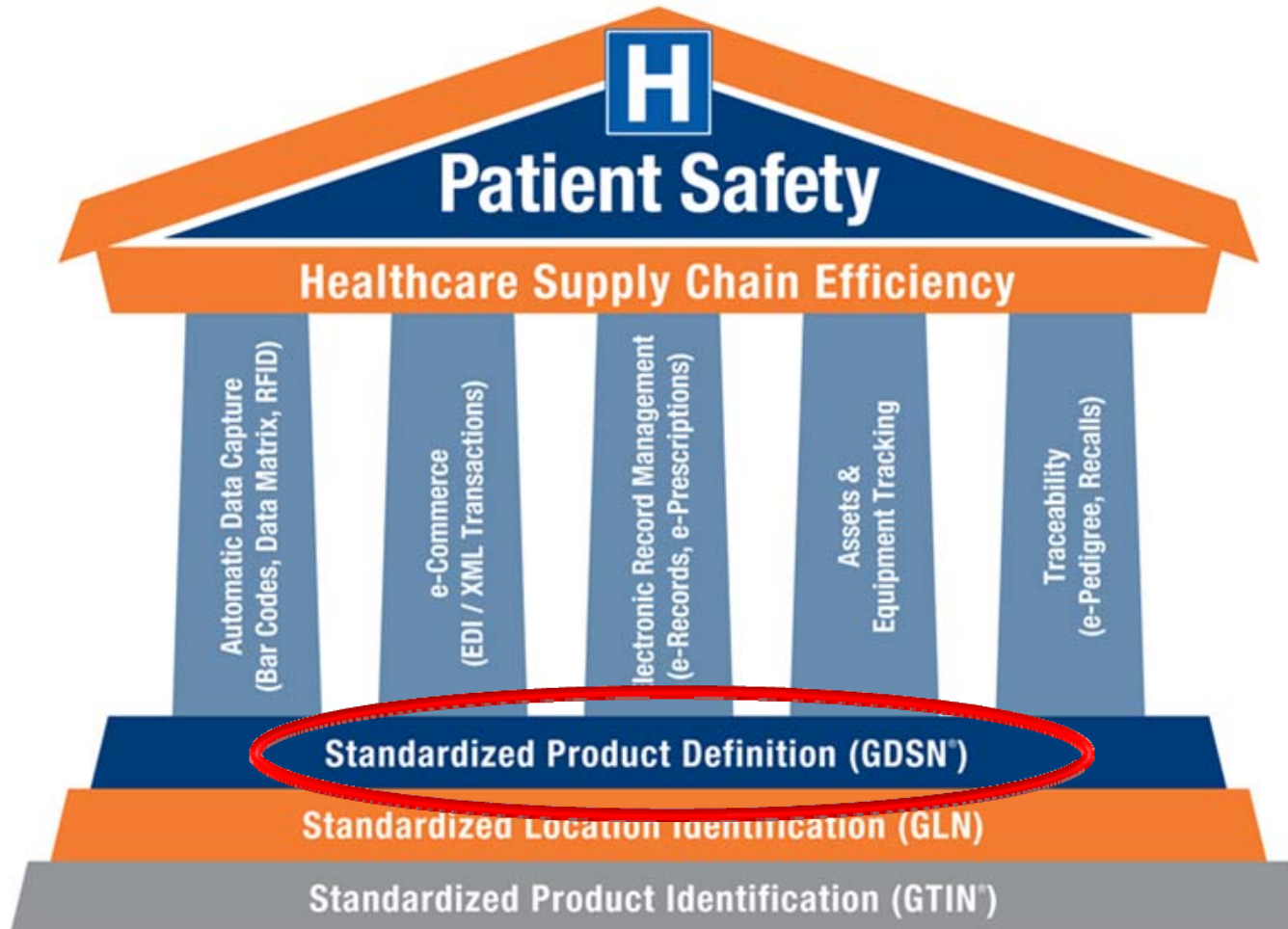


- Supported by the GTIN (Global Trade Item Number) and Serial Number





Building Patient Safety



Standardization → Interoperability



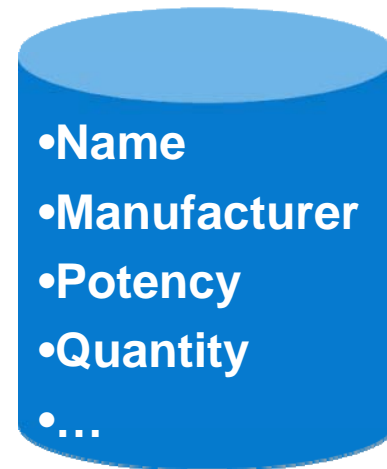
Traceability / Visibility

What do you need to know



- Supported by the GTIN (Global Trade Item Number) and Serial Number

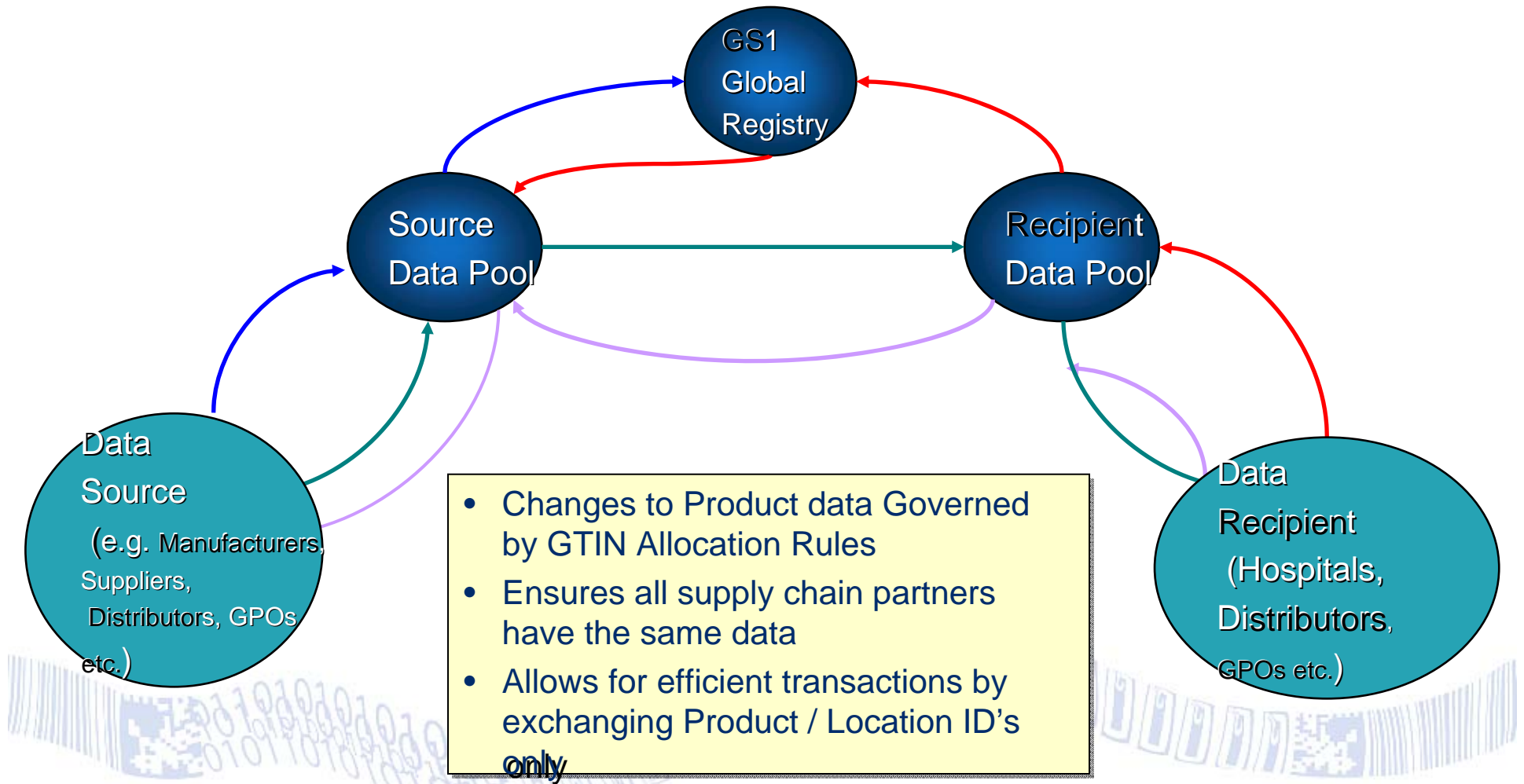
GTIN



The GTIN can be used to “Look up” information about the Product
Product data is accessed through the Global Data Synchronization Network

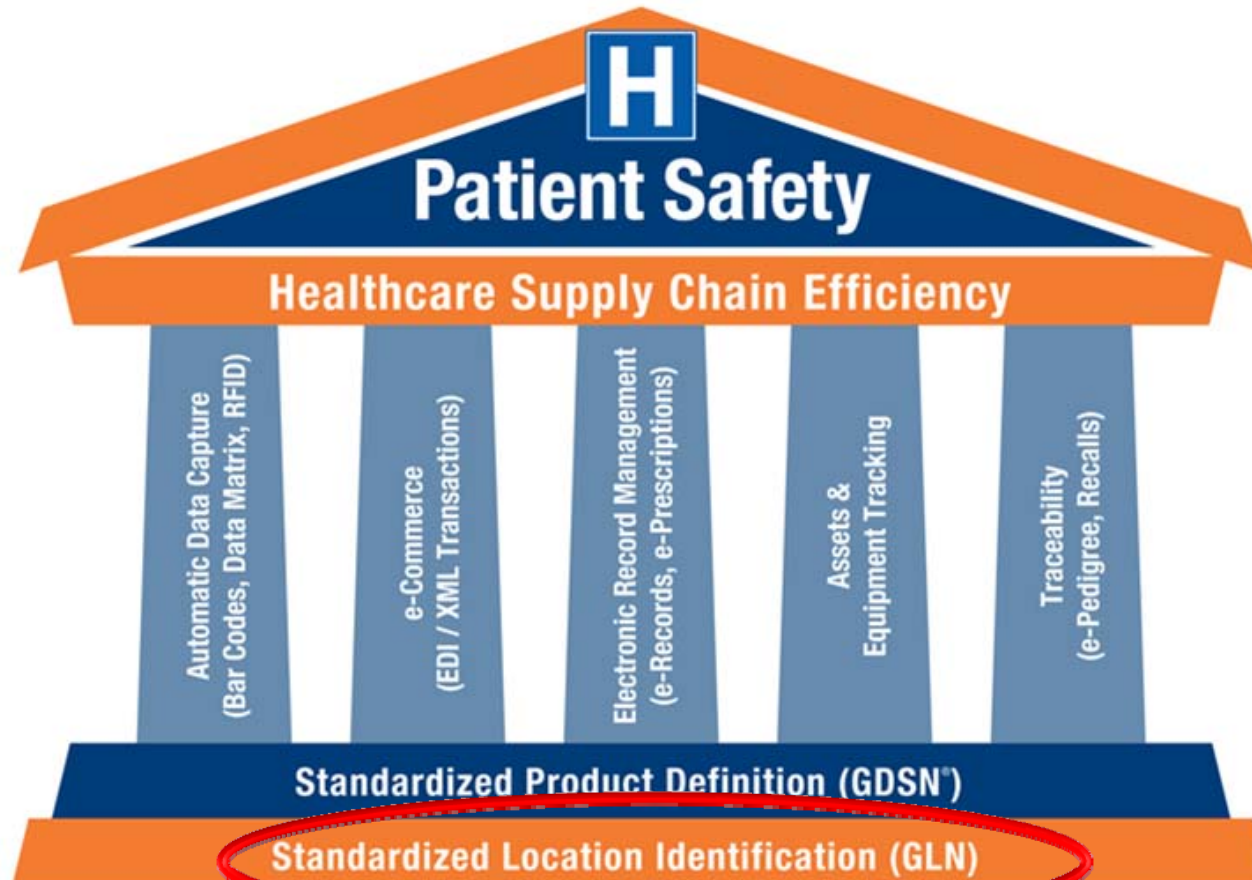


Global Data Synchronization Network (GDSN®)





Building Patient Safety





What is the Provider Pain?

Too many identifiers for the same healthcare location -- confusion, finger pointing, inefficiency

SAINT JOHN'S QUEENS HOSPITAL
1100004570208

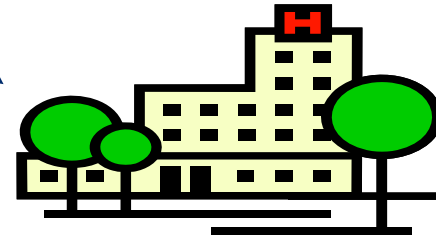
ST JOHN'S QUEENS HOSPITAL
100084547

SAINT **JOHNS** QUEENS HOSPITAL
JAOE

SAINT JOHN'S **QUEEN** HOSPITAL
50003000431

SAINT JOHN'S **QUEEN'S** HOSPITAL
CA2053

ST. JOHN'S QUEENS HOSPITAL
OM 12345



Many different names
different location numbers
for 1 hospital





Traceability / Visibility

Where do you need to know

Who

- Supported by GSRN (Global Service Relationship Number)

What

- Supported by the GTIN (Global Trade Item Number) and Serial Number

Where

- Supported by the GLN (Global Location Number)

When

- Supported by time/date stamps

Why

- Supported by Event types (ship, receive, etc.)



Traceability / Visibility

Where do you need to know



- Supported by the GLN (Global Location Number)

GLN



Serial
Number

- The GLN is used for Identifying Physical Locations and Company Entities (Accounts Payable, Shipping, etc.)
- Serial Number can be used to identify Locations at a very granular level (Stent Cabinet, Shelf, Shelf Position)



Traceability / Visibility

“Where” do you need to know

Where

- Supported by the GLN (Global Location Number)

GTIN



- Name
- Address
- Email
- Location
- Type...

- The GLN can be used to “Look up” information about the Location
- Location data is accessed through the **GLN Registry for Healthcare** (6,500 Hospitals, 147,780 Locations)



Traceability / Visibility

“Where” do you need to know



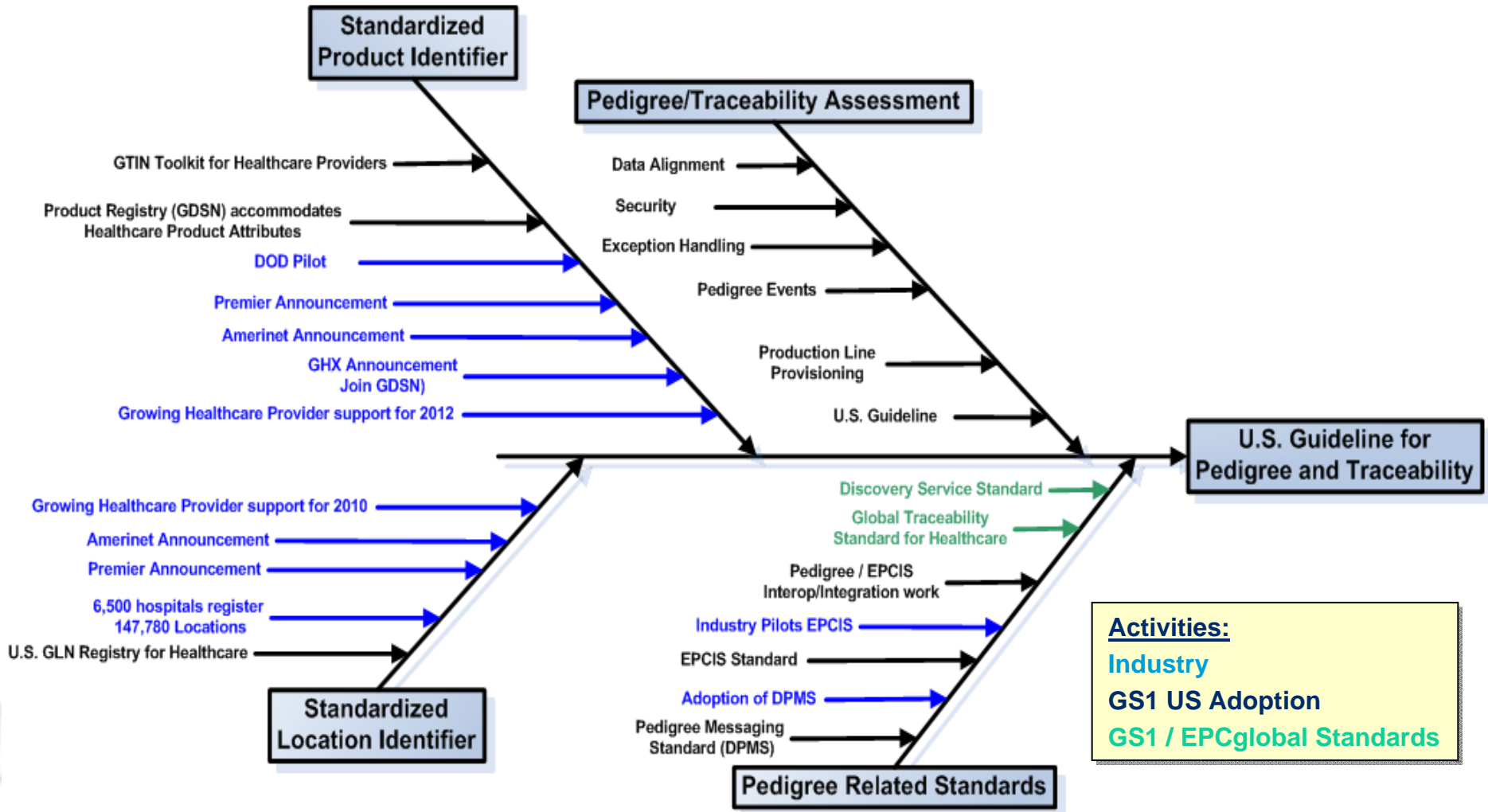


Significant Events Related to Pedigree Adoption



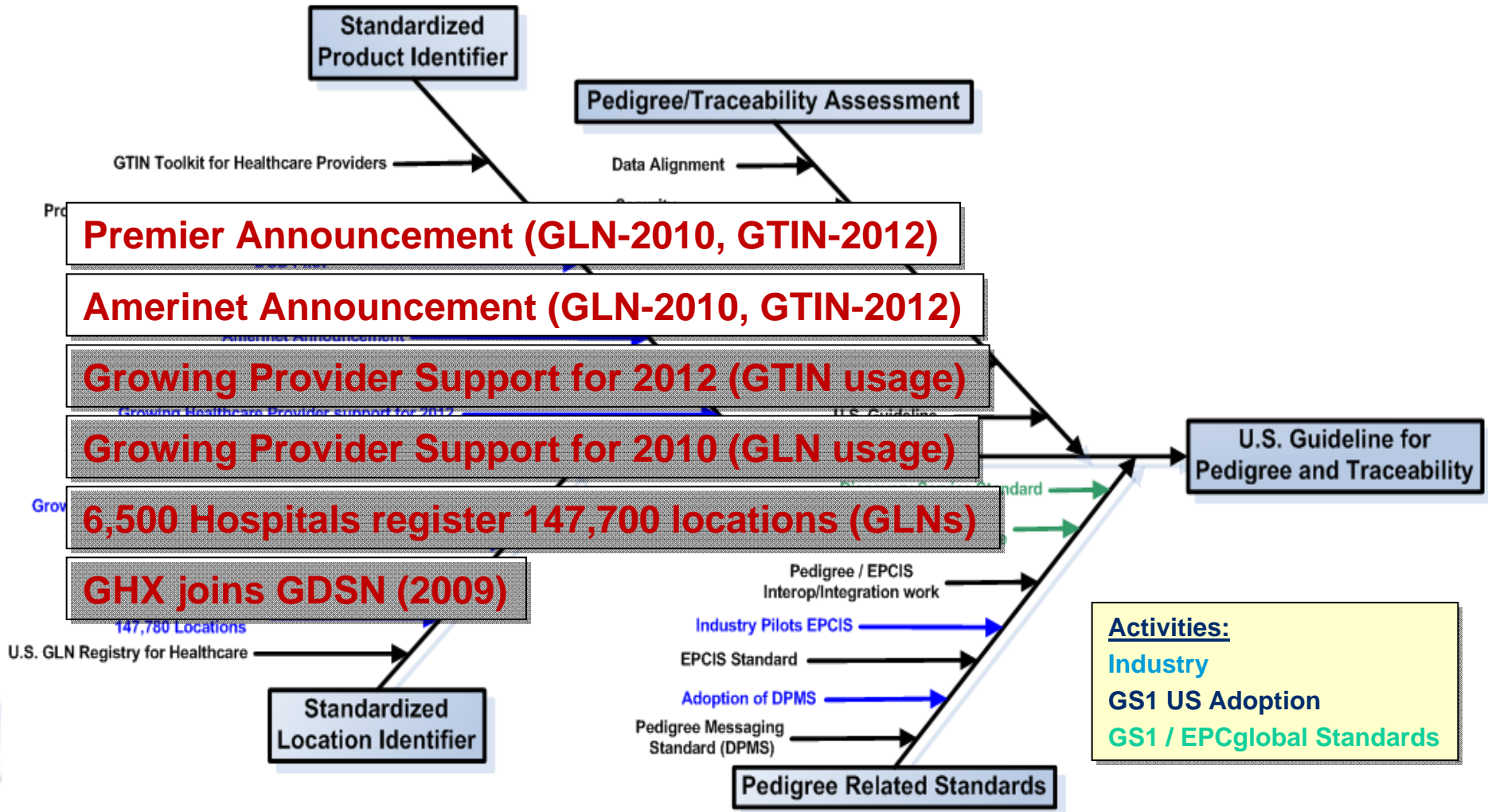


Significant Events affecting Adoption





Significant Events affecting Adoption



2010 GLN Sunrise

“The elimination of Custom Account numbers by 2010”

- GLNs assigned by all trading partners.
- GLN hierarchy defined and maintained for all trading partners.
- GLNs used in all business transactions.
- GLN Registry used by all trading partners.
- GLNs used to identify GPO members

2012 GTIN Sunrise

“The elimination of Custom Product numbers by 2012”

- GTINs assigned to all products.
- GTINs used in appropriate business transactions.
- GTINs marked on all packaging levels.
- GTINs scanned at point of receipt.
- GTINs scanned at point of care.
- GTINs used in product returns and recalls.
- GTINs registered in a GS1 GDSN certified data pool.



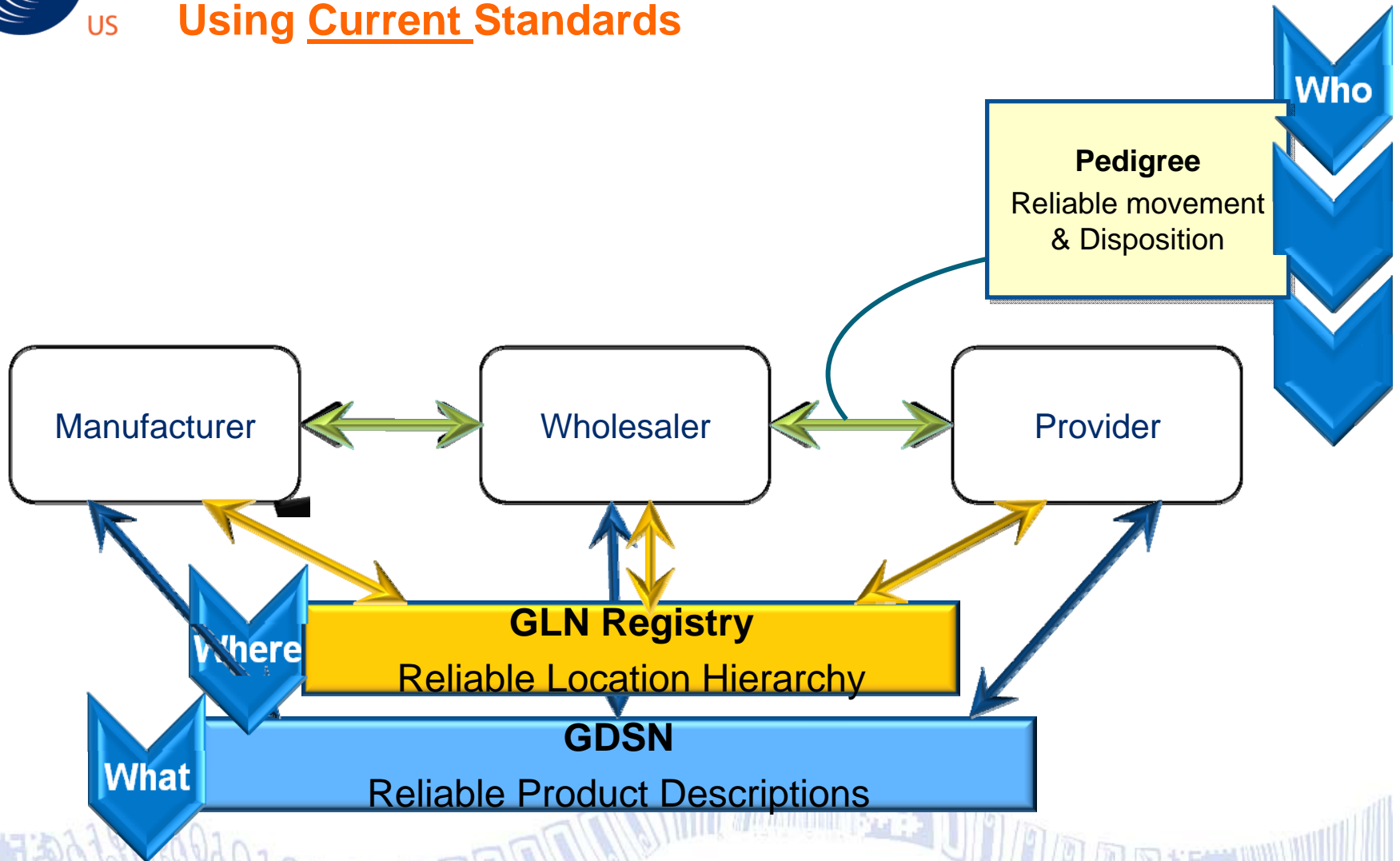
How does this help Pedigree and Track & Trace Efforts





Today - Pedigree

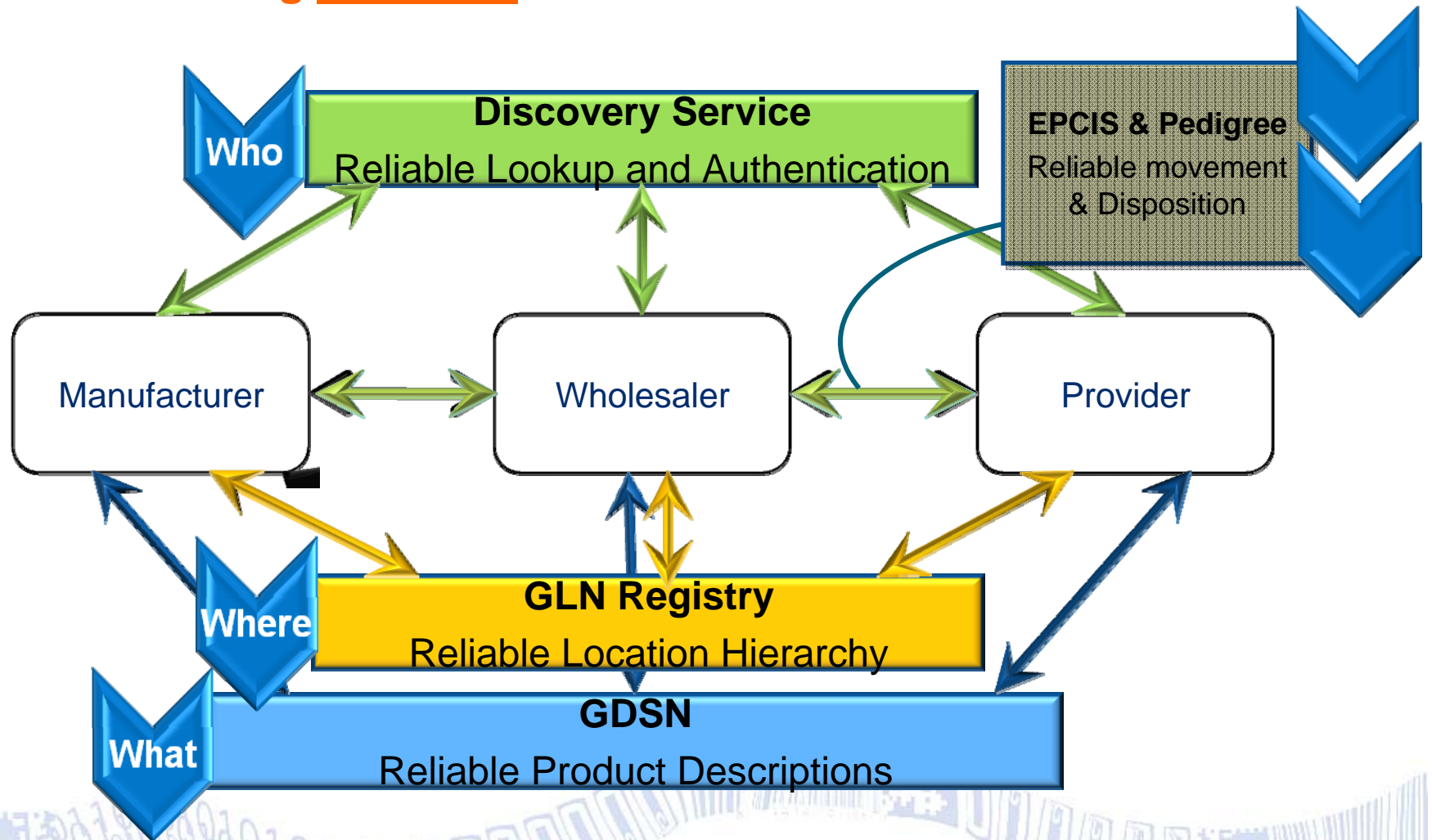
Using Current Standards





Tomorrow – Track and Trace

Using Emerging Standards





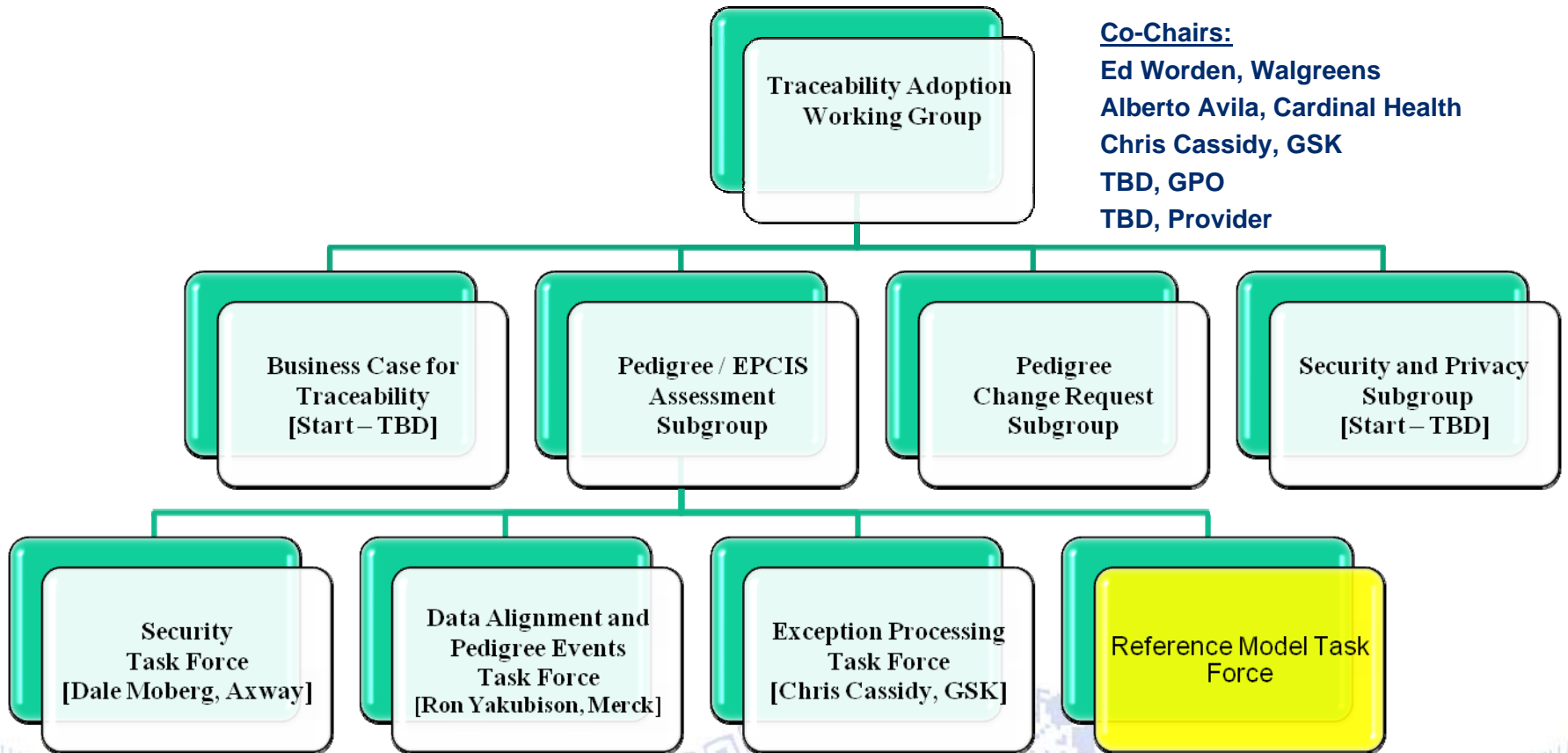
U.S. Adoption Work





GS1 Healthcare US

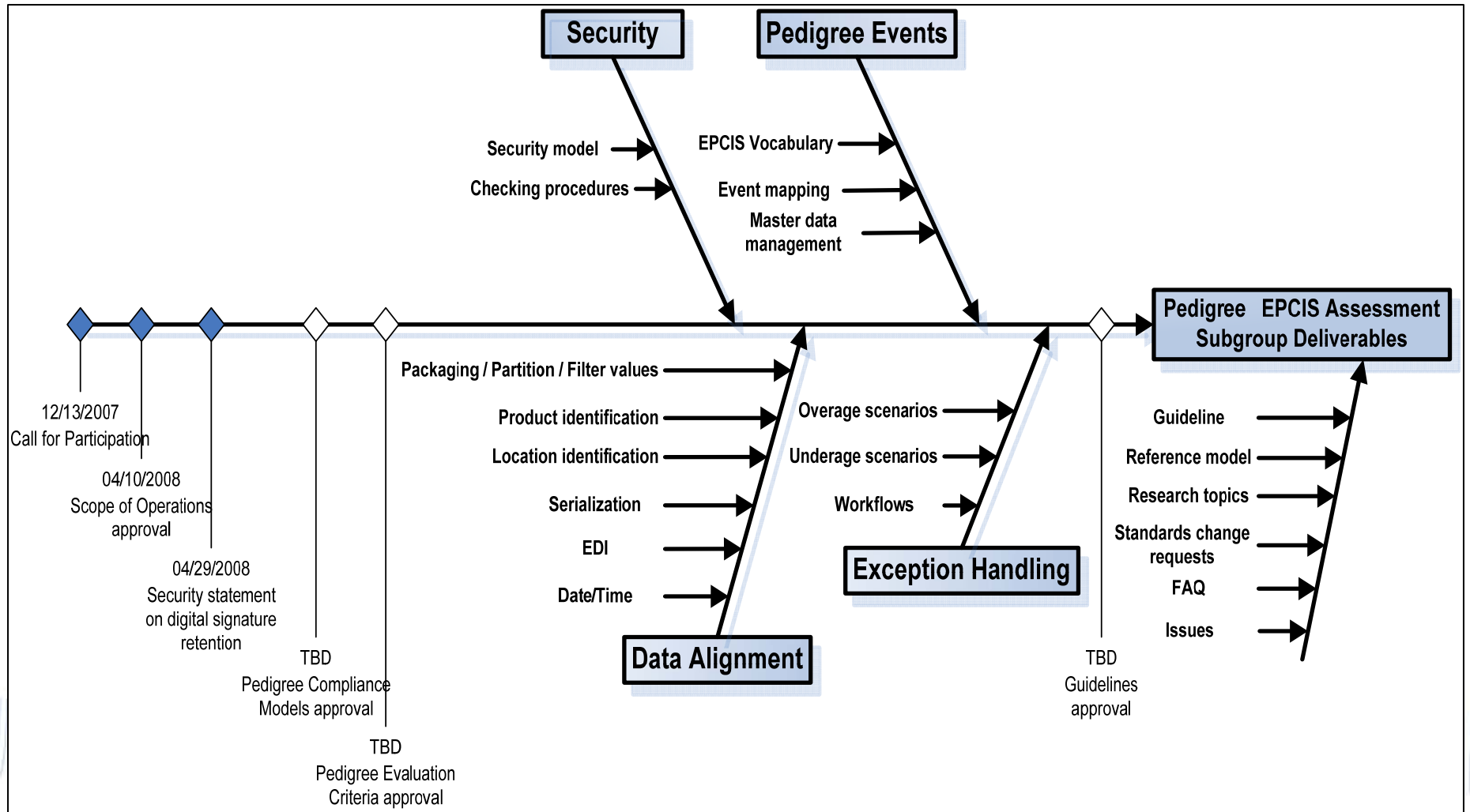
Traceability Adoption Working Group





GS1 Healthcare US

Pedigree / EPCIS Assessment - Roadmap





Questions?

Bob Celeste

Director, Healthcare

GS1 Healthcare US

rceleste@gs1us.org





California Prescription Drug Pedigree Requirement

Virginia Herold
Executive Officer
CA State Board of Pharmacy



Pedigree Overview

First Law 2004

- 1/1/2005 legislation enacted & some sections implemented
- 1/1/2007 original pedigree implementation date, board could extend to 2008

Current California Law Amended 2006

- 1/1/2009 pedigree implementation date
- CA Board of Pharmacy may delay implementation of pedigree until 1/1/11

Pedigree Definition

- “Pedigree” means a record, in electronic form, containing information regarding each transaction resulting in a change of ownership of a given dangerous drug, from sale by a manufacturer, through acquisition(s) and sale(s) by one or more wholesalers, manufacturers, or pharmacies, until final sale to a pharmacy or other person furnishing, administering or dispensing the dangerous drug.

Pedigree Definition

- Pedigree shall be created and maintained in an interoperable electronic system, ensuring compatibility throughout all stages of distribution

Interoperable electronic system defined

- Electronic track and trace system for prescription drugs
- Uses unique identification number
- Established at point of manufacture
- Contained within standardized non-proprietary data format and architecture
- Uniformly used by manufacturers, wholesalers and pharmacies

Electronic Pedigree Requirements

- Prescription Drug Information
- Transaction and Source Information
- Ownership Information
- Certification

Historical Context

- 1988 to 2008, 20 years under the PDMA does not stem diversion or counterfeiting
Publication of final regulations implementing PDMA (as amended by the Prescription Drug Amendments of 1992 (PDA)) in 1999.
Pedigree regulations stayed repeatedly.
Rising concern over counterfeiting leads FDA Commissioner Mark McClellan to establish Counterfeit Drug Task Force in July 2003.

Historical Context

- Beginning in 2003, states spurred to act
Numerous contributing factors, including
2003: Florida grand jury investigation reports
2003: FDA Counterfeit Drug Task Force convened
2003-2005: News reports on counterfeits and patient harm, including Washington Post series, segment of 60 Minutes, *Dangerous Doses*, events leading to “Tim Fagan’s Law,” and others
Patients in CA among those potentially affected
2003-2005: Nevada, Florida, and California

Historical Context

- In 2004, published substantive Report of FDA Counterfeit Drug Task Force
 - Restated threat from recent increase in and sophistication of counterfeits/counterfeiters.
 - Among other findings, Report concluded that adoption and common use of reliable track and trace technology based on RFID tagging of products was feasible for use by 2007.
 - Encouraged use of electronic track and trace technologies and electronic pedigrees.

Historical Context

- In 2004, California passed legislation requiring electronic pedigrees
Original compliance date: January 1, 2007
Basic framework of pedigree established, not changed by 2006 subsequent legislation, *including requirement of unit-level serialization.*

Historical Context

- In 2005 and 2006, follow-up Reports by FDA Counterfeit Drug Task Force
Progress toward electronic track and trace and RFID adoption, but disappointment that industry had not voluntarily met 2007 projections for electronic track and trace, RFID implementation, mass serialization.
“We believe that members of the drug supply chain should be able to implement e-pedigrees in the very near future. We applaud those members who already are taking steps . . . and States that have championed this cause, such as California.”
(2006 Update)
Recommended universal pedigree requirement (not just non-ADRs) to document all drug movements.
Recommended lifting PDMA regulations stay 12/06.

Historical Context

- In 2006, as January 1, 2007 deadline drew near, California enacted current law (SB 1476), extended date to January 1, 2009. Primary motivation was to give more time. Still no specification of particular technology, though interoperability, track and trace, and unique identifier requirements were added – made serialization requirement more explicit. Gave Board of Pharmacy authority to extend deadline further, to January 1, 2011.

Historical Context

- In 2007-2008, always close relationship between FDA and California draws closer on pedigree
- FDA repeatedly states support for the California model, including electronic track and trace, mass serialization with unique unit identifier, end-to-end universal pedigree (all drugs, all entities).
FDA has said FDAAA standard-setting supports, does not deter, California pedigree compliance.

Problem

- Of 4 billion US prescriptions in 2007, up to 40 million may have been filled with counterfeits, up to 10% in California; projected \$75 billion worldwide by 2010.
- FDA counterfeit drug cases: number opened 2004-2007 was more than double 2000-2003, while number opened in 2003 was itself five times that opened in 2000.
In 2007, FDA counterfeit cases resulted in 71 arrests, 50 convictions, and \$26.5 million in fines and restitution.
- In April 2008 the FDA had 20 open counterfeiting cases from just one of two regional California offices.

Still Problems in Supply Chain

- Example: Board of Pharmacy in ongoing investigation with FDA involving counterfeit/adulterated drugs passed through both licensed and unlicensed hands, through at least nine states, using fraudulent paper pedigree.
- It appears Heparin incidents had fraudulent motive.

Purpose of Pedigree

- The pedigree is an important part of a series of provisions intended to address threats to the prescription drug supply from counterfeit, misbranded, adulterated or diverted drugs. The overall intent is to secure the drug distribution system and sustain and increase confidence in authenticity of prescription drugs in California

What Vendors Have Told Us

- Many of the pieces are available now, and each company must develop its strategy.
- Actual pedigree record/transmission may be the easiest (and final) piece. Hardest piece may be serialization infrastructure.
- Many industry participants are working on outdated, non-integrated, legacy systems.
- RFID prices will continue to come down.

Next Steps Forward

- Work with FDA, GS1, and industry on standards/technologies.
 - Formal and informal participation with FDA.
 - Expect to incorporate/use FDA standards.
- Continue work with other states and Congress on law.
- Seek international consensus (EU/EFPIA).
- Continue working with industry on various initiatives to increase implementation.
 - Including GS1/EPCglobal standards-setting.
- Encourage technological development.

SB 1307 (2008 legislation):

Signed by Governor Schwarzenegger

Sequenced implementation & timeline moved out

- Manufacturers (generic and brand) must pedigree:
 - 50 percent of their products by 2015,
 - the remaining 50 percent by 2016
- Wholesalers and repackagers must accept and pass pedigrees by July 2016
- Pharmacies and pharmacy warehouses must accept pedigrees by July 2017

Percentages can be based upon:

- Unit volume
- Product package (SKU) type
- Drug product family

SB 1307 (2008 legislation):

Legislative Intent (SB 1307)

California's electronic pedigree system will "provide tremendous benefits to the public and to all participants in the distribution chain. Those benefits should be made available as quickly as possible through the full cooperation of prescription drug supply chain participants. To this end all drug manufacturers and repackagers are strongly encouraged to serialize drug products and initiate electronic pedigrees as soon as possible, and all participants in the supply chain are encouraged to immediately ready themselves to receive and pass electronic pedigrees.

SB 1307 (2008 legislation):

At the same time, it is recognized that the process of implementing serialized electronic pedigrees for all prescription drugs in the entire chain of distribution is a complicated technological and logistical undertaking for manufacturers, wholesalers, repackagers, pharmacies, and other supply chain participant. The Legislature seeks to ensure continued availability of prescription drugs in California while participants implement these requirements.

SB 1307 (2008 legislation):

Exemptions:

- Radiologic drugs
- Drugs labeled “for veterinary use only”
- Compressed medical gases
- Solutions:
 - IV solutions for replenishment
 - IV solutions used to maintain equilibrium of water and minerals (dialysis)
 - Solutions for irrigation or reconstitution
- Surgical kits containing a device and medical supplies, sealed by the Mfg.
- Kits containing a drug/device, biologic/device, drug/biologic/device that are physically or chemically or combined as produced as single entity
- Kits containing two or more products packaged together in a single package comprised of a drug and device or biologic and device
- Drugs received by a state or local government agency from a federal govt. agency

SB 1307 (2008 legislation):

Expanded or new definitions:

- Manufacturer includes NDA, ANDA, and BLA holders; contract Mfgs
- “Smallest package or immediate container” which must be pedigreed is further defined as the smallest unit made by the mfg. “for sale to the pharmacy”
- Third party logistics provider: a licensed wholesaler who takes possession of, but not ownership of, drugs. Does not need to append pedigree but must maintain copies of it.
- Invoice Annotation to Pedigree: allows a customer-specific shipping number referenced to the sales invoice number in place of invoice number

SB 1307 (2008 legislation):

“Repackager” added to various sections to clarify that repackagers are:

- a manufacturer that must pedigree repackaged items
- Must reference original pedigree information on repackaged products
- Must create a unique identification number for pedigree of repackaged items

SB 1307 (2008 legislation):

Inference

- Board to establish regulations
- Allows a unique identifier to be applied to a case, pallet or other “aggregate” without individually reading each serialized unit
- Specifies intent that Mfgs, WIs, Phys distribute and receive electronic pedigrees, and verify and validate pedigrees at the unit level except where efficiency and safety can be secured through inference

SB 1307 (2008 legislation):

Grandfathering

- Establishes process for Mfgs, WIs, and Phys to designate drugs already in their possession when pedigree requirements kick in
- Exempts from pedigree requirements drugs described in written lists submitted to board
- These lists are confidential
- Board may establish requirements for the lists

SB 1307 (2008 legislation):

Drop Shipment

- Provides definition: Products shipped from Mfg to Phy; Ownership/Pedigree goes from Mfg to WIs to Phy
- Regulations may be developed to establish alternative pedigree

SB 1307 (2008 legislation):

Preemption of CA law, if:

- Federal legislation or federal regulations are enacted addressing pedigree or serialization measures for dangerous drugs
 - Within 90 days board must publish notice of inoperation of pedigree requirements
 - Within 90 days board must adopt emergency regs stating inoperation of requirements
- If FDA enacts any rules or takes action inconsistent with any provision of CA law, that CA provision is inoperative
 - Within 90 days board must publish notice of inoperation
 - Within 90 days board must adopt emergency regs stating inoperation of specific requirements



Resource Conservation and Recovery Act (RCRA)
Title 40, Code of Federal Regulations (40 CFR)

DRUG

NO

YES

Regulated as a
RCRA Waste

“Presumptive” California-Only Hazardous Waste

CA Hazardous Waste Control Law

(CA HS&C, Chapter 6.5)

Title 22, California Code of Regulations

(22 CCR, Division 4.5)

CA-Only Hazardous Waste or Solid Waste if
Non-Hazardous



DRUG



Resource Conservation and Recovery Act (RCRA)
Title 40, Code of Federal Regulations (40 CFR)

NO

YES

Regulated as a
RCRA Waste

“Presumptive” California-Only Hazardous Waste

CA Hazardous Waste Control Law
(CA HSC, Chapter 6.5)

Title 22, California Code of Regulations
(22 CCR, Division 4.5)

CA-Only Hazardous Waste (or Solid
Waste if Non-Hazardous)

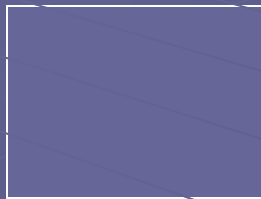
**SB 1966
(Wright)**

Medical Waste Management

**CA HSC Sections 117600 -
118360**

Medical Waste Management Act

DRUG
(PHARMACEUTICAL)



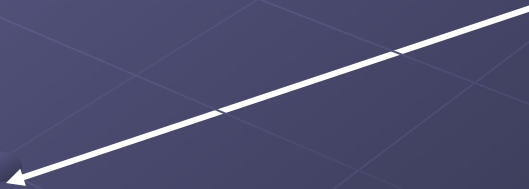
Transported by a
Registered Hauler



Permitted
Transfer
Station



Permitted Offsite
Treatment Facility



Permitted Medical Waste Incinerator – Out of State

Current Disposal of Home-Generated Drugs



Resident



Household Hazardous
Waste Collection

Generated
Drugs

Consolidation Location

Solid Waste Disposal

Not Medical Waste

- 117670 - Household Waste

- “Household waste” means any material, including garbage, trash, and sanitary wastes in septic tanks and medical waste, that is derived from households, farms, or ranches. Household waste does not include trauma scene waste.

Not Medical Waste

- 117700 - Not Medical Waste

Medical waste does not include any of the following:

...

- (e) Hazardous waste, radioactive waste, or **household waste**, including, but not limited to, home generated sharps waste, as defined in Section 117671.

Medical Waste

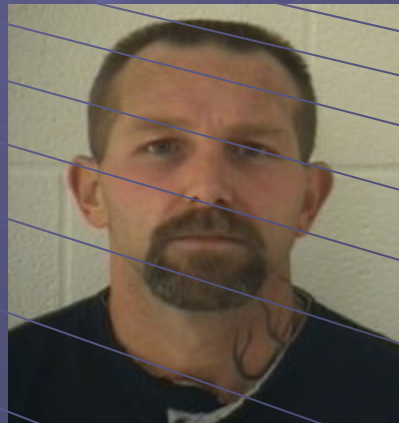
Once Home Generated Pharmaceuticals are consolidated, they become regulated medical waste

Criminal Exploitation of the System

Posted: 6:10 PM Sep 7, 2008

Last Updated: 10:20 PM Sep 7, 2008

Reporter: Leslie Cebuia



Patrick Slider Found, Arrested in Michigan

Set to go to trial on **12 felony counts of allegedly stealing and reselling hundreds of thousands of pills from his past employer Stericycle.** For these charges alone, he could face up to 82 years in prison.